# **FORM 10-Q**

# 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 October 31, 2005

OR

Π 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 (State or other jurisdiction of incorporation or organization)

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

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

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

N/A

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

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

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

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

Common Stock, \$0.0001 par value Class

30,914,583 **Outstanding at November 30 2005** 

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# PART I. FINANCIAL INFORMATION

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# ALEXION PHARMACEUTICALS, INC. Condensed Consolidated Balance Sheets (amounts in thousands) (UNAUDITED)

	October 31, 2005	July 31, 2005
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 62,992	\$ 46,951
Marketable securities	167,534	148,453
Prepaid expenses and other current assets	5,083	5,758
Total current assets	235,609	201,162
Property, plant and equipment, net	10,849	11,546
Goodwill, net	19,954	19,954
Prepaid manufacturing costs	10,000	10,600
Other assets	4,688	4,860
	¢ 201 100	¢ 240 122
Total Assets	\$ 281,100	\$ 248,122
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 1,869	\$ 7,455
Accrued expenses	21,148	16,364
Deferred revenue	810	820
Current portion of obligations under capital lease	128	75
Total current liabilities	23,955	24,714
Obligations under capital lease	110	149
Deferred revenue, less current portion	5,441	5,588
Convertible notes	150,000	150,000
Total Liabilities	179,506	180,451
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; 30,901 and 28,227 shares issued at October 31, 2005 and July 31, 2005, respectively	3	3
Additional paid-in capital	586,216	518,883
Treasury Stock, at cost, 50 and 37 shares at October 31, 2005 and July 31, 2005, respectively	(981)	(600)
Deferred stock-based compensation expense		(1,938)
Accumulated deficit	(483,185)	(448,111)
Accumulated other comprehensive loss	(459)	(566)
Total Stockholders' Equity	101,594	67,671
Total Liabilities and Stockholders' Equity	\$ 281,100	\$ 248,122

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

# ALEXION PHARMACEUTICALS, INC. Condensed Consolidated Statements of Operations and Comprehensive Income (amounts in thousands, except per share amounts)

(UNAUDITED)

	T	Three months ended October 31,		d
	20	05	200	)4
CONTRACT RESEARCH REVENUES	\$	460	\$	147
OPERATING EXPENSES				
Research and development	30	),274	18,	,663
General and administrative	e	5,484	3,	,679
Total operating expenses	36	5,758	22,	,342
Operating loss	(36	5,298)	(22,	,195)
OTHER INCOME AND EXPENSE				
Investment income	1	,832	1,	,049
Interest expense		(733)	(1,	,908)
Gain from extinguishment of note payable		—	3,	,804
				—
Loss before state tax benefit	(35	5,199)	(19,	,250)
STATE TAX BENEFIT		125		62
Net Loss	\$(35	5,074)	\$(19,	.188)
	+ (	,- ,	- ( - )	/
OTHER COMPREHENSIVE INCOME/LOSS				
Foreign currency translation		2		
Unrealized gains on marketable securities		105		56
Comprehensive Loss	\$(34	1,967)	\$(19,	,132)
		_	_	
BASIC AND DILUTED LOSS PER SHARE DATA				
Net loss per share	\$	(1.16)	\$ ((	0.70)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	30	),355	27,	,607

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

# ALEXION PHARMACEUTICALS, INC. Condensed Consolidated Statements Of Cash Flows (amounts in thousands) (UNAUDITED)

	Three mor Octob	
	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (35,074)	\$(19,188)
Adjustments to reconcile net loss to net cash used by operating activities:		
Gain from extinguishment of note payable		(3,804)
Depreciation and amortization	983	803
Stock-based compensation expense	2,436	7
Changes in operating assets and liabilities		
Prepaid expenses and other assets	678	4,816
Prepaid manufacturing costs	600	(3,200)
Accounts payable	(5,586)	2,140
Accrued expenses	4,798	(1,292)
Deferred revenue	(157)	(147)
Deferred research and development costs		(48)
Net cash used by operating activities	(31,322)	(19,913)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(267,016)	(79,520)
Proceeds from maturity or sale of marketable securities	248,040	33,545
Purchase of property, plant and equipment	(117)	(415)
r arenade of property, plant and equipment	(117)	(110)
Net cash used by investing activities	(19,093)	(46,390)
	(15,055)	(40,550)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exchange of 13,713 common shares in 2005	(381)	_
Net proceeds from issuance of common stock	66,835	563
Net cash provided by financing activities	66,454	563
Effect of exchange rate changes	2	
Net change in cash and cash equivalents	16,041	(65,740)
Cash and cash equivalents at beginning of period	46,951	113,224
cum and cam clar rating at period		110,224
Cash and cash equivalents at end of period	\$ 62,992	\$ 47,484

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except per share amounts) (Unaudited)

# 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements included in this Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the fiscal year ended July 31, 2005.

In our opinion, the unaudited condensed consolidated financial statements reflect all adjustments (including those that are normal and recurring) that are necessary in the judgment of management for a fair presentation of such statements in conformity with accounting principles generally accepted in the United States ("GAAP") for interim reporting. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

# 2. Accounting for Stock-Based Compensation

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment ("SFAS 123R"), effective August 1, 2005. SFAS 123R requires the recognition of the fair value of stock-based compensation in net earnings. We have one stock-based compensation plan known as the 2004 Incentive Plan. Under this plan, restricted stock, stock options and other stock-related awards may be granted to directors, officers, employees and consultants or advisors of the Company or any subsidiary. To date, stock-based compensation issued under the plan consists of incentive and non-qualified stock options and restricted stock. Stock options are granted to employees at exercise prices equal to the fair market value of our stock at the dates of grant. Generally, stock options and restricted stock granted to employees fully vest four years from the grant date. Stock options have a term of 10 years. We recognize stock-based compensation expense over the requisite service period of the individual grants, which generally equals the vesting period.

On March 29, 2005, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 107 ("SAB 107"), which expresses views of the SEC staff regarding the interaction between SFAS 123R and certain SEC rules and regulations and provide the SEC staff's views regarding the valuation of share-based payment arrangements for public companies. In particular, SAB 107 provides guidance related to share-based payment transactions with non-employees, the transition from nonpublic to public entity status, valuation methods (including assumptions such as expected volatility and expected term), 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 123R 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 123R, the modification of employee share options prior to adoption of SFAS 123R and disclosures in Management's Discussion and Analysis subsequent to adoption of SFAS 123R.

Prior to August 1, 2005, we accounted for the 2004 Incentive Plan and preceding plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB No. 25) and related Interpretations as permitted by Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation." (SFAS 123). When applying the intrinsic value method, we did not record stock-based compensation cost in net income because the exercise price of our stock options equaled the market price of the underlying stock on the date of grant. We have elected to utilize the modified prospective transition method for adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in net income in the periods after the date of adoption.

SFAS 123R requires us to present pro forma information for periods prior to the adoption as if we had accounted for all stock-based compensation under the fair value method of SFAS 123. For purposes of pro forma disclosure, the estimated fair value of the options at the date of grant is amortized to expense over the requisite service period, which generally equals the vesting period. The following table illustrates the effect on net loss and earnings per share as if we had applied the fair value recognition provisions of SFAS 123 to our stock-based employee compensation.

#### ALEXION PHARMACEUTICALS, INC.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except per share amounts)

(Unaudited)

		Three onths ended october 31, 2004
Net loss, as reported	\$	(19,188)
Add: Stock-based employee compensation expense included in reported net loss		5
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards		(2,897)
Pro forma net loss	\$	(22,080)
	_	
Basic and diluted-as reported	\$	(0.70)
Basic and diluted-pro forma	\$	(0.80)

Upon adoption of SFAS 123R, we recognized the compensation expense associated with awards granted after August 1, 2005, and the unvested portion of previously granted awards that remain outstanding as of August 1, 2005, in our condensed consolidated statement of income for the first quarter of fiscal 2006. During the quarter ended October 31, 2005, we recognized compensation expense of \$2,287 for stock options and \$149 for restricted stock, which were charged to our condensed consolidated statement of income. Due to our net loss position, a windfall tax benefit was not realized during the period. Upon the adoption of SFAS 123R, we reversed the deferred stock-based compensation account of \$1,938 through additional paid-in-capital.

For the period ended October 31, 2005, the adoption of SFAS 123R had the following effect on reported amounts that would have been reported using the intrinsic value method under APB No. 25:

		Three Months Ended October 31, 2005		
	Using APB No. 25 Accounting	SFAS 123R Adjustments	As Reported	
Income from operations	\$ (34,013)	\$ (2,285)	\$ (36,298)	
Income before income taxes	(32,914)	(2,285)	(35,199)	
Net income	(32,789)	(2,285)	(35,074)	
Basic and diluted earnings per share	(1.08)	(0.08)	(1.16)	

The adoption of SFAS 123R had no effect on the statement of cash flows due to our current loss position.

# ALEXION PHARMACEUTICALS, INC.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except per share amounts)

(Unaudited)

A summary of the status of our stock option plans at October 31, 2005 and changes during the three months then ended is presented in the table and narrative below:

	Options	A	eighted- verage rcise Price
Options outstanding at July 31, 2005	4,729,793	\$	23.40
Options granted	520,300		27.58
Options cancelled	(32,971)		18.86
Options exercised	(153,712)		15.08
Options outstanding at October 31, 2005	5,063,410		24.11
Options exercisable at October 31, 2005	3,185,783	\$	25.97

Options exercisable at October 31, 2005 had an aggregate intrinsic value of \$4,530 and a weighted average remaining contractual life of 5 years. The following table presents weighted average price information about significant option groups exercisable at October 31, 2005:

Range of Exercise Prices	Number Exercisable	Weighted- Average Exercise Price
\$2.37 to 9.00	237,325	\$ 8.87
\$9.01 to 20.99	1,328,174	12.68
\$ 21.00 to 24.50	915,906	21.54
\$ 24.51 to 54.00	150,211	37.74
\$ 54.01 to 87.00	524,167	67.06
\$ 87.01 to 108.00	30,000	107.88
	3,185,783	\$ 25.97

As of October 31, 2005, there was \$25,789 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 1.7 years.

A summary of the status of our non-vested restricted stock as of October 31, 2005, and changes during the quarter ended October 31, 2005 are as follows:

	Restricted Stock	Avera	eighted- age Grant Fair Value
Nonvested at August 1, 2005	105,500	\$	20.38
Granted	20,000		27.58
Vested	—		
Canceled			—
Nonvested at October 31, 2005	125,500		21.53

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except per share amounts) (Unaudited)

Consistent with our valuation method for the disclosure-only provisions of SFAS 123, we are using the Black-Scholes model to value the compensation expense associated with our stock-based awards under SFAS 123R. In addition, we estimate forfeitures when recognizing compensation expense, and we will adjust our estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative true-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

During the three months ended October 31, 2005, the weighted-average fair value of the options granted under the stock option plans was \$17.90, using the following assumptions:

Expected life in years	6.25
Interest rate	4.20
Volatility	67%
Dividend yield	

The expected stock price volatility rates are based on historical volatilities of our common stock. The risk free interest rates are based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The average expected life represents the weighted average period of time that options granted are expected to be outstanding giving consideration to vesting schedules and our historical exercise patterns. For the quarter ended October 31, 2005, the average expected life was determined using the simplified approach. As noted above, the Company adopted SFAS No. 123R on August 1, 2005 and estimated the expected term and the related period over which expected volatility is calculated, in accordance with SAB 107.

# 3. 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 other potential common shares outstanding during the period. Other potential common shares represent dilutive stock options, unvested restricted stock, and convertible debt. These outstanding stock options, convertible debt, and unvested restricted stock entitled holders to acquire 9,957,431 and 5,842,438 shares of common stock at October 31, 2005 and 2004, respectively. There is no difference in basic and diluted net loss per common share for the three months ended October 31, 2005 and 2004 as the effect of common share equivalents is anti-dilutive.

# 4. Capital Structure

In August 2005, we issued 2,500,000 shares of common stock in a public offering at \$26.75 per share, resulting in gross proceeds from the sale of \$66,875. We incurred underwriting discounts and commissions of \$2,145, or \$0.86 per share as well as other expenses, resulting in net proceeds of \$64,517.

During the quarter ended October 31, 2005, we issued 153,712 shares of common stock with proceeds of \$2,318 upon the exercise of outstanding stock options. Through stock-based exercises of employee options, we increased our holdings of common stock in treasury by 13,713 shares. The shares were exchanged at fair market value for \$381 in total.

# 5. Commitments and Contingencies

We enter into agreements that contain 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

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except per share amounts) (Unaudited)

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 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 of October 31, 2005.

# 6. Subsequent Event

On November 23, 2005, we reported that preliminary results from the Phase III PRIMO-CABG2 study of pexelizumab failed to show statistical significance in reducing the study's primary endpoint of the combined incidence of nonfatal myocardial infarction (heart attack) or death through 30 days following coronary artery bypass graft surgery. These preliminary results are unlikely to support filing for licensing approval of pexelizumab in the CABG indication. We intend to complete analysis of the data from the PRIMO-CABG2 study and expect the results to be presented at an upcoming scientific meeting. Together with Procter & Gamble Pharmaceuticals, Inc. (P&G), we are assessing the implications of the results of PRIMO-CABG2 on our second international pivotal Phase III study of pexelizumab, the APEX-AMI trial, which is investigating the benefits of using pexelizumab in patients experiencing a heart attack who are treated with primary percutaneous coronary intervention (PCI), or angioplasty.

(amounts in thousands, except per share amounts)

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

#### **Note Regarding Forward-Looking Statements**

This report contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward looking statements are based on current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by our management and may include, but are not limited to, statements regarding the status of our ongoing clinical trials and prospects for regulatory approval, the uncertainties involved in the drug development process, the safety and efficacy of our product candidates, our future research and development activities, estimates of the potential markets for our products, assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support our products, the sufficiency of our existing capital resources and projected cash needs, sales and marketing plans, as well as assumptions relating to the foregoing. Words such as "anticipates," "expects," "intends," "may," plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled "Risk Factors". Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission. 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, 2005 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, 2005.

#### 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, eculizumab and pexelizumab, 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. Our pexelizumab activities are pursued in collaboration with Procter & Gamble Pharmaceuticals, Inc. (P&G).

On November 23, 2005, we reported that preliminary results from the Phase III PRIMO-CABG2 study of pexelizumab failed to show statistical significance in reducing the study's primary endpoint of the combined incidence of nonfatal myocardial infarction (heart attack) or death through 30 days following coronary artery bypass graft surgery. These preliminary results are unlikely to support filing for licensing approval of pexelizumab in the CABG indication. We intend to complete analysis of the data from the PRIMO-CABG2 study and expect the results to be presented at an upcoming scientific meeting. Together with P&G, we are assessing the implications of the results of PRIMO-CABG2 on our second international pivotal Phase III study of pexelizumab, the APEX-AMI trial, which is investigating the benefits of using pexelizumab in patients experiencing a heart attack who are treated with primary percutaneous coronary intervention (PCI), or angioplasty.

# ALEXION PHARMACEUTICALS, INC.

#### (amounts in thousands, except per share amounts)

We remain on track to complete both the TRIUMPH and SHEPHERD Phase III pivotal trials with our lead drug candidate eculizumab in the orphan blood disorder Paroxysmal Nocturnal Hemoglobinuria ("PNH"). We expect topline results from TRIUMPH during the first quarter of 2006.

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 October 31, 2005, we had an accumulated deficit of \$483,185. 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.

#### **Results of Operations**

#### Comparison of the Three Months ended October 31, 2005 and October 31, 2004

#### Revenues

A summary of revenues recognized from contract research collaboration and grant awards is as follows for the three months ended:

	October 31	October 31,	
		2004	
P&G	\$147 \$	147	
U.S. government grants	313		
Total revenues	\$460 \$	147	

We earned contract research revenues of \$460 and \$147 for the three months ended October 31, 2005 and 2004, respectively. Our first 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 funded research grant revenue related to our research programs.

# **Research and Development**

We incurred research and development expenses of \$30,274 and \$18,663 for the three months ended October 31, 2005 and 2004, respectively. 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 October 31, 2005 and 2004:

(amounts in thousands, except per share amounts)

	Octol	October 31,	
	2005	2004	
esearch and development expenses:			
Clinical development	\$13,984	\$ 7,024	
Manufacturing and manufacturing development	7,096	4,930	
Payroll and benefits	6,139	4,029	
Operating and occupancy	1,341	1,181	
Discovery research	1,044	952	
Depreciation and amortization	670	547	
	\$30,274	\$18,663	

The \$11,611 increase in research and development expenses resulted primarily from higher clinical development costs related to our current clinical trials and increased manufacturing expenses related to our core development programs for eculizumab and pexelizumab. Payroll and benefits costs are impacted significantly by the adoption of SFAS 123R and the resulting expensing of stock options grants as well as increased headcount to support our research and development activities.

# General and Administrative Expenses

Our general and administrative expenses were \$6,484 and \$3,679 for the three months ended October 31, 2005 and 2004, respectively. The \$2,805 increase resulted principally from increased payroll and benefits expenses of approximately \$1,703 from a combination of the adoption of SFAS 123R and growth of our headcount dedicated to commercial development activities, higher professional fees of approximately \$578 principally for patent and compliance activities. The remainder of the increase in expenses from 2004 to 2005 was caused mostly by recruitment expenses, public relations and other items.

# **Total Operating Expenses**

Total operating expenses for the quarter ended October 31, 2005 and 2004 were \$36,758 and \$22,342, respectively.

# **Other Income and Expense**

Investment income was \$1,832 and \$1,049 for the three months ended October 31, 2005 and 2004, respectively. The increase was due primarily to higher market interest rates and a higher principal balance. The higher principal balance is a result of the August 2005 issuance of 2,500,000 shares of common stock in a public offering at \$26.75 per share, resulting in net proceeds from the sale of \$64.5 million as well as an increase in convertible debt due to the sale of \$150 million principal amount of 1.375% convertible senior notes ("1.375% Notes") in January 2005, partly offset by the redemption of the Company's \$120 million principal amount of 5.75% convertible subordinated notes in March 2005. Interest expense was \$733 and \$1,908 for the three months ended October 31, 2005 and 2004, respectively. The decrease in interest expense is attributable to the lower interest rate for the 1.375% Notes as compared to the 5.75% interest rate on the redeemable notes which were repaid during fiscal 2005. During the three month period ended October 31, 2004, we recorded a gain on extinguishment of note payable of \$3,804 pursuant to the termination of the Unigraft xenotransplantation program at CFC.

# **Income Taxes**

We recorded a state tax benefit of approximately \$125 and \$62 for the three months ended October 31, 2005 and 2004, respectively. The benefit is the result of the exchange for cash of our estimated fiscal 2005 and fiscal 2006 incremental research and development tax credits with the State of Connecticut.

# Net Loss

The Company incurred a net loss for the quarter ended October 31, 2005 of \$35,074 or \$1.16 per common share, versus a net loss of \$19,188 or \$0.70 per common share, for the same three month period in 2004.

(amounts in thousands, except per share amounts)

# Liquidity and Capital Resources

Our primary source of cash is through public offerings of our common stock and the sale of convertible notes. Other sources include debt financing, payments received under corporate collaborations and grants, and equipment and leasehold improvements financing. Our primary use of cash includes business development activities and research and development.

As of October 31, 2005, cash, cash equivalents, and marketable securities were \$230,526 compared with \$195,404 at July 31, 2005. The increase was primarily due to the issuance of 2,500,000 shares of common stock in a public offering at \$26.75 per share, resulting in gross proceeds from the sale of \$66,875. We incurred underwriting discounts and commissions of \$2,145, or \$0.86 per share as well as other expenses, resulting in net proceeds of \$64,517, which was partially offset by cash used to fund operating activities.

### **Operating Activities**

Net cash used in operating activities for the three months ended October 31, 2005 was \$31,322. The increase compared to the prior year is primarily due to increased Research and Development spending in the current year.

#### **Investing Activities**

Net cash used in investing activities for the three months ended October 31, 2005 was \$19,093. This included \$18,976 of purchases of marketable securities, net of proceeds from the maturity or sale of marketable securities, and \$117 of property, plant and equipment additions.

#### **Financing Activities**

Net cash provided by financing activities for the three months ended October 31, 2005 was \$66,454, consisting of proceeds from the sale of common stock of \$64,517, the exercise of stock options of \$2,318, offset by the exchange of 13,713 treasury shares at a cost of \$381.

#### **Sufficiency of Cash Resources**

We anticipate that our existing capital resources together with the anticipated funding from our revised collaboration with P&G, as well as interest and investment income earned on available cash and marketable securities should provide us adequate resources to fund our operating expenses and capital requirements as currently planned for at least the next twenty-four months.

#### **Critical Accounting Policies**

The preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are summarized in our Annual Report on Form 10-K for the year ended July 31, 2005, in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "Critical Accounting Policies and the Use of Estimates." We have reviewed those policies and determined that, except as noted below they remain our critical accounting policies for the three months ended October 31, 2005.

During the quarter ended October 31, 2005, we formed a wholly-owned subsidiary, Alexion Europe SAS. We consider the euro as the functional currency of this subsidiary, and as a result we have included a translation adjustment in the consolidated presentation of stockholders' equity. Prior to the formation of this subsidiary, we did not have foreign currency translations. Accordingly, we have added the following critical accounting policy:

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For foreign subsidiaries with a functional currency different from U.S. dollars, we translate their financial statements into U.S. dollars using:

- the current exchange rate at each balance sheet date for assets and liabilities;
- the average exchange rate prevailing during each period for revenues and expenses; and
- the historical exchange rate for our investments in our foreign subsidiaries.

Adjustments from translating these financial statements into U.S. dollars are included in "Accumulated other comprehensive loss".

# Adoption of SFAS 123R

We have elected to utilize the modified prospective transition method for adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in net income in the periods after the date of adoption. Prior to August 1, 2005, we accounted for the 2004 Incentive Plan and preceding plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB No. 25) and related Interpretations as permitted by Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation." (SFAS 123). When applying the intrinsic value method, we did not record stock-based compensation cost in net income because the exercise price of our stock options equaled the market price of the underlying stock on the date of grant.

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# **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 October 31, 2005, we had an accumulated deficit of approximately \$483,185. 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 indication for each drug that we intend to sell and for each facility where such drug is manufactured. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed outside the United States and facilities outside the United States where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain foreign jurisdictions we would be required to obtain pricing approvals prior to marketing our products. 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. As a condition of approval for marketing our product, FDA, or governmental authorities in other countries may require us to conduct additional clinical trials. Our manufacturing facilities and those of any third parties manufacturing our products will be subject to inspection prior to grant of marketing approval and subject to continued review and periodic inspections by the regulatory authorities. Any third party we would use to manufacture our products for sale must also be licensed by applicable regulatory authorities. Failure to comply with the laws, including statutes and regulations, administered by the FDA 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; withdrawal of a previously granted approval; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution.

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We may be unable to obtain necessary regulatory approvals in the United States and foreign countries on a timely basis, if at all, for any of our product candidates or maintain such approvals if obtained. Any delays in obtaining necessary regulatory approvals or failure to maintain them could prevent us from marketing our products.

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, fast track status does not modify the substantive requirements of safety and efficacy necessary for the FDA to approve marketing of a drug; nor can there be any assurance that a drug granted fast track status would be reviewed more expeditiously for their "fast-track" indications than would otherwise have been the case or would 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 is the first drug of its type to receive 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.

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/or 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 payers.

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. Preliminary results from the PRIMO-CABG2 study indicate that the trial is unlikely to support filing for licensing approval of pexelizumab in the CABG indication. Even if the results of the other 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. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance. Further, before a product candidate is approved for marketing, we, or any third party manufactures are not in compliance with current good manufacturing facilities and the FDA will not approve the product for 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, may pose other restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. A narrowed indication or other restrictions may limit the market potential for the affected product and obligation to conduct additional clinical trials would result in increased expenditures and lower revenues. 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.

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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. The FDA typically requires two well controlled clinical trials that demonstrate efficacy in order to obtain FDA approval to market a product candidate. The SPA for each of our ongoing Phase III clinical programs for eculizumab and pexelizumab provides for only a single efficacy trial and the FDA has indicated that the trials should provide compelling evidence of clinically meaningful benefit in order to warrant consideration for marketing approval of the product candidate. The FDA has noted that a study that is merely statistically positive may not provide the evidence necessary to support filing or approval of a product candidate. Our clinical programs may not demonstrate statistically significant results or show that such results are adequate to support approval for commercialization of eculizumab or pexelizumab. Inconclusive or negative final data from our Phase III clinical programs would have a significant negative impact on our prospects. If the results in our clinical programs are not positive, the potential commercialization of our top product candidates would be at risk, which would likely have a materially negative impact on our ability to generate revenue and our ability to secure additional funding. Preliminary results from the PRIMO-CABG2 study indicate that the trial is unlikely to support filing for licensing approval of pexelizumab in the CABG indication. In addition, the FDA has noted that it may require additional safety information before granting marketing approval. 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. In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries.

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

In September 2000, we announced the completion of enrollment in 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 PRIMO-CABG 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. In August 2005, we completed enrollment of approximately 4,250 patients in a confirmatory, pivotal Phase III PRIMO-CABG2 trial in multiple risk CABG patients. The primary endpoint of PRIMO-CABG2 was the combined incidence of nonfatal myocardial infarction or death through 30 days following CABG surgery in moderate-to-high risk patients. In November 2005, we disclosed that pexelizumab reduced the primary endpoint, but did not meet the pre-specified threshold for statistical significance.

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.



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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, that 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, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

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

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. 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. We may decide to abandon development of a product candidate at any time, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

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

- slow patient enrollment;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product candidate;
- disruption of operations at the clinical trial sites;
- adverse medical events or side effects in treated patients;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support effectiveness of the product candidates;
- lack of effectiveness of the product candidate being tested;
- lack of sufficient funds;
- inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; or
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured.

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:

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- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- diverting our management's attention away from other business concerns;
- risks of entering markets in which we have limited or no direct experience; and
- the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company.

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 twenty four 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. 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;

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- 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.

On October 31, 2005, we had outstanding \$150 million principal amount of 1.375% convertible senior notes. These notes remain outstanding, and the degree to which we are leveraged could, among other things:

- make it difficult for us to make payments on our notes;
- 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 could result in significant additional development costs to us if we were to continue developing pexelizumab. 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

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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.

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 common stock.

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, 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 senior 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 common 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.

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In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We may obtain patents 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 and maintain patents, the patents may not be broad enough to protect our drugs from copycat products.

If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and 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 technology, techniques and proprietary compounds and potential drug candidates, including those which are in-licensed, may be found to infringe 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, including our two leading product candidates, eculizumab and pexelizumab, are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies.

We have received notices from the owners of some of these patents claiming that their patents may be infringed by the development, manufacture or sale of some of our drug candidates, including pexelizumab and eculizumab. We are also aware of other patents owned by third parties that might be claimed to be infringed by the development and commercialization of some of our drug candidates, including pexelizumab and eculizumab. In respect to some of these patents, 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; or
- 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 holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

There can be no assurance that we would prevail in a patent infringement action; 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.

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

Inability to contract with third-party manufacturers on commercially reasonable terms, or failure or delay by us or our third-party manufacturers, if any, in manufacturing our drug products for testing, and later for potential sale in the market in the volumes and quality required, would have a material adverse effect on 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.

We have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales and we can provide no assurance that we will be able to do so successfully. If either eculizumab or pexelizumab is approved for sale, we expect we would be required to manufacture substantially more than we have been required to manufacture for clinical and preclinical trials. We may experience higher manufacturing failure rates than we have in the past if and when we attempt to substantially increase production volume.

### (amounts in thousands, except per share amounts)

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

Currently, we are relying on P&G to retain appropriate commercial-scale manufacturing for pexelizumab through one or more third-party manufacturers. P&G has contracted with Chiron Corporation, or Chiron, for the commercial-scale manufacture of pexelizumab. The failure of P&G to obtain and maintain appropriate commercial-scale manufacturing for pexelizumab in accordance with all regulatory requirements on a timely basis, or at all, may prevent or impede the commercialization of pexelizumab. We have executed a commercial-scale product supply agreement with Lonza Biologics, plc, or Lonza, 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. Prior to granting an approval for marketing of pexelizumab or eculizumab, Chiron's facilities with respect to manufacturing of eculizumab will be subject to inspection by the FDA in the United States and by regulatory agencies from foreign countries. 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 with P&G, on up to a 50-50 basis, 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, private third-party payers and other third-party payers, including Medicare and Medicaid, to defray the cost of our products to the consumer.

#### (amounts in thousands, except per share amounts)

If these entities refuse to provide coverage and reimbursement with respect to our products or determine to provide an insufficient level of coverage and reimbursement, our products may be too costly for general use and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage for higher-priced drugs, as our product candidates are likely to be.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability and worsen our financial condition. In the United States, there have been and we expect will continue to be actions and proposals to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

Since our products will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. 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.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control and we may be unable to negotiate coverage, pricing and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operation may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

#### 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 President, Chief Operating Officer and a member of our Board of Directors, and Stephen P. Squinto, Ph.D., our

#### (amounts in thousands, except per share amounts)

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 carry forwards to reduce future tax payments may be limited if there is a change in ownership of Alexion.

As of July 31, 2005, we had approximately \$440 million of net operating loss carry forwards, or NOLs, available to reduce taxable income in future years. We believe that some of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

Our ability to utilize our NOLs may be further limited if we undergo an ownership change, as defined in section 382, as a result of subsequent changes in the ownership of our outstanding stock. 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.

Based upon our review of the aggregate change in percentage ownership during the current testing period, 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 in August 2005. However, such a determination is complex and 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.

(amounts in thousands, except per share amounts)

### 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 short-term duration of our investments and our investment policy of investing in U.S. Government obligations and high credit quality notes and bonds, 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 October 31, 2005, had maturities of less than two years. The weighted-average interest rate on marketable securities at October 31, 2005 was approximately 4.21%. The fair value of marketable securities held at October 31, 2005 was \$167,118.

# Item 4. Controls and Procedures.

We have carried out an evaluation, as of the end of the period covered by this report, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that 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 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.

# ALEXION PHARMACEUTICALS, INC.

(amounts in thousands, except per share amounts)

# PART II. OTHER INFORMATION

# Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table discloses the total shares of stock exchanged for the quarter ended October 31, 2005:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of shares Purchased as Part of Publicly Announced Program	Maximum Number of Shares that may yet be Purchased Under the Program
August 1 to August 31	4,227	26.24		_
September 1 to September 30	7,500	28.57	_	_
October 1 to October 31	1,986	28.03	_	
		<u> </u>		
Total	13,713	27.61	—	—

The Company currently does not have a stock repurchase plan. All shares exchanged during the quarter ended October 31, 2005 were all made through openmarket transactions.

# Item 6. Exhibits

(a) Exhibits

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended October 31, 2005.

31.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended October 31, 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 Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended October 31, 2005.

32.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended October 31, 2005.

# (b) Reports on Form 8-K

Report on Form 8-K, filed on August 8, 2005, announcing executive compensation information for the Company's named executives

Report on Form 8-K, filed on August 15, 2005, announcing the Company's entry into an underwriting agreement with Morgan Stanley relating to the sale of 2,500,000 shares of the Company's common stock

# ALEXION PHARMACEUTICALS, INC.

(amounts in thousands, except per share amounts)

Report on Form 8-K, filed on August 17, 2005, announcing the issuance of 2,500,000 shares of the Company's common stock

Report on Form 8-K, filed on September 2, 2005, announcing the Company's hiring of Vikas Sinha as Senior Vice President and Chief Financial Officer

Report on Form 8-K, filed on September 26, 2005, announcing the establishment of the 2006 incentive bonus plan for executives of the Company

Report on Form 8-K, filed on October 5, 2005, announcing the results of operations for the year ended July 31, 2005

Report on Form 8-K, filed on November 14, 2005, announcing the Company's hiring of Patrice Coissac as President of Alexion Europe, SAS

# **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: December 6, 2005	By: /s/ Leonard Bell, M.D.	
	Leonard Bell, M.D. Chief Executive Officer, Secretary and Treasurer (principal executive officer)	
Date: December 6, 2005	By: /s/ Vikas Sinha	
	Vikas Sinha Senior Vice President and Chief Financial Officer (principal financial officer)	
Date: December 6, 2005	By: /s/ Barry P. Luke	
	Barry P. Luke Vice President, Finance (principal accounting officer)	
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I, Leonard Bell, M.D., certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 6, 2005

/s/ Leonard Bell, M.D.

Leonard Bell, M.D. Chief Executive Officer I, Vikas Sinha, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 6, 2005

/s/ Vikas Sinha

Vikas Sinha Senior Vice President and Chief Financial Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended October 31, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Leonard Bell M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: December 6, 2005

/s/ Leonard Bell, M.D.

Leonard Bell, M.D. Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended October 31, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Vikas Sinha, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: December 6, 2005

/s/ Vikas Sinha

Vikas Sinha Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.