ALEXION PHARMACEUTICALS INC
Form 10-Q/A
June 10, 2005
Table of Contents

FORM 10-Q/A

(Amendment No. 1)

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

For the quarterly period ended April 30, 2005

OR

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number: 0-27756

Alexion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3648318**

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

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of principal executive offices) (Zip Code)

203-272-2596

(Registrant s telephone number, including area code)

N/A

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x No ¨

Common Stock, $0.0001 par value	28,114,845 shares
Class	**Outstanding at May 31, 2005**

Table of Contents

EXPLANATORY NOTE

This Form 10-Q/A is being filed solely to revise information contained under the caption Liquidity and Capital Resources of Item 2 of Part I of Alexion Pharmaceutical, Inc. s quarterly report on Form 10-Q for the quarterly period ended April 30, 2005. The revisions have been made to correct two inadvertent errors: (1) net cash used in operating activities for the nine months ended April 30, 2005 should have been reported as $64.4 million; and (2) net cash provided by financing activities for the nine months ended April 30, 2005 should have been reported as $27.3 million. The financial statements included in the Form 10-Q as originally filed have not been revised. This Form 10-Q/A includes the original filing in its entirety for the convenience of the reader.

With the exception of the foregoing, no other information in the quarterly report on Form 10-Q has been supplemented, updated or amended.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

INDEX

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(UNAUDITED)

(amounts in thousands)

	April 30, 2005	July 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,141	$ 113,224
Marketable securities	191,435	153,277
Milestone receivable		4,000
Reimbursable contract costs	120	826
State tax receivable	953	1,493
Prepaid expenses and other current assets	4,387	3,513
Total current assets	232,036	276,333
Property, plant and equipment, net	11,958	11,336
Property, plant and equipment held for sale (see Note 7)		450
Goodwill	19,954	19,954
Prepaid manufacturing costs (see Note 8)	11,600	9,500
Deferred financing costs, net (see Note 3)	4,574	1,547
Other assets	457	455
TOTAL ASSETS	**$ 280,579**	**$ 319,575**
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Note payable (see Note 7)	$	$ 3,920
Accounts payable	2,878	3,973
Accrued expenses	22,529	11,004
Capital lease obligation current	123	
Deferred revenue	826	588
Deferred research and development payments		188
Total current liabilities	26,356	19,673
Deferred revenue, less current portion	5,735	6,177
Deferred research and development payments, less current portion		1,203
Capital lease obligation non-current	88	
Convertible notes (see Note 3)	150,000	120,000
Total liabilities	182,179	147,053
Stockholders Equity:		
Preferred stock $.0001 par value; 5,000 shares authorized; no shares issued or outstanding		
Common stock $.0001 par value; 145,000 shares authorized; 28,091 and 27,557 shares issued at April 30, 2005 and July 31, 2004, respectively	3	3
Additional paid-in capital	517,154	512,827
Stock subscription receivable	(5)	

Deferred stock-based compensation	(2,072)	
Accumulated deficit	(415,469)	(339,361)
Accumulated other comprehensive loss	(611)	(347)
Treasury stock, at cost; 37 shares	(600)	(600)
Total stockholders equity	98,400	172,522
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	**$ 280,579**	**$ 319,575**

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(UNAUDITED)

(amounts in thousands, except per share amounts)

	Three months ended April 30,		Nine months ended April 30,	
	2005	**2004**	**2005**	**2004**
CONTRACT RESEARCH REVENUES	$ 151	$ 168	$ 861	$ 462
OPERATING EXPENSES:				
Research and development	25,021	10,792	63,772	42,004
General and administrative	4,777	3,569	12,736	9,683
Total operating expenses	29,798	14,361	76,508	51,687
Operating loss	(29,647)	(14,193)	(75,647)	(51,225)
OTHER INCOME AND EXPENSE:				
Investment income	1,729	720	3,946	2,715
Interest expense	(1,600)	(1,926)	(5,429)	(5,781)
Gain from extinguishment of note payable			3,804	
Loss from early extinguishment of convertible notes	(3,184)		(3,184)	
Loss before state tax benefit	(32,702)	(15,399)	(76,510)	(54,291)
State tax benefit	252	186	402	319
Net loss	$ (32,450)	$ (15,213)	$ (76,108)	$ (53,972)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (1.16)	$ (0.69)	$ (2.74)	$ (2.54)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	27,938	21,969	27,793	21,268

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)

(amounts in thousands)

	Nine months ended April 30,	
	2005	**2004**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (76,108)	$ (53,972)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from extinguishment of note payable	(3,804)	
Write-off of remaining deferred financing costs	1,212	
Depreciation and amortization	2,617	2,547
Stock based compensation expense	205	115
Change in assets and liabilities:		
Milestone receivable and reimbursable contract costs	4,706	326
State tax receivable	540	(109)
Prepaid expenses and other assets	(876)	107
Prepaid manufacturing costs	(2,100)	
Accounts payable	(1,095)	(3,084)
Accrued expenses	11,858	(2,301)
Deferred revenue	(204)	(441)
Deferred research and development payments	(1,391)	1,438
Net cash used in operating activities	(64,440)	(55,374)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(399,061)	(122,566)
Proceeds from maturity or sale of marketable securities	360,642	182,766
Investments in patents and licensed technology		(5)
Purchases of property, plant and equipment	(2,511)	(1,291)
Net cash (used in) provided by investing activities	(40,930)	58,904
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from convertible note offering	145,242	
Redemption of convertible notes	(120,000)	
Net proceeds from issuance of common stock	2,045	46,186
Net cash provided by financing activities	27,287	46,186
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(78,083)	49,716
CASH AND CASH EQUIVALENTS, beginning of period	113,224	24,844
CASH AND CASH EQUIVALENTS, end of period	$ 35,141	$ 74,560

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

(Unaudited)

1. Organization and Operations -

Alexion Pharmaceuticals, Inc. (Alexion) was incorporated in 1992 and is engaged in the discovery and development of therapeutic products to treat patients with a wide array of severe disease states, including hematologic and cardiovascular disorders, autoimmune diseases, and cancer.

The accompanying condensed consolidated financial statements include Alexion Pharmaceuticals, Inc. and our wholly owned subsidiaries, Alexion Antibody Technologies (AAT) and Columbus Farming Corporation (CFC). All significant inter-company balances and transactions have been eliminated in consolidation.

The condensed consolidated financial statements included herein have been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and include, in the opinion of management, all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation of interim period results. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The results for the interim periods presented are not necessarily indicative of results to be expected for any future period. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Form 10-K Annual Report for the fiscal year ended July 31, 2004. Certain reclassifications have been made to prior period accounts payable balances and accrued expenses to conform to current year classifications. The year-end balance sheet data presented does not include all disclosures required by accounting principles generally accepted in the United States of America.

2. Accounting for Stock-Based Compensation -

As permitted by Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of SFAS 123 , we account for our stock-based compensation awards, which include grants of both stock options and restricted stock, using the intrinsic method and disclose the effect on the net loss per share as if the fair value method had been used.

At April 30, 2005, we have one stock-based compensation plan for employees, directors and consultants of Alexion, the 2004 Incentive Plan. We account for employees and directors in the plan under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations. We account for non-employees in the plan under the fair value method as defined by SFAS No. 123. In December 2004, the Financial Accounting Standards Board (FASB) issued a revised FASB 123(R), Share-based Payments. The adoption of this standard will require us to measure compensation cost for all share-based payments (including employee stock options) at fair value and recognize such costs in the statement of operations. The effective date for public companies (not considered small business issuers) is for annual periods beginning after June 15, 2005. We have begun to evaluate the effect of the adoption of this standard on our stock-based compensation plan.

The following table illustrates the pro-forma effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the three and nine months ended April 30, 2005 and 2004 (dollars in thousands, except per share amounts):

	Three months ended April 30,		Nine months ended April 30,	
	2005	2004	2005	2004
Net loss, as reported	$ (32,450)	$ (15,213)	$ (76,108)	$ (53,972)
Add: Stock-based employee compensation expense included in reported net loss	78	16	83	48
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(2,634)	(3,673)	(7,777)	(10,765)
Pro forma net loss	$ (35,006)	$ (18,870)	$ (83,802)	$ (64,689)
Net loss per share:				
Basic and diluted - as reported	$ (1.16)	$ (0.69)	$ (2.74)	$ (2.54)
Basic and diluted - pro forma	$ (1.25)	$ (0.86)	$ (3.02)	$ (3.04)

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The effects of applying the fair value recognition provisions of SFAS No. 123 in this pro forma disclosure are not necessarily indicative of future amounts. Reported net loss includes non-employee compensation expense of $120,000 and $122,000 for the three and nine months ended April 30, 2005 respectively, and $23,000 and $67,000 for the three and nine months ended April 30, 2004 respectively. In March of 2005, we issued approximately 106,000 shares of restricted stock with a vesting period of four years to certain employees. We recognized approximately $78,000 as compensation expense for these shares during the three months ended April 30, 2005. This expense is included in the table above. Deferred stock-based compensation expense related to these shares was $2,072,000 and will be recognized over the remaining vesting period.

3. Convertible Notes -

In January 2005 we sold $150 million principal amount of 1.375% Convertible Senior Notes due February 1, 2012 (the 1.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. 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 and a conversion premium of 35% to the last reported sale price on January 19, 2005) per $1,000 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.

If a holder elects to convert its 1.375% Notes upon the occurrence of a transaction or event such as a liquidation, tender offer, consolidation, merger, recapitalization, or otherwise, in connection with which 50% or more of our common stock is exchanged for consideration which is not at least 90% common stock that is listed on a U.S. national exchange or market (such as NASDAQ), the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.91 per $1,000 principal amount).

A shelf registration statement covering the resale of the notes and the common stock issuable upon conversion of these notes was declared effective by the SEC on May 25, 2005.

We incurred interest expense of approximately $515,000 and $555,000 for the three and nine months ended April 30, 2005 respectively, related to the 1.375% Notes. We incurred deferred financing costs related to this offering of

approximately $4.8 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the seven year term of the notes.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The net proceeds of approximately $145.2 million from this offering were used to redeem our entire outstanding $120 million principal amount of 5.75% Convertible Subordinated Notes due March 2007 (5.75% Notes) and for general corporate purposes. On March 15, 2005, we redeemed all of the 5.75% Notes outstanding at the redemption price of 101.643% for each $1,000 principal amount of 5.75% Notes. We paid a redemption premium related to these notes of approximately $2.0 million during this quarter. We incurred interest expense of approximately $862,000 and $4.3 million for the three and nine months ended April 30, 2005 respectively, and approximately $1.7 million and $5.2 million for the three and nine months ended April 30, 2004 respectively, related to these notes. We incurred deferred financing costs related to this offering of approximately $4.0 million, which was recorded in the condensed consolidated balance sheet and was amortized as a component of interest expense over the term of these notes. The remaining balance of deferred financing costs was approximately $1.2 million at the redemption date. The difference between the amount paid, including the redemption premium, and the carrying value of the notes, including the remaining deferred financing costs, was recognized as a $3.2 million loss from early extinguishment of convertible notes.

4. Deferred Revenue -

In January 1999, we and Procter & Gamble Pharmaceuticals (P&G) entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense. We are recognizing a non-refundable up-front license fee of $10 million related to the P&G collaboration as revenue over 17 years representing the average of the remaining patent lives of the underlying technologies at the time the payment was received in fiscal 1999. We recorded this payment as deferred revenue. The balance at April 30, 2005 and July 31, 2004 was $6.3 million and $6.8 million, respectively.

5. Deferred Research and Development Payments - XOMA Ltd. Collaboration -

In December 2003, we and XOMA (U.S.) LLC (XOMA) entered into a collaborative agreement for the development and commercialization of a rationally designed human c-MPL agonist antibody to treat chemotherapy-induced thrombocytopenia. Thrombocytopenia is an abnormal blood condition in which the number of platelets is reduced, potentially leading to bleeding complications.

In November 2004, we and XOMA determined that the lead molecule in this c-MPL agonist antibody collaboration did not meet the criteria established in the program for continued development. In the first calendar quarter of 2005, we and XOMA determined not to continue with this joint development program and terminated the collaboration in April 2005.

Under the terms of the agreement, we received a $1.5 million upfront non-refundable payment upon initiation of the collaboration. We recorded the payment as a deferred research and development payment. During the quarter ended April 30, 2005, we recognized the remaining balance of approximately $1.3 million of the deferred payment as a reduction of research and development expense.

6. Net Loss Per Common Share -

Basic net loss per common share is computed by dividing the net loss by the weighted average shares of common stock outstanding during the respective period. Diluted net loss per common share assumes in addition to the above, the dilutive effect of common share equivalents outstanding during the period. Common share equivalents represent dilutive stock options, convertible subordinated debt, and/or convertible senior debt. These outstanding stock options, convertible subordinated debt, and/or convertible senior debt entitled holders to acquire 9,648,481 and

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

5,732,311 shares of common stock at April 30, 2005 and 2004, respectively. There is no difference in basic and diluted net loss per common share for the three and nine months ended April 30, 2005 and 2004 as the effect of common share equivalents is anti-dilutive.

7. Note Payable

In February 1999, CFC purchased substantially all of the assets of the UniGraft xenotransplantation program, including principally, land, buildings and laboratory equipment, from its then partner in the program, U.S. Surgical Corporation, now a division of Tyco International, Ltd. (Tyco). The purchase was financed through the issuance by CFC of a $3.9 million note payable to Tyco. Interest on the $3.9 million note payable, at 6% per annum, was payable quarterly by CFC. The xenotransplantation manufacturing assets of CFC that were purchased from Tyco, including the real estate, were pledged as security for this note. The principal balance under the note was due in May 2005. Upon CFC s failure to make its quarterly interest payment due to Tyco in August 2003, CFC defaulted on the note.

In the quarter ended October 31, 2003, in conjunction with the event of default, we notified Tyco that the UniGraft xenotransplantation program and CFC activities had been terminated. In the quarter ended October 31, 2004 an offer of $450,000 from a third-party was accepted by Tyco for CFC s assets. Tyco retained the proceeds from the sale of CFC s assets and extinguished the note and unpaid interest. We transferred the assets to Tyco as of October 31, 2004. Since CFC s assets, consisting of property, plant and equipment, were insufficient to satisfy the $3.9 million note, unpaid interest of $0.3 million, and other obligations of CFC, Tyco formally discharged CFC of any further obligations. As a result, we extinguished the $3.9 million note and unpaid interest of $0.3 million offset by the transfer of CFC s assets of $450,000 to Tyco. Consequently, we recorded the resulting gain of $3.8 million as gain from extinguishment of note payable on a consolidated basis in the first quarter of fiscal 2005.

8. Prepaid Manufacturing Costs - Lonza Large-Scale Product Supply Agreement -

The Large-Scale Product Supply Agreement dated December 18, 2002 (the Lonza Agreement) between Lonza Biologics PLC (Lonza) and Alexion, relating to the manufacture of our product candidate eculizumab, was amended (the Lonza Amendment) in April 2004. Under the Lonza Amendment, the facility in which Lonza will manufacture eculizumab was changed; the manufacturing capacity we are required to purchase was reduced; and future potential payments of $10 million by us to Lonza relating to achievement of eculizumab sales milestones and of up to $15 million by us relating to manufacturing yields achieved by Lonza were eliminated. Per the Lonza Agreement, we remitted cash advances aggregating $10 million through July 31, 2004 for the long-term commercial manufacture of our C5 antibody, eculizumab. In the first quarter of fiscal 2005, we paid Lonza an additional $3.5 million as a non-refundable advance under the Lonza Amendment. These prepaid manufacturing costs are amortized as Lonza completes production batches as stipulated in the contract. We amortized $0.9 million and $1.4 million of the prepaid advance as an expense in the three and nine months ended April 30, 2005, respectively. We amortized $0.5 million of the prepaid advance as an expense in fiscal 2004.

9. Commitments and Contingencies -

We enter into indemnification provisions under our agreements with other companies in our ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products, or otherwise in connection with the use or testing of our product candidates. The term of these indemnification agreements is generally perpetual. The potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have not

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as April 30, 2005.

10. Comprehensive Loss -

A summary of total comprehensive loss is as follows (dollars in thousands):

	Three months ended April 30,		Nine months ended April 30,	
	2005	2004	2005	2004
Net loss	$ (32,450)	$ (15,213)	$ (76,108)	$ (53,972)
Unrealized losses on marketable securities	(42)	(308)	(264)	(753)
Total comprehensive loss	$ (32,492)	$ (15,521)	$ (76,372)	$ (54,725)

11. Recently Issued Accounting Pronouncements -

In December 2004, the FASB issued SFAS No. 123(R) (revised 2004), Share-Based Payment (SFAS 123(R)), which replaces SFAS No. 123, Accounting for Stock-Based Compensation and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, beginning with the first annual period after June 15, 2005. Pursuant to revisions to SFAS No. 123(R) in April 2005 by the FASB, we are obligated to start expensing options at the commencement of our fiscal year on August 1, 2005. We are evaluating the requirements of the pronouncement and expect that the adoption of SFAS 123(R) will have a material impact on our results of operations and loss per share. We are currently reviewing the method of adoption, including the transition method, valuation methods and support for the assumptions that underlie the valuation of the awards.

In March 2005, the FASB issued Staff Accounting Bulletin No. 107 (SAB 107) which is to provide guidance regarding the interaction between SFAS 123(R) and certain SEC rules and regulations and provide additional guidance regarding the valuation of share-based payment arrangements for public companies. In addition SAB 107 includes interpretive guidance related to share-based payment transactions with non-employees, the transition from nonpublic to public entity status, valuation methods, the accounting for certain redeemable financial

instruments issued under share-based payment arrangements, the classification of compensation expense, non-GAAP financial measures, first-time adoption of SFAS 123(R) in an interim period, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123(R), the modification of employee share options prior to adoption of SFAS 123(R) and disclosures in MD&A subsequent to adoption of SFAS 123(R). As of April 30, 2005, we had not yet adopted SAB 107.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

This report contains forward-looking statements which involve risks and uncertainties. Such statements are subject to certain factors which may cause our plans and results to differ significantly from plans and results discussed in forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in in the section under the caption Risk Factors below and a variety of other risks set forth from time to time in our filings with the SEC. The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Financial Statements and Notes thereto for the fiscal year ended July 31, 2004 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended July 31, 2004.

Overview

Business:

We are engaged in the discovery and development of therapeutic products to treat patients with a wide array of severe disease states, including hematologic and cardiovascular disorders, autoimmune diseases, and cancer. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. Additionally, through our wholly owned subsidiary, Alexion Antibody Technologies, Inc., or AAT, we are engaged in the discovery and development of a portfolio of additional antibody therapeutics targeting severe unmet medical needs.

Our two lead product candidates, pexelizumab and eculizumab, are currently undergoing evaluation in several clinical development programs, including two Phase III trials of eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), a pivotal Phase III trial of pexelizumab in coronary artery bypass graft (CABG) surgery patients undergoing cardiopulmonary bypass (CPB), and a pivotal Phase III trial of pexelizumab in acute myocardial infarction (AMI) patients. We are developing pexelizumab in collaboration with P&G.

To date, we have studied our two lead antibody product candidates in a variety of clinical development programs enrolling over 10,000 patients in clinical trials. In addition to our Phase III programs, we have an ongoing global registry for PNH patients, and may pursue additional indications for eculizumab. We also have other product candidates in earlier stages of development.

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of April 30, 2005, we had an accumulated deficit of $415.5 million. We expect to incur substantial and increasing operating losses for the next several years due to expenses associated with product research and development, pre-clinical studies and clinical testing, regulatory activities, manufacturing development, scale-up and commercial-scale manufacturing, pre-commercialization activities and developing a sales and marketing force. We will need to obtain additional financing to cover these costs.

We plan to develop and commercialize on our own those product candidates for which the clinical trials and commercialization requirements can be funded and accomplished by our own resources. For those products which require greater resources, our strategy is to form corporate partnerships for product development and commercialization.

Convertible Notes:

In January 2005 we sold $150 million principal amount of 1.375% Convertible Senior Notes due February 1, 2012 (the 1.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. 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 and a conversion premium of 35% to the last reported sale price on January 19, 2005) per $1,000 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

If a holder elects to convert its 1.375% Notes upon the occurrence of a transaction or event such as a liquidation, tender offer, consolidation, merger, recapitalization, or otherwise, in connection with which 50% or more of our common stock is exchanged for consideration which is not at least 90% common stock that is listed on a U.S. national exchange or market (such as NASDAQ), the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.91 per $1,000 principal amount).

A shelf registration statement covering the resale of the notes and the common stock issuable upon conversion of these notes was declared effective by the SEC on May 25, 2005.

We incurred deferred financing costs related to this offering of approximately $4.8 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the seven year term of the notes.

The net proceeds of approximately $145.2 million from this offering both have been used to redeem our entire outstanding $120 million principal amount of 5.75% Convertible Subordinated Notes due March 2007 (the 5.75% Notes) and the balance will be utilized for general corporate purposes. On March 15, 2005, we redeemed all of the 5.75% Notes outstanding at the redemption price of 101.643% for each $1,000 principal amount of 5.75% Notes. We paid a redemption premium related to these notes of approximately $2.0 million. We incurred interest expense of approximately $862,000 and $4.3 million for the three and nine months ended April 30, 2005 respectively, and approximately $1.7 million and $5.2 million for the three and nine months ended April 30, 2004 respectively, related to these notes. We incurred deferred financing costs related to this offering of approximately $4.0 million, which was recorded in the condensed consolidated balance sheet and was amortized as a component of interest expense over the term of these notes. The remaining balance of deferred financing costs was approximately $1.2 million at the redemption date. The difference between the amount paid, including the redemption premium, and the carrying value of these notes, including the remaining deferred financing costs, was recognized as a $3.2 million loss from early extinguishment of convertible notes.

Results of Operations

A summary of revenues recognized from contract research collaboration and grant awards is as follows for the three and nine months ended April 30 (dollars in thousands):

	Three months ended April 30,		Nine months ended April 30,	
	2005	2004	2005	2004
Collaboration/Grant Awards				
P&G	$ 147	$ 147	$ 441	$ 441
U.S. government grants	4	21	420	21
Contract Research Revenues	$ 151	$ 168	$ 861	$ 462

Three Months Ended April 30, 2005

Compared with Three Months ended April 30, 2004

We earned contract research revenues of $151,000 for the three months ended April 30, 2005 and $168,000 for the same period ended April 30, 2004. Our third fiscal quarter revenue reflects the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab and U.S. government grant revenue related to our research programs.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

We incurred research and development expenses of $25.0 million for the three months ended April 30, 2005 and $10.8 million for the three months ended April 30, 2004. Our research and development expenses consist primarily of payroll and benefits costs, clinical trial costs and other clinical-related development costs, manufacturing development and manufacturing costs, discovery research costs, depreciation and amortization expense, and occupancy related facility operating costs. The following table summarizes the major research and development expense categories for the three months ended April 30, 2005 and 2004, respectively (dollars in thousands):

	Three months ended April 30,	
($ in thousands)	**2005**	**2004**
Research and development expenses:		
Payroll and benefits	$ 4,932	$ 3,537
Clinical development	12,740	4,440
Manufacturing development and manufacturing	6,058	47
Discovery research	(564)	1,173
Operating and occupancy	1,274	1,039
Depreciation and amortization	581	556
Total research and development	$ 25,021	$ 10,792

The $14.2 million increase in research and development expenses resulted primarily from higher clinical development costs related to our four ongoing Phase III clinical trials, higher payroll and benefits costs and increased occupancy costs due to increased headcount to support progressing enrollment in the clinical trials, higher manufacturing expenses due to the timing of such activities, partially offset by the $1.7 million decrease in discovery research costs due principally to the recognition of the $1.3 million non-refundable deferred payment received from XOMA (U.S.) LLC (XOMA) after the collaboration with XOMA was terminated this quarter. (see Note 5). Absent the effect of the XOMA termination, discovery research costs were approximately $686,000 during the three months ended April 30, 2005.

Our general and administrative expenses were $4.8 million for the three months ended April 30, 2005 and $3.6 million for the three months ended April 30, 2004. The $1.2 million increase resulted principally from increased pre-marketing and commercial development activities of approximately $600,000 in support of our clinical trials, higher professional fees of approximately $300,000 principally for compliance activities, and higher personnel related costs to support the growth of operations of approximately $200,000.

Total operating expenses were $29.8 million and $14.4 million for the three months ended April 30, 2005 and 2004, respectively.

Investment income was $1.7 million for the three months ended April 30, 2005 compared to $720,000 for the three months ended April 30, 2004. The increase was due primarily to higher market interest rates and higher principal amounts. Interest expense was $1.6 million for the three months ended April 30, 2005 compared to $1.9 million for the three months ended April 30, 2004. The decrease in interest expense is attributable to the lower interest rate for the 1.375% Notes. We recorded a $3.2 million loss from early extinguishment of the 5.75% Notes, which consisted of the write-off of the remaining balance of deferred financing costs of approximately $1.2 million and the redemption premium of approximately $2.0 million.

We recorded a state tax benefit of approximately $252,000 for the three months ended April 30, 2005 and $186,000 for the three months ended April 30, 2004. The benefit is the result of the exchange of our estimated fiscal 2004 and fiscal 2005 incremental research and development tax credits.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

As a result of the above factors, we incurred a net loss of $32.5 million or $1.16 basic and diluted net loss per common share for the three months ended April 30, 2005 compared to a net loss of $15.2 million or $0.69 basic and diluted net loss per common share for the three months ended April 30, 2004.

Nine Months Ended April 30, 2005

Compared with Nine Months ended April 30, 2004

We earned contract research revenues of $861,000 for the nine months ended April 30, 2005 compared to $462,000 for the same period ended April 30, 2004. Our fiscal nine month revenue reflects the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab and U.S. government grant revenue related to our research programs.

We incurred research and development expenses of $63.8 million for the nine months ended April 30, 2005 and $42.0 million for the nine months ended April 30, 2004. Our research and development expenses consist primarily of payroll and benefits costs, clinical trial costs and other clinical-related development costs, manufacturing development and manufacturing costs, discovery research costs, depreciation and amortization expense, and occupancy related facility operating costs. The following table summarizes the major research and development expense categories for the nine months ended April 30, 2005 and 2004, respectively (dollars in thousands):

	Nine months ended April 30,	
($ in thousands)	**2005**	**2004**
Research and development expenses:		
Payroll and benefits	$ 13,045	$ 11,200
Clinical development	29,750	13,023
Manufacturing development and manufacturing	14,384	10,034
Discovery research	1,242	3,203
Operating and occupancy	3,664	2,781
Depreciation and amortization	1,687	1,763
Total research and development	$ 63,772	$ 42,004

The $21.8 million increase in research and development expenses resulted primarily from higher clinical development costs related to our four ongoing Phase III clinical trials, higher payroll and benefits costs and increased occupancy costs due to increased headcount to support progressing clinical enrollment and late-stage development activities, increased manufacturing development and manufacturing expenses due to the timing of such activities, partially offset by the decrease in discovery research costs due principally to the recognition of the non-refundable deferred payment received from XOMA. Absent the effect of the XOMA termination, discovery research costs were approximately $2.5 million during the nine months ended April 30, 2005.

Our general and administrative expenses were $12.7 million for the nine months ended April 30, 2005 compared to $9.7 million for the nine months ended April 30, 2004. The increase of $3.0 million resulted principally from increased headcount, personnel related costs, and professional fees of approximately $1.7 million to support the growth of our operations, and increased costs associated with our pre-marketing and commercial development activities of approximately $1.3 million.

Total operating expenses were $76.5 million and $51.7 million for the nine months ended April 30, 2005 and 2004, respectively.

Investment income was $3.9 million for the nine months ended April 30, 2005 compared to $2.7 million for the nine months ended April 30, 2004. The increase in investment income of $1.2 million resulted primarily from higher interest rates and higher principal amounts. Interest expense was $5.4 million for the nine months ended April 30,

Table of Contents

ALEXION PHARMACEUTICALS, INC.

2005, compared with $5.8 million for the nine months ended April 30, 2004. The decrease in interest expense is attributable to the lower interest rate for the 1.375% Notes. We recorded a $3.2 million loss from early extinguishment of the 5.75% Notes, which consisted of the write-off of the remaining balance of non-refundable deferred financing costs of approximately $1.2 million and the redemption premium of approximately $2.0 million.

During the first fiscal quarter we recorded a net gain of $3.8 million to complete the termination of the Unigraft xenotransplantation program at CFC. This consisted of the extinguishment of the $3.9 million note payable used to purchase the xenotransplantation assets and the extinguishment of the accrued interest of $0.3 million on the note, partially offset by the transfer to Tyco of the remaining assets of $450,000 used to secure the note.

We recorded a state tax benefit of approximately $402,000 for the nine months ended April 30, 2005 and $319,000 for the nine months ended April 30, 2004. The benefit is the result of the exchange of our estimated fiscal 2004 and fiscal 2005 incremental research and development tax credits.

As a result of the above factors, we incurred a net loss of $76.1 million, or $2.74 basic and diluted net loss per common share, for the nine months ended April 30, 2005 compared to a net loss of $54.0 million, or $2.54 basic and diluted net loss per common share, for the nine months ended April 30, 2004.

Liquidity and Capital Resources

As of April 30, 2005, cash, cash equivalents, and marketable securities were $226.6 million compared with $266.5 million at July 31, 2004. The decrease was primarily due to the redemption of our $120 million 5.75% Notes and the funding of operating activities, partially offset by the sale of our 1.375% convertible senior notes for approximately $145.2 million net of financing fees. The net proceeds from the sale of the 1.375% Notes, less the redemption of the 5.75% Notes including the redemption premium, was $23.3 million.

Net cash used in operating activities for the nine months ended April 30, 2005 was $64.4 million. This consisted primarily of our net loss of $76.1 million, the add-back to the net loss of the non-cash gain on the extinguishment of the note payable and interest of $3.8 million net, and the $3.0 million advance payment made to Lonza Biologics PLC (Lonza) as per the Amendment to the Large-Scale Product Supply Agreement in April 2004. The uses of cash are partially offset by the collection of a $4.0 million milestone receivable from P&G concurrent with the dosing of our first patient in the APEX-AMI Phase III clinical trial, and increased accrued expenses of $11.9 million principally related to the four Phase III clinical trials.

Net cash used in investing activities for the nine months ended April 30, 2005 was $40.9 million. This included $38.4 million of purchases of marketable securities, net of proceeds from the maturity or sale of marketable securities, and $2.5 million of property, plant and equipment additions.

Net cash provided by financing activities for the nine months ended April 30, 2005 was $27.3 million primarily consisting of $145.2 million from the sale of our 1.375% Notes and the $2.0 million proceeds from stock option exercises, partially offset by the redemption of our $120 million 5.75% Notes.

We anticipate that our existing capital resources together with the anticipated funding from our revised collaboration with P&G, as well as the addition of our 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 eighteen months.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

The following table summarizes our current contractual obligations at April 30, 2005 and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. These do not include milestones and assume non-termination of agreements. These obligations, commitments, and supporting arrangements represent estimated payments based on current operating forecasts, which are subject to change ($ amounts in millions):

	Total for remainder of fiscal 2005	2006	2007	2008	2009	2010 and thereafter
Contractual obligations:						
Convertible senior notes	$	$	$	$	$	$ 150.0
Interest expense		2.1	2.1	2.1	2.1	6.3
Operating and capital leases	0.6	2.5	2.6	2.1	1.9	4.2
Total contractual obligations	$ 0.6	$ 4.6	$ 4.7	$ 4.2	$ 4.0	$ 160.5
Commercial commitments:						
Clinical and manufacturing development	$ 24.0	$ 47.3	$ 20.6	$ 23.4	$ 20.8	$
Licenses	0.5	0.8	0.7	0.7	0.4	1.5
Research and development		0.1				
Total commercial commitments	$ 24.5	$ 48.2	$ 21.3	$ 24.1	$ 21.2	$ 1.5

Contractual Obligations

Our contractual obligations include our $150 million of 1.375% Notes due February 2012, our annual payments of approximately $2.3 million for operating and capital leases, principally for facilities and equipment, and, an open letter of credit of $200,000 which serves as a security deposit on our facility in Cheshire, Connecticut.

Convertible Senior Notes

In January 2005 we completed the sale of $150 million principal amount of our 1.375% Convertible Senior Notes due 2012 in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The closing included the exercise in full by the initial purchasers of their option to purchase an additional $25 million principal amount of notes. The 1.375% Notes are convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock per $1,000 principal amount of 1.375% Notes, subject to adjustment (equivalent to a conversion price of approximately $31.46 per share and a conversion premium of 35% to the last reported sale price on January 19, 2005). We do not have the right to redeem any of the 1.375% Notes prior to maturity.

The net proceeds of approximately $145.2 million from this offering both were used to redeem our entire outstanding $120 million principal amount of 5.75% Notes on March 15, 2005 and the balance will be utilized for general corporate purposes.

We incurred deferred financing costs related to this offering of the 1.375% Notes of approximately $4.8 million, which are recorded in the consolidated balance sheet and are being amortized as a component of interest expense over the seven-year term of the notes.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Commercial Commitments

Our commercial commitments consist of cancelable research and development, licenses, operations, clinical development including clinical trials, and manufacturing cost commitments along with anticipated supporting arrangements, subject to certain limitations and cancellation clauses and payments. The timing and level of our commercial scale manufacturing costs (assuming we utilize our long-term commercial scale product manufacturing capacity), which may or may not be realized, are contingent upon our clinical development programs progress as well as our commercialization plans. Our commercial commitments are represented principally by our agreement with Lonza and our collaboration with P&G.

Lonza Agreement

The Large-Scale Product Supply Agreement dated December 18, 2002, (the Lonza Agreement) between Lonza and us, relating to the manufacture of our product candidate eculizumab, was amended (the Lonza Amendment) in April 2004. Under the Lonza Amendment, the facility in which Lonza will manufacture eculizumab is changed; the manufacturing capacity we are required to purchase is reduced; and future potential payments of $10 million by us to Lonza relating to achievement of eculizumab sales milestones and of up to $15 million payable by us relating to manufacturing yields achieved by Lonza are eliminated. In August 2004 we paid Lonza an additional $3.5 million as a non-refundable advance under the Lonza Amendment. In addition, the amounts we would be required to pay in connection with a voluntary termination of the Lonza Agreement by us have been changed. Under the Lonza Agreement, as amended by the Lonza Amendment, if we terminate the Lonza Agreement on or prior to September 30, 2006, we may be required to pay different amounts, depending on when the Lonza Agreement is terminated, which are between zero and approximately $10 million and, if we terminate the Lonza Agreement after September 30, 2006, we may be required to pay for batches of product scheduled for manufacture up to 12 months following termination.

P&G Pharmaceuticals Collaboration

In December 2001, we and P&G entered into a binding memorandum of understanding (MOU) pursuant to which our January 1999 collaboration with P&G was revised. Under the revised structure per the MOU, we and P&G share decision-making and responsibility for all future U.S. development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. The revised collaboration per the MOU provides that we and P&G each incur approximately 50% of all Phase III clinical trial, product development and manufacturing, and commercialization costs necessary for the potential approval and marketing of pexelizumab in the U.S. and that we will receive approximately 50% of the gross margin on U.S. sales, if any. P&G agreed to retain responsibility for future development and commercialization costs outside the U.S., with us receiving a royalty on sales outside the U.S., if any. We are responsible for royalties on certain third party intellectual property worldwide, if such intellectual property is necessary. Additionally, as part of the MOU, we will receive milestone payments for achieving specified development steps, regulatory filings and approvals.

P&G has the right to terminate the collaboration or sublicense its rights at any time. If P&G terminates the collaboration, as per the MOU, P&G is required to contribute its share of agreed to obligations and costs incurred prior to the termination, but may not be required to contribute towards obligations incurred after termination. In such circumstance, all rights and the exclusive license to our intellectual property related to pexelizumab would revert back to us and we would be entitled to all future pexelizumab revenues, if any, without any sharing of revenues, if any, with P&G. If P&G were to sublicense its rights, the sublicensee would be required to assume all of P&G s obligations under the collaboration.

We rely on P&G for the development, manufacture and potential commercialization of pexelizumab. Termination of our agreement by P&G or sublicense of its collaboration rights could cause significant delays in the development, manufacture and potential commercialization of pexelizumab and result in significant additional costs to us. Under terms of our MOU we may be obligated to reimburse P&G for 50% of cancellation costs under P&G s third-party pexelizumab manufacturing contract. Our portion of those cancellation costs could amount to as much as $9.8 million.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

XOMA Collaboration

In November 2004, we and XOMA determined that the lead molecule in this c-MPL agonist antibody collaboration did not meet the criteria established in the program for continued development. In the first calendar quarter of 2005, we and XOMA determined not to continue with this joint development program and terminated the collaboration in April 2005. We received a $1.5 million upfront non-refundable payment upon initiation of the collaboration. We recorded the payment as a deferred research and development payment. During the quarter ended April 30, 2005, we recognized the remaining balance of the deferred payment of approximately $1.3 million as a reduction of research and development expense.

Additional Payments

Additional payments for research and license fees, aggregating up to $24 million, would be required if we elect to continue development under our current pre-clinical development programs and if specified development milestones are reached (including achievement of commercialization). Approximately $3 million of these costs may be incurred in the next three years.

Liquidity

We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts and continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our operating expenses will depend on many factors, including:

- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- the time and cost necessary to develop sales, marketing and distribution capabilities;
- the cost necessary to sell, market and distribute our products, if any are approved;

changes in applicable governmental regulatory policies; and

any new collaborative, licensing and other commercial relationships that we may establish.

We expect to incur substantial additional costs for research, pre-clinical and clinical testing, manufacturing process development, additional capital expenditures related to personnel and facilities expansion, clinical and commercial manufacturing requirements, securing commercial contract manufacturing capacity, and marketing and sales in order to commercialize our products currently under development. Furthermore, we will owe royalties to parties we have licensed intellectual property from, or may in the future license intellectual property from, in connection with the development, manufacture or sale of our products.

In addition to milestone payments we may receive from our collaboration with P&G and our interest and investment income that are subject to market interest rate fluctuations, we will need to raise or generate substantial additional funding in order to complete the development and commercialization of our product candidates. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. Any additional financing may include 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. There can be no assurance that funds will be available on terms acceptable to us, if at all, or that discussions with potential strategic or collaborative partners will result in any agreements on a timely basis, if at all. The unavailability of additional financing when and if required could require us to delay, scale back or eliminate certain research and product development programs or to enter into license agreements with third parties to commercialize products or technologies that we would otherwise undertake ourselves, any of which could have a material adverse effect.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 risk 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 occur, our business, financial condition and results of operations could be materially and adversely affected.

*If we continue to incur operating losses, we may be unable to continue our operations***.**

We have incurred losses since we started our company in January 1992. As of April 30, 2005, we had an accumulated deficit of approximately $415 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. Since we began our business, we have focused on research and development of product candidates. We have no products that are available for sale and do not know when we will have products available for sale, if ever. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our future profitability depends on our receiving regulatory approval of our product candidates and our ability to successfully manufacture and market approved drugs. The extent and the timing of our future losses and our profitability, if we are ever profitable, are highly uncertain.

We are subject to extensive government regulation; if we do not obtain regulatory approval for our drug products, we will not be able to sell our drug products.

We and our partners cannot sell or market our drugs without regulatory approval. If we or our partners do not obtain and maintain regulatory approval for our products, the value of our company and our results of operations will be harmed. In the United States, we or our partners must obtain and maintain approval from the FDA for each drug that we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed outside the United States, whose approval can also be lengthy, expensive and highly uncertain. None of our product candidates has received regulatory approval to be marketed and sold in the United States or any other country. We may not receive regulatory approval for any of our product candidates for at least the next several years, if ever.

We and our 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 apply both before and after approval of our product candidates, if our product candidates are ever approved, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, and export of biologics. Failure to comply with the laws, including statutes and regulations, administered by the FDA or other agencies could result in administrative and judicial sanctions, including, warning letters; fines and other civil penalties; delay in approving or refusal to approve a product candidate; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution.

The FDA has granted fast track status for pexelizumab for use during CPB and for treatment of AMI, and for eculizumab in treatment of membranous nephritis. Although fast track status may expedite development and FDA review of an application, there can be no assurance that pexelizumab or eculizumab will be reviewed more expeditiously for their fast-track indications than would otherwise have been the case or will be approved promptly, or at all. Further, the FDA could revoke fast track status for pexelizumab or eculizumab.

The FDA has granted orphan drug designation for eculizumab in the treatment of PNH and membranous nephritis. Orphan drug designation does not convey any advantage in, or shorten the duration of, the FDA review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances.

Table of Contents

We depend heavily on the success of our lead product candidates, eculizumab and pexelizumab, which are still under development. If we do not obtain FDA approval of our lead product candidates, or if FDA delays approval or narrows the indications for which we may market these product candidates, our business will be materially harmed.

We anticipate that in the near term our ability to generate revenues will depend on the successful development and commercialization of eculizumab and pexelizumab. The commercial success of our lead product candidates will depend on several factors, including the following: successful completion of our ongoing Phase III clinical trials for these product candidates; receipt of marketing approvals from the FDA and similar foreign regulatory authorities; establishing commercial manufacturing capabilities ourselves or through third party manufacturers; successfully launching commercial sales of the products; and acceptance of the products in the medical community and by third party payors.

If the data from our ongoing Phase III pivotal clinical trials for our lead product candidates are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for one or both of our lead product candidates or we may be forced to delay the filing. Even if the results of the ongoing pivotal trials appear satisfactory and we file a BLA, the FDA and similar foreign regulatory agencies may not accept our filing, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for one or both of our product candidates, they may narrow the indications for which we are permitted to market one or both products, or may pose other restrictions on the use or marketing of the product. A narrowed indication or other restrictions may limit the market potential for the affected product. If we are not successful in commercializing one or both of our lead product candidates, or are significantly delayed or limited in doing so, our business will be materially harmed and we may need to curtail or cease operations.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

If our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our products.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval for our products. We need to conduct both preclinical animal testing and clinical human trials. These tests and trials may not achieve favorable results. We would need to reevaluate any drug that did not test favorably and either alter the study, the drug or the dose and perform additional or repeat tests, or abandon the drug development project. In those circumstances, we would not be able to obtain regulatory approval on a timely basis, if ever. Even if approval is granted, the approval may require limitations on the indicated uses for which the drug may be marketed.

Clinical trials completed to date have not achieved their primary endpoints.

In December 1999, we completed a Phase IIb trial of pexelizumab for the treatment of complications in patients after CABG with CPB including the reduction of the frequency and severity of myocardial infarctions and frequency of death. The primary therapeutic pre-set goal of the trial, referred to as the primary endpoint, was not achieved. However, in the pre-specified population that included approximately 90% of the patient population, (i.e. the 800 patients who had CABG surgery without valve surgery), those that received pexelizumab at the highest dose level experienced a statistically significant reduction in larger post-surgical heart attacks. Based on these results, in January 2002, we commenced enrollment of a Phase III clinical trial of pexelizumab in patients undergoing CABG with CPB. We completed the target patient enrollment of approximately 3,000 patients in February 2003. In August 2003, we disclosed preliminary results that indicated that the primary endpoint was not achieved with statistical significance. The primary endpoint in this Phase III trial was a composite of the incidence of death or myocardial infarction, measured at 30 days post-procedure, in patients undergoing CABG without simultaneous valve surgery.

We have concluded two Phase II studies with pexelizumab in AMI: one study in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart, and the other in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels. The angioplasty study, called COMMA, and the thrombolytic study, called COMPLY, completed patient enrollment in April 2002 and January 2002, respectively. Results from both studies were reported at the November 2002 annual meeting of the American Heart Association. In both studies, the primary endpoint of a reduction of myocardial infarction, was not reached; however in the COMMA study, pexelizumab treatment was associated with a statistically significant, dose-dependent reduction in death.

In 2001, we announced the completion of a Phase IIa trial of eculizumab for the treatment of rheumatoid arthritis, or RA. The primary endpoint for this trial was met by the group of patients who received the mid-level, monthly dosing regimen of eculizumab, but patients who received higher or lower doses of eculizumab in the clinical trial did not achieve the primary endpoint. The primary endpoint in this Phase IIa trial was ACR 20 at 3.25 months.

In January 2004, we announced preliminary results of a Phase IIb study of eculizumab in approximately 350 RA patients. Results of the trial indicate that the primary endpoint was achieved with statistical significance in the one of the dosing regimens (the monthly dosing arm), but not in the higher, bimonthly dosing arm.

Completion of these and other trials does not guarantee that we will initiate additional trials for our product candidates, that if the trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if the trials are completed, the results will provide a sufficient basis to proceed with further trials or to apply for or receive regulatory approvals or to commercialize products. Results of 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 trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies will be required if we determine to continue development of the product candidate, and reduces the likelihood of timely development of and regulatory approval to market the product candidate.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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. Also, 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.

Additional factors that can cause delay or termination of our clinical trials include:

- slow patient enrollment;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product candidate;
- adverse medical events or side effects in treated patients;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- lack of effectiveness of the product candidate being tested; and
- lack of sufficient funds.

We may expand our business through new 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 stock, which could dilute current stockholders ownership interest in our company, or securities convertible into our stock, which could dilute current stockholders ownership interest in our company upon conversion.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.

We believe we have sufficient capital to fund our operations and product development for at least eighteen months. We may need to raise additional capital before or after that time to complete the development and commercialization of our product candidates. We are currently conducting or initiating several clinical trials. Funding needs may shift between programs and potentially accelerate and increase if we initiate new pivotal trials for our product candidates, including any pivotal clinical trial of pexelizumab for AMI patients undergoing angioplasty. We rely heavily on P&G to fund development of pexelizumab. If P&G were to terminate the pexelizumab collaboration, we could have to raise additional capital or find new collaboration partners in order to continue the development of pexelizumab.

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 existence, terms and status of collaborative arrangements and strategic partnerships, such as our collaboration with P&G;
- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- the time and cost necessary to develop sales, marketing and distribution capabilities;
- the cost necessary to sell, market and distribute our products, if any are approved;
- changes in applicable governmental regulatory policies; and
- any new collaborative, licensing and other commercial relationships that we may establish.

We may not get 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. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions

would harm our business.

We are significantly leveraged.

We currently have outstanding $150 million principal amount of 1.375% convertible senior notes. The degree to which we are leveraged could, among other things:

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

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

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

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

If our collaboration with P&G is terminated or P&G reduces its commitment to our collaboration, our ability to develop and commercialize pexelizumab in the time expected, or at all, and our business would be harmed.

We rely heavily on P&G to perform development, obtain commercial manufacturing, and provide sales and marketing for pexelizumab. While we cannot assure you that pexelizumab will ever be successfully developed and commercialized, if P&G does not perform its obligations in a timely manner, or at all, our ability to commercialize pexelizumab will be significantly adversely affected. We rely on P&G to provide funding and additional resources for the development and commercialization of pexelizumab. These include funds and resources for:

clinical development and clinical and commercial manufacturing;

obtaining regulatory approvals; and

sales, marketing and distribution efforts worldwide.

P&G has the right to terminate the collaboration or sublicense its collaboration rights at any time. Termination of our agreement with P&G would cause significant delays in the development of pexelizumab and result in significant additional development costs to us. If we were to continue development of pexelizumab following termination by P&G, we would need to fund the development and commercialization of pexelizumab on our own or identify a new development partner. We would need to develop or acquire replacement expertise in many areas necessary for the development and potential commercialization of pexelizumab, or enter into agreements with other companies with respect to those matters. We do not have the resources to replace some of the functions provided or funded by P&G. Accordingly, we might have to stop the development of pexelizumab or shift resources from other product development programs until alternative resources were obtained. Sublicense by P&G also could cause significant delays in the development of pexelizumab and result in substantial additional development costs to us. We might also have to repeat testing already completed with P&G. In addition, sublicense would introduce a new collaboration partner which could create new and additional risks to the development of pexelizumab that cannot be identified at this time.

We cannot guarantee that P&G will devote the resources necessary to successfully develop and commercialize pexelizumab in a timely manner, if at all. Furthermore, P&G may devote the necessary resources, but we may still not successfully develop and commercialize pexelizumab.

If we are unable to engage and retain third-party collaborators, our research and development efforts may be delayed.

We depend upon third-party collaborators to assist us in the development of our product candidates. If any of our existing collaborators breaches or terminates its agreement with us or does not perform its development work under an agreement in a timely manner, or at all, we would experience significant delays in the development or commercialization of our product candidates. We would also experience significant delays if we could not engage additional collaborators when required. In either event, we would be required to devote additional funds or other resources to these activities or to terminate them. This would divert funds or other resources from other parts of our business.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

We cannot assure you that:

- current collaboration arrangements will be continued in their current form;
- 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
- current or potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

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 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, including, but not limited to P&G, changes in our prospects, and market conditions for biotechnology stocks in general could have a significant impact on the future trading prices of our common stock and our convertible subordinated notes. In particular, the trading price of the common stock of many biotechnology 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, the announcement of the results of our clinical trials or product development and the results of our attempts to obtain FDA approval for our products. In particular, since August 1, 1999, the sales price of our common stock has ranged from a low of $9.05 per share to a high of $119.88 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our stock may result in considerable uncertainty for an investor.

If we cannot protect the confidentiality and proprietary nature of our trade secrets, 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, since we are a small company, we also rely heavily on collaboration with suppliers, outside scientists and other drug companies. Collaboration presents a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

In order to protect our drugs and technology more effectively, we need to obtain patents covering the drugs and technologies we develop. We may obtain patents through ownership or license. Our drugs 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 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 obtain a license to continue the manufacture, sale or development of our drugs and/or pay damages. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our drugs.

Parts of our, including our in-licensed, technology, techniques and proprietary compounds and potential drug candidates may conflict with patents owned by or granted to others. If we cannot resolve these conflicts, we may be liable for damages, be required to obtain costly licenses or be stopped from manufacturing, using or selling our products or conducting other activities. For example, 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. Many of our product candidates are genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies.

ALEXION PHARMACEUTICALS, INC.

We have received notices from the owners of some of these patents claiming that their patents may be relevant to the development, manufacture or sale of some of our drug candidates, including pexelizumab and eculizumab. In response to some of these notices, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have either determined in our judgment that:

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

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. A required license may be costly or may not be available on acceptable terms, if at all.

There can be no assurance that we would prevail in a patent infringement action; will 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 our product candidates could have a material adverse effect on our business and prospects.

If the testing or use of our products harms people, 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 could give rise to product liability claims against us. We might have to recall our products, if any, from the marketplace. Some of these risks are unknown at this time.

In addition, we may be sued by people who participate in our trials. A number of patients who participate in such trials are already very ill when they enter the trial. Any informed consents or waivers obtained from people who sign up for our trials may not protect us from liability or litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any covered liabilities. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to a product liability claim may make it more difficult, or impossible, for us to recruit patients for our clinical trials or to market and sell our products. 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.

Use of C5 Inhibitors, such as pexelizumab and eculizumab, is associated with an increased risk for infection with Neisseria bacteria. One patient in our trials of eculizumab for the treatment of membranous nephritis became infected with Neisseria bacteria. Serious cases of Neisseria infection can result in brain damage, loss of limbs or parts of limbs, kidney failure, or death.

We are subject to the 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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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.

If we cannot manufacture our drug candidates in sufficient amounts at acceptable costs and on a timely basis, we may be unable to have the necessary materials for product testing, and later for potential sale in the market. Either event would harm our business.

For our drug trials, we need to produce sufficient amounts of product for testing. Our small manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. In addition, we do not have the capacity to produce more than one product candidate at a time. We depend on a few outside suppliers for manufacturing. 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. If we are unable to find an acceptable outside manufacturer on reasonable terms, we will have to divert our own resources to manufacturing, which may not be sufficient to produce the necessary quantity or quality of product. 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. Our competitive position and our prospects for achieving 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. We cannot assure you that we or our third-party collaborators will successfully comply with all of those regulations, which failure would have a materially 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 can not 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 can not 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. Inability to contract with third-party manufacturers on commercially reasonable terms, or failure or delay by our third-party manufacturers, if any, in manufacturing our drug products in the volumes and quality required, would have a material adverse effect on our business.

We have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales. If we are unable to establish and maintain commercial scale manufacturing within our planned time and cost parameters, sales of our products and our financial performance would be adversely affected.

Currently, we are relying on P&G to retain appropriate commercial manufacturing for pexelizumab through one or more third-party manufacturers. P&G has contracted with one third-party manufacturer for the large-scale commercial manufacture of pexelizumab. The failure of P&G to obtain appropriate commercial manufacturing for pexelizumab on a timely basis, or at all, may prevent or impede the commercialization of pexelizumab. We have executed a large-scale product supply agreement with Lonza Biologics, plc for the long-term manufacture of eculizumab. The failure of Lonza to manufacture appropriate supplies of eculizumab on a timely basis, or at all, may prevent or impede the commercialization of eculizumab.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Due to the nature of the current market for third-party commercial manufacturing arrangements, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity contracted for. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity we contracted for, and we could be required to share on an equal basis with P&G substantial penalty payments owed by P&G for its failure to utilize the manufacturing capacity it contracted for with third-party manufacturers for the supply of pexelizumab. The payment of a substantial penalty would harm our financial condition.

If we are unable to establish sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell future drug products.

We have no sales or distribution personnel or capabilities. We have only recently established core pre-commercial marketing capabilities. If we are unable to continue developing those capabilities, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell our future drug products. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Currently, we are relying on P&G for sales, marketing and distribution of pexelizumab. P&G, or any future third-party collaborators, may not succeed at selling, marketing or distributing any of our future drug products.

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

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if we cannot depend on governmental and private third-party payors to defray the cost of our products to the consumer. If these entities refuse to provide reimbursement with respect to our products or determine to provide an insufficient level of reimbursement, our products may be too costly for general use. Our profitability may be adversely impacted if we choose to offer our products at a reduced price. Any limitation on the use of our products or any decrease in the price of our products without a corresponding decrease in expenses will have a material adverse effect on our ability to achieve profitability.

If our competitors get to the marketplace before we do with better or cheaper drugs, our drugs may not be profitable to sell or to continue to develop.

Each of Abbott Laboratories Inc., Adprotech Ltd., Avant Immunotherapeutics, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc., Neurogen Corporation, Tanox, Inc., and XOMA, Ltd. have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that GlaxoSmithKline, plc, Merck & Co., Inc., and Pfizer, Inc. are also attempting to develop complement inhibitor therapies. Each of Cambridge Antibody Technology Group, plc, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Abgenix, 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 we, may develop, manufacture and market better or cheaper drugs than our product candidates. They may establish themselves in the marketplace before we are able even to finish our clinical trials. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may

not be able to find equivalent opportunities elsewhere.

If we fail to recruit and retain personnel, our research and product development programs may be delayed.

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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. There is intense competition in the biotechnology industry for qualified scientific and technical personnel. Since our business is very 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 a key man life insurance policy for Dr. Bell and 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 lose the services of our management and scientific personnel and fail to recruit other scientific and technical personnel, our research and product development programs 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 development objectives.

Our ability to use net operating loss carryforwards to reduce future tax payments may be limited if there is a change in ownership of Alexion.

As of July 31, 2004, we had approximately $320 million of net operating loss carryforwards, 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. We would undergo an ownership change if, among other things, the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated thereunder, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOLs arising after the date of an ownership change would not be affected.

We do not believe that we experienced a change in ownership within the meaning of section 382 as a result of the offering of our common stock on July 30, 2004. However, there can be no assurance that the Internal Revenue Service could not successfully challenge our conclusion. Even if the offering of our common stock did not cause an ownership change to occur immediately, the issuance, directly or indirectly, of a relatively large number of shares in that offering may mean that we may not be able to engage in transactions involving the issuance or deemed issuance of stock within the subsequent three-year period without triggering an ownership change within the meaning of section 382. In addition, there are circumstances beyond our control, such as market purchases of our stock by investors who are existing 5% shareholders, or become 5% shareholders as a result of such purchases, which could result in an ownership change with respect to our stock. Thus, there can be no assurance that our future actions, or future actions by our stockholders, will not result in the occurrence of an ownership change, which may limit our use of the NOLs and negatively affect future cash flows.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Item 3. Quantitative and Qualitative Disclosure about Market Risks.

As part of our investment portfolio we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. Our short-term investments and investments consist of U.S. Government obligations, high-grade corporate notes and commercial paper. All of our investments in debt securities are classified as available-for-sale and are recorded at fair value. Our investments are subject to interest rate risk, and could decline in value if interest rates increase. Due to the conservative nature of our short-term investments and investments policy we do not believe that we have a material exposure to interest rate risk. Although our investments are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

Our available-for-sale marketable securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of these financial instruments due to the difference between the market interest rate and the rate at the date of purchase of the financial instrument. A 10% decrease in year-end market interest rates would result in no material impact on the net fair value of such interest-sensitive financial instruments.

A 10% increase or decrease in market interest rates would result in no material impact on our 1.375% Convertible Senior Notes. The marketable securities as of April 30, 2005, had maturities of less than two years. The weighted-average interest rate on marketable securities at April 30, 2005 was approximately 3.1%. The fair value of marketable securities held at April 30, 2005 was $191.4 million.

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 Acting 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 Acting Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that material information relating to us and required to be included in the reports we file under the Securities Exchange Act of 1934, as amended, (the Exchange Act) is accumulated and communicated to the Chief Executive Officer and Acting Chief Financial Officer or other persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

There have been no changes in our internal controls 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

PART II. OTHER INFORMATION

Item 2. Redemption of $120 million principal amount of 5.75% Convertible Subordinated Notes

We redeemed all of our $120 million 5.75% Notes due March 15, 2007 on March 15, 2005 along with the redemption premium of approximately $2.0 million based upon the redemption price of 101.643% for each $1,000 principal amount of the 5.75% Notes with the net proceeds from the issuance of the 1.375% Convertible Senior Notes due February 1, 2012.

Item 6. Exhibits

(a) Exhibits

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Amendment No. 1 to Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q/A for the quarter ended April 30, 2005.

31.2 Certification by David W. Keiser, President, Chief Operating Officer, and Acting Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Amendment No. 1 to Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q/A for the quarter ended April 30, 2005.

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 Amendment No. 1 to Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q/A for the quarter ended April 30, 2005.

32.2 Certification by David W. Keiser, President, Chief Operating Officer, and Acting 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 Amendment No. 1 to Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q/A for the quarter ended April 30, 2005.

(b) Reports on Form 8-K

Report on Form 8-K, filed on March 14, 2005, announcing the appointment of Ruedi E. Waeger, Ph.D. to Alexion s Board of Directors.

Report on Form 8-K, filed on March 16, 2005, announcing the resignation of Carsten Boess as Alexion s Vice-President and Chief Financial Officer, effective April 1, 2005.

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: June 10, 2005

By: /s/ Leonard Bell, M.D.

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

Date: June 10, 2005

By: /s/ David W. Keiser

David W. Keiser
President and Chief Operating Officer
(principal financial officer)

Date: June 10, 2005

By: /s/ Barry P. Luke

Barry P. Luke
Vice President of Finance and Administration
(principal accounting officer)