

ALEXION PHARMACEUTICALS INC

Form 10-Q/A

March 31, 2004

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM 10-Q/A

(Amendment No. 1)

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

For the quarterly period ended January 31, 2004

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-27756

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## Alexion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other

**13-3648318**  
(I.R.S. Employer

jurisdiction of

Identification No.)

incorporation or

organization)

**352 Knotter Drive, Cheshire, Connecticut 06410**

(Address of principal executive offices) (Zip Code)

**203-272-2596**

(Registrant's telephone number, including area code)

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N/A

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

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

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

**Common Stock, \$0.0001 par value**  
Class

**21,956,277 shares**  
Outstanding at March 10, 2004

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**Explanatory Note**

The purpose of this Form 10-Q/A is to amend and restate in its entirety Items 1 and 2 of our Quarterly Report on Form 10-Q for the quarter ended January 31, 2004 entitled Consolidated Financial Statements (Unaudited) and Management's Discussion and Analysis of Financial Condition and Results of Operations. This restatement is the result of management's subsequent determination that the abandonment of our UniGraft xenotransplantation program which included our wholly owned subsidiary, Columbus Farming Corporation (CFC), was the cessation of a discrete research and development program and not a discontinuation of an operation. Accordingly, the accompanying consolidated financial statements and management's discussion and analysis of financial condition and results of operations have been restated so as not to show CFC as a discontinued operation. Such restatement, which affects only the classification of certain items in our unaudited financial statements, has no net impact on our net loss or net loss per share and no material impact on working capital. The financial information previously reported and the amounts as restated are shown in Note 15 to this Amendment No. 1 to this Form 10-Q. This Amendment No. 1 to Form 10-Q does not reflect events occurring after the filing of the original Form 10-Q or modify or update those disclosures affected by subsequent events. No other modifications or changes have been made to the Form 10-Q as originally filed or the exhibits filed therewith.

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**Table of Contents****ALEXION PHARMACEUTICALS, INC.****Consolidated Balance Sheets**

(UNAUDITED)

(amounts in thousands)

	<b>January 31, 2004</b>	<b>July 31, 2003</b>
	(as restated, see Note 15)	(as restated, see Note 15)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,532	\$ 24,844
Marketable securities	212,691	190,566
Reimbursable contract costs	92	390
State tax receivable	933	1,012
Prepaid expenses and other current assets	2,946	2,948
	<hr/>	<hr/>
Total current assets	227,194	219,760
Property, plant, and equipment, net	10,577	12,276
Assets held for sale	1,210	
Goodwill	19,954	19,954
Deferred financing costs, net	1,833	2,119
Prepaid manufacturing costs	10,000	10,000
Other assets	1,351	1,968
	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<b>\$ 272,119</b>	<b>\$ 266,077</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,985	\$ 7,560
Accrued expenses	2,904	4,312
Accrued interest	2,764	2,646
Deferred revenue	589	589
Deferred research and development payments	188	
Note payable (See Note 9)	3,920	
	<hr/>	<hr/>
Total current liabilities	18,350	15,107
Deferred revenue, less current portion included above	6,470	6,764
Deferred research and development payments, less current portion included above	1,296	
Note payable (See Note 9)		3,920
Convertible subordinated notes	120,000	120,000
	<hr/>	<hr/>
Total liabilities	146,116	145,791
	<hr/>	<hr/>
Commitments and contingencies (see Note 12)		
Stockholders' Equity:		
Preferred stock \$.0001 par value; 5,000 shares authorized; no shares issued or outstanding		
	2	2

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Common stock \$.0001 par value; 145,000 shares authorized; 21,959 and 18,257 shares issued at January 31, 2004 and July 31, 2003, respectively

Additional paid-in capital	430,419	385,498
Accumulated deficit	(304,025)	(265,266)
Other comprehensive income	207	652
Treasury stock, at cost; 37 shares	(600)	(600)
	<hr/>	<hr/>
Total stockholders' equity	126,003	120,286
	<hr/>	<hr/>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 272,119</b>	<b>\$ 266,077</b>
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The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****Consolidated Statements of Operations**

(UNAUDITED)

(amounts in thousands, except per share amounts)

	Three months ended January 31,		Six months ended January 31,	
	2004  (as restated, see Note 15)	2003  (as restated, see Note 15)	2004  (as restated, see Note 15)	2003  (as restated, see Note 15)
<b>CONTRACT RESEARCH REVENUES</b>	\$ 147	\$ 220	\$ 294	\$ 543
<b>OPERATING EXPENSES:</b>				
Research and development	14,524	18,667	31,212	38,439
General and administrative	3,300	2,754	6,114	4,900
Total operating expenses	17,824	21,421	37,326	43,339
Operating loss	(17,677)	(21,201)	(37,032)	(42,796)
<b>OTHER INCOME AND EXPENSE</b>				
Investment income	994	1,662	1,995	3,544
Interest expense	(1,926)	(1,926)	(3,855)	(3,853)
Loss before state tax benefit	(18,609)	(21,465)	(38,892)	(43,105)
State tax benefit	62		133	
Net loss	\$ (18,547)	\$ (21,465)	\$ (38,759)	\$ (43,105)
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	\$ (0.85)	\$ (1.18)	\$ (1.85)	\$ (2.37)
<b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	21,893	18,207	20,924	18,206

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

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****Consolidated Statements Of Cash Flows**

(UNAUDITED)

(amounts in thousands)

	Six months ended January 31,	
	2004	2003
	(as restated, see Note 15)	(as restated, see Note 15)
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (38,759)	\$ (43,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,737	1,809
Compensation expense related to grant of stock options	57	67
Change in assets and liabilities:		
Reimbursable contract costs	298	474
State tax receivable	79	
Prepaid expenses	2	(635)
Other assets	601	(176)
Prepaid manufacturing costs		(7,250)
Accounts payable	425	(3,554)
Accrued expenses	(1,408)	(1,312)
Accrued interest	118	19
Deferred revenue	(294)	(251)
Deferred research and development payments	1,484	
Net cash used in operating activities	(35,660)	(53,914)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of marketable securities	(72,539)	(49,667)
Proceeds from maturity or sale of marketable securities	49,969	109,649
Investments in patents and licensed technology	(5)	(27)
Purchases of property, plant and equipment	(941)	(1,364)
Net cash provided by (used in) investing activities	(23,516)	58,591
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net proceeds from issuance of common stock	44,864	50
Net cash provided by financing activities	44,864	50
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(14,312)	4,727
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	24,844	47,574
<b>CASH AND CASH EQUIVALENTS, end of period</b>	\$ 10,532	\$ 52,301



**SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION**

Cash paid for interest	\$ 3,450	\$ 3,568
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The accompanying notes are an integral part of these consolidated financial statements.

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**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

*1. Organization and Operations -*

Alexion Pharmaceuticals, Inc. ( Alexion ) was organized in 1992 and is engaged in the discovery and development of therapeutic products for the treatment of a wide array of severe disease states, including cardiovascular, hematologic and autoimmune disorders, inflammation, and cancer.

The accompanying consolidated financial statements include Alexion Pharmaceuticals, Inc. and our wholly owned subsidiaries, Alexion Antibody Technologies ( AAT ) and Columbus Farming Corporation ( CFC ). All significant inter-company balances and transactions have been eliminated in consolidation. Certain reclassifications have been made to the prior year operating expenses for the three and six months ended January 31, 2003 to conform prior year expense classifications to current year expense classifications. With the abandonment of our UniGraft xenotransplantation research and development program in fiscal 2003, CFC activities were suspended (see Note 9). As further discussed in Note 15, these financial statements have been restated as a result of management's determination that the abandonment of our UniGraft xenotransplantation program which included our wholly owned subsidiary, Columbus Farming Corporation (CFC), was the cessation of a discrete research and development program and not a discontinuation of an operation.

The consolidated financial statements included herein have been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ( SEC ) and include, in the opinion of management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of interim period results. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The results for the interim periods presented are not necessarily indicative of results to be expected for any future period. Certain amounts in the fiscal 2003 financial statements have been reclassified to conform to the fiscal 2004 presentation. These consolidated condensed financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Form 10-K Annual Report for the fiscal year ended July 31, 2003. The year-end balance sheet data presented does not include all disclosures required by accounting principles generally accepted in the United States of America.

*2. Accounting for Stock-Based Compensation -*

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

At January 31, 2004, we have two stock-based compensation plans for employees, directors and consultants of Alexion. We account for the plans under the recognition and measurement principles of Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations.



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## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the three and six months ended January 31, 2004 and 2003 (dollars in thousands, except per share amounts):

	Three months ended January 31,		Six months ended January 31,	
	2004	2003	2004	2003
Net loss, as reported	\$ (18,547)	\$ (21,465)	\$ (38,759)	\$ (43,105)
Add: Stock-based employee compensation expense included in reported net loss	16	45	32	67
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(3,572)	(4,220)	(7,092)	(8,293)
Pro forma net loss	\$ (22,103)	\$ (25,640)	\$ (45,819)	\$ (51,331)
Net loss per share:				
Basic and diluted - as reported	\$ (0.85)	\$ (1.18)	\$ (1.85)	\$ (2.37)
Basic and diluted - pro forma	\$ (1.01)	\$ (1.41)	\$ (2.19)	\$ (2.82)

The table does not include non-employee compensation expense of \$7,000 and \$25,000 for the three and six months ended January 31, 2004 respectively.

The effects of applying the fair value recognition provisions of SFAS No. 123 in this pro forma disclosure are not necessarily indicative of future amounts.

### 3. Issuance of Common Stock -

In September 2003, we sold 3.6 million shares of our common stock at a price of \$13.00 per share resulting in net proceeds of approximately \$43.9 million, net of underwriting discounts, fees and other expenses of approximately \$2.9 million related to the transaction. We expect to use the net proceeds of the sale of common stock to fund working capital and other general corporate purposes, including additional clinical trials of pexelizumab and eculizumab, as well as other research and product development activities.

*4. Procter & Gamble Pharmaceuticals Collaboration -*

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

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

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

We agreed to bear the first 50% of projected costs associated with the Phase III clinical trial in coronary artery bypass graft surgery ( CABG ) (called PRIMO-CABG ) and P&G agreed to bear the second 50% as part of our revised collaboration. As of January 31, 2004, we and P&G both completed each of our obligations with respect to the originally projected costs. Additional costs incurred over the original projected costs are shared equally by us and P&G. Reimbursements received by us from P&G in connection with P&G 's 50% share of our services and related personnel are recorded as a reduction of research and development expense. As part of the revised collaboration per the MOU, P&G funded 100% of the costs for the two acute myocardial infarction ( AMI ) Phase II clinical trials in myocardial infarction, or heart attack, patients.

We and P&G have agreed, as per the MOU, that each will share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any future AMI or CABG Phase III clinical trial costs.

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

Under terms of our MOU we may be obligated to reimburse P&G for 50% of cancellation costs under P&G 's third-party pexelizumab manufacturing contract. Our portion of those cancellation costs could amount to as much as \$9.8 million.

*5. XOMA Ltd. Collaboration*

In December 2003, we and XOMA (U.S.) LLC ( XOMA ) entered into a collaborative agreement for the development and commercialization of a rationally designed human c-MPL agonist antibody to treat chemotherapy-induced thrombocytopenia. Thrombocytopenia is an abnormal blood condition in which the number of platelets is reduced, potentially leading to bleeding complications. The compound was discovered at AAT and is in pre-clinical development. The c-MPL antibody was designed to mimic the activity of human thrombopoietin ( TPO ), a naturally occurring protein responsible for platelet production. The collaboration will initially focus on preclinical, process development and scale-up work in preparation for future clinical testing.

Under the terms of the agreement, we and XOMA will jointly develop and commercialize the c-MPL agonist antibody for chemotherapy-induced thrombocytopenia. We will share development and commercialization expenses, clinical development, manufacturing and marketing costs world-wide, as well as revenues, on generally a 70 / 30 basis, with us retaining the larger portion. In addition, we received a \$1.5 million upfront non-refundable payment upon initiation of the collaboration and will receive a similar sized payment upon the achievement of a regulatory milestone. We are recognizing the \$1.5 million upfront payment as a reduction of research and development expenses over 8

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years, which represents the estimated length of time to achieve commercial viability. XOMA will be entitled to royalty payments and milestones from Alexion related to its bacterial cell expression technology.

### *6. Revenues -*

Our current revenue is deferred revenue from cash received from P&G (see Note 4). The prior fiscal year includes deferred revenue from P&G and revenue from government grants.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

We record contract research revenues from research and development support payments, license fees and milestone payments under collaboration with third parties, and amounts received from various government grants. We evaluate all deliverables in our collaborative agreements to determine whether they represent separate units of accounting. Deliverables qualify for separate accounting treatment if they have standalone value to the customer and if there is objective evidence of fair value. Up-front, non-refundable license fees received in connection with a collaboration are deferred and amortized into revenue over the life of the agreement or underlying technologies. Revenues derived from the achievement of milestones are recognized when the milestone is achieved, provided that the milestone is substantive and a culmination of the earnings process has occurred. Research and development support revenues are recognized as the related work is performed and expenses are incurred under the terms of the contracts for development activities. Revenues derived from the achievement of milestones or recognition of related work when performed under terms of a contract may cause our operating results to vary considerably from period to period. Deferred revenue results from cash received or amounts receivable in advance of revenue recognition under research and development contracts.

*7. Net Loss Per Common Share -*

We compute and present net loss per common share in accordance with SFAS No. 128, Earnings Per Share. Basic net loss per common share is based on the weighted average shares of common stock outstanding during the period. Diluted net loss per common share includes in addition to the above, the dilutive effect of common share equivalents outstanding during the period. Common share equivalents represent dilutive stock options and convertible subordinated debt. These outstanding stock options and convertible subordinated debt entitled holders to acquire 5,459,387 and 4,732,749 shares of common stock at January 31, 2004 and 2003, respectively. There is no difference in basic and diluted net loss per common share for the three and six months ended January 31, 2004 and 2003 as the effect of common share equivalents is anti-dilutive.

*8. Accrued Research and Development Expenses -*

Accrued research and development expenses are comprised of amounts owed to suppliers for research and development work performed on behalf of us. At each period end we evaluate the accrued expense balance related to these activities based upon information received from the supplier and estimated progress toward completion of the research or development objectives to ensure that the balance is appropriately stated. Such estimates are subject to changes as additional information becomes available. Accrued research and development expenses were \$1.4 million at January 31, 2004 and \$1.1 million at July 31, 2003.

*9. Note Payable*

In February 1999, CFC purchased substantially all of the assets of the UniGraft xenotransplantation program, including principally, land, buildings and laboratory equipment, from its then partner in the program, U.S. Surgical Corporation, now a division of Tyco International, Ltd. ( Tyco ). The purchase was financed through the issuance by CFC of a \$3.9 million note payable to Tyco. Interest on the \$3.9 million note payable, at 6% per annum, is payable quarterly by CFC. The xenotransplantation manufacturing assets of CFC that were purchased from Tyco,



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including the real estate, are pledged as security for this note. The principal balance under the note is due in May 2005, and accordingly was classified as a long-term obligation as of July 31, 2003. However, upon CFC's failure to make its quarterly interest payment due to Tyco in August 2003, CFC defaulted on the note. As a result of the event of default, the note is classified as a current liability as of January 31, 2004. We continue to recognize CFC's interest expense on the note payable as such obligations have not been discharged.

In the quarter ended October 31, 2003, in conjunction with the event of default, we notified Tyco that the UniGraft xenotransplantation program and CFC activities had been suspended. CFC is seeking to liquidate itself to fulfill its debt obligation in whole or in part. CFC further notified Tyco that it does not have the funds or assets to satisfy the \$3.9 million note. During the quarter ended January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. If CFC's assets, consisting of property, plant and

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

equipment with a current estimated fair value of \$1.2 million, are insufficient to satisfy the \$3.9 million note and other obligations of CFC, then the unpaid amount of the note may be discharged debt, recognized as other income in a future period to CFC. As of January 31, 2004 we have classified the property, plant and equipment of CFC as assets held for sale as per the guidelines set forth in SFAS No. 144.

*10. Convertible Subordinated Notes -*

In March 2000, we completed a \$120 million private placement of 5.75% Convertible Subordinated Notes due March 15, 2007. The notes bear interest payable semi-annually on September 15 and March 15 of each year, beginning September 15, 2000. The holders may convert all or a portion of the notes into common stock at any time on or before March 15, 2007 at a conversion price of \$106.425 per share resulting in the issuance of 1,127,555 shares of common stock, in aggregate. We incurred interest expense of approximately \$1.7 million and \$3.5 million for the three and six months ended January 31, respectively, for both 2004 and 2003 related to these notes.

We incurred deferred financing costs related to this offering of approximately \$4.0 million, which are recorded in the consolidated balance sheet and are being amortized as a component of interest expense over the seven-year term of the notes. Amortization expense associated with the financing costs was approximately \$143,000 and \$286,000 for the three and six months ended January 31, respectively, for both 2004 and 2003.

*11. Lonza Large-Scale Product Supply Agreement -*

In January 2003, we remitted a cash advance of \$7.25 million to Lonza Biologics, plc ( Lonza ) pursuant to a large-scale product supply agreement for the long-term commercial manufacture of our C5 inhibitor antibody, eculizumab. We expect to amortize this advance, along with a previously paid commitment fee of \$2.75 million, over the large-scale manufacture of eculizumab. The amounts advanced are subject to refund or forfeiture pursuant to contractual terms related to cancellation, termination, or failure to purchase a minimum volume of product. These amounts are included within prepaid manufacturing costs within the accompanying balance sheets. Under terms of the agreement with Lonza, we could owe penalties for failure to purchase a minimum volume of product or if we terminate the agreement prior to its expiration. On a quarterly basis, we evaluate our plans to proceed with production under the agreement which depends upon our clinical development programs progress as well as commercialization plans. In addition, we evaluate the prepaid manufacturing costs, which will be amortized over the large-scale manufacture of eculizumab, against estimated net realizable value ( NRV ). If estimated NRV is not positive, then all or a portion of the prepaid manufacturing cost may have to be recognized as an expense. If we terminate the agreement, we could be required to complete the purchase of product scheduled for manufacture up to 18 months following termination, or at our election to make a termination payment of up to \$25 million, less partial return of the unused portion of prepaid manufacturing costs. Any portion of the prepaid manufacturing cost that becomes unusable, due to amendment or termination of the agreement, may have to be recognized as an expense at such time.

*12. Commitments and Contingencies -*

In November 2002, the FASB issued FASB Interpretation No. ( FIN ) 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others, an interpretation of SFAS Nos. 5, 57 and 107 and Rescission of FIN 34 . FIN 45 clarifies the requirements of SFAS No. 5, Accounting for Contingencies , relating to the guarantor s accounting for, and disclosure of, the issuance of certain types of guarantees. Adoption of FIN 45 did not have a material impact on either our operating results or our financial position.

We enter into indemnification provisions under our agreements with other companies in our ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the

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(Unaudited)

indemnified parties in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products, or 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 January 31, 2004.

*13. Comprehensive Income (Loss) -*

We report and present comprehensive income (loss) in accordance with SFAS No. 130, *Reporting Comprehensive Income*, which establishes standards for the reporting and display of comprehensive income (loss) and its components in a full set of general purpose financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners (comprehensive income (loss)). Our other comprehensive income (loss) arises from net unrealized gains (losses) on marketable securities. We have elected to display comprehensive income (loss) as a component of the statements of stockholders' equity and comprehensive loss.

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

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>January 31,</b>		<b>January 31,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Net loss	\$ (18,547)	\$ (21,465)	\$ (38,759)	\$ (43,105)
Other comprehensive income	(139)	(306)	(445)	(146)
<b>Total comprehensive loss</b>	<b>\$ (18,686)</b>	<b>\$ (21,771)</b>	<b>\$ (39,204)</b>	<b>\$ (43,251)</b>

*14. Recently Issued Accounting Pronouncements -*

In January 2003, the FASB issued FIN 46, *Consolidation of Variable Interest Entities*, an interpretation of Accounting Research Bulletin No. 51. FIN 46 requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. Variable interest entities that effectively disperse risk will not be consolidated unless a single

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party holds an interest or combination of interests that effectively recombines risks that were previously dispersed. FIN 46 also requires enhanced disclosure requirements related to variable interest entities. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period ending after December 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 did not have a material effect on our financial statements.

In November 2003, the Emerging Issues Task Force ( EITF ) reached a consensus on EITF Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, regarding the issue of disclosures for marketable securities and debt securities accounted for under Statement of Financial Accounting Standards ( SFAS ) No. 115, Accounting for Certain Investments in Debt and Equity Securities. The EITF requires additional quantitative disclosure related to unrealized losses, specifically presentation of the aging of such losses. It also requires additional qualitative disclosures to help users understand why the quantitative disclosures are not other-than-temporarily impaired. The adoption of these disclosure requirements are effective for companies with years ending after December 15, 2003.

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**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

In December 2003, the Securities and Exchange Commission ( SEC ) issued Staff Accounting Bulletin No. 104 ( SAB 104 ), Revenue Recognition , which supercedes SAB 101, Revenue Recognition in Financial Statements. SAB 104 s primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superceded as a result of the issuance of EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. The issuance of SAB 104 reflects the concepts contained in EITF 00-21; the other revenue recognition concepts contained in SAB 101 remain unchanged. The issuance of SAB 104 did not have a material impact on our results of operations or financial position.

*15. Explanatory Note for Restatement -*

This restatement is the result of management s subsequent determination that the abandonment of our UniGraft xenotransplantation program which included our wholly owned subsidiary, Columbus Farming Corporation (CFC), was the cessation of a discrete research and development program and not a discontinuation of an operation. Accordingly, the accompanying consolidated financial statements and management s discussion and analysis of financial condition and results of operations have been restated so as not to show CFC as a discontinued operation. Such restatement, which affects only the classification of certain items in the Company s unaudited financial statements, has no net impact on the Company s net loss or net loss per share and no material impact on working capital.

The following summarized financial information shows the amounts previously reported and the amounts as restated.

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****Consolidated Balance Sheets**

(UNAUDITED)

(amounts in thousands)

	<b>January 31, 2004</b>	<b>January 31, 2004</b>	<b>July 31, 2003</b>	<b>July 31, 2003</b>
	<b>(previously reported)</b>	<b>(as restated)</b>	<b>(previously reported)</b>	<b>(as restated)</b>
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 10,525	\$ 10,532	\$ 24,816	\$ 24,844
Marketable securities	212,691	212,691	190,566	190,566
Reimbursable contract costs	92	92	390	390
State tax receivable	933	933	1,012	1,012
Prepaid expenses and other current assets	2,946	2,946	2,939	2,948
Assets of discontinued operations held for sale	1,217		1,247	
<b>Total current assets</b>	<b>228,404</b>	<b>227,194</b>	<b>220,970</b>	<b>219,760</b>
Property, plant, and equipment, net	10,577	10,577	11,066	12,276
Assets held for sale		1,210		
Goodwill	19,954	19,954	19,954	19,954
Deferred financing costs, net	1,833	1,833	2,119	2,119
Prepaid manufacturing costs	10,000	10,000	10,000	10,000
Other assets	1,351	1,351	1,968	1,968
<b>TOTAL ASSETS</b>	<b>\$ 272,119</b>	<b>\$ 272,119</b>	<b>\$ 266,077</b>	<b>\$ 266,077</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>				
Current liabilities:				
Accounts payable	\$ 7,985	\$ 7,985	\$ 7,560	\$ 7,560
Accrued expenses	2,904	2,904	4,312	4,312
Accrued interest	2,587	2,764	2,587	2,646
Deferred revenue	589	589	589	589
Deferred research and development payments	188	188		
Liabilities of discontinued operations held for sale	4,097		59	
Note payable (see Note 9) (Previously reported as liability of discontinued operations held for sale)		3,920		
<b>Total current liabilities</b>	<b>18,350</b>	<b>18,350</b>	<b>15,107</b>	<b>15,107</b>
Deferred revenue, less current portion included above	6,470	6,470	6,764	6,764
Deferred research and development payments, less current portion included above	1,296	1,296		
Note payable (See Note 9)			3,920	3,920
Convertible subordinated notes	120,000	120,000	120,000	120,000
<b>Total liabilities</b>	<b>146,116</b>	<b>146,116</b>	<b>145,791</b>	<b>145,791</b>

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Total stockholders' equity	126,003	126,003	120,286	120,286
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 272,119</b>	<b>\$ 272,119</b>	<b>\$ 266,077</b>	<b>\$ 266,077</b>

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**Table of Contents****Alexion Pharmaceuticals, Inc.****Consolidated Statements of Operations**

(UNAUDITED)

(amounts in thousands, except per share amounts)

	Three months ended January 31,		Three months ended January 31,		Six months ended January 31,		Six months ended January 31,	
	2004 (previously reported)	2004 (as restated)	2003 (previously reported)	2003 (as restated)	2004 (previously reported)	2004 (as restated)	2003 (previously reported)	2003 (as restated)
<b>CONTRACT RESEARCH REVENUES</b>	\$ 147	\$ 147	\$ 220	\$ 220	\$ 294	\$ 294	\$ 543	\$ 543
<b>OPERATING EXPENSES:</b>								
Research and development	14,565	14,524	18,243	18,667	31,212	31,212	37,436	38,439
General and administrative	3,300	3,300	2,754	2,754	6,114	6,114	4,900	4,900
Total operating expenses	17,865	17,824	20,997	21,421	37,326	37,326	42,336	43,339
Operating loss	(17,718)	(17,677)	(20,777)	(21,201)	(37,032)	(37,032)	(41,793)	(42,796)
<b>OTHER INCOME AND EXPENSE</b>								
Investment income	994	994	1,662	1,662	1,995	1,995	3,544	3,544
Interest expense	(1,867)	(1,926)	(1,867)	(1,926)	(3,737)	(3,855)	(3,735)	(3,853)
Loss before state tax benefit	(18,591)	(18,609)	(20,982)	(21,465)	(38,774)	(38,892)	(41,984)	(43,105)
State tax benefit	62	62			133	133		
Net loss from continuing operations	(18,529)		(20,982)		(38,641)		(41,984)	
Loss from discontinued operations of Columbus Farming Corporation	(18)		(483)		(118)		(1,121)	
Net loss	\$ (18,547)	\$ (18,547)	\$ (21,465)	\$ (21,465)	\$ (38,759)	\$ (38,759)	\$ (43,105)	\$ (43,105)
<b>BASIC AND DILUTED NET LOSS PER SHARE:</b>								

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Loss from continuing operations	\$ (0.85)		\$ (1.15)		\$ (1.84)		\$ (2.31)
Loss from discontinued operations of Columbus Farming Corporation	\$		\$ (0.03)		\$ (0.01)		\$ (0.06)
<b>NET LOSS PER SHARE</b>	<b>\$ (0.85)</b>	<b>\$ (0.85)</b>	<b>\$ (1.18)</b>	<b>\$ (1.18)</b>	<b>\$ (1.85)</b>	<b>\$ (1.85)</b>	<b>\$ (2.37)</b>

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****Consolidated Statements Of Cash Flows**

(UNAUDITED)

(amounts in thousands)

	Six months ended January 31,		Six months ended January 31,	
	2004  (previously reported)	2004  (as restated)	2003  (previously reported)	2003  (as restated)
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				
Net loss	\$ (38,759)	\$ (38,759)	\$ (43,105)	\$ (43,105)
Adjustments to reconcile net loss to net cash used in operating activities:				
Loss from discontinued operations	118		1,121	
Depreciation and amortization	1,737	1,737	1,567	1,809
Compensation expense related to grant of stock options	57	57	67	67
Change in assets and liabilities:				
Reimbursable contract costs	298	298	474	474
State tax receivable	79	79	0	0
Prepaid expenses	(7)	2	(628)	(635)
Other assets	601	601	(176)	(176)
Prepaid manufacturing costs			(7,250)	(7,250)
Accounts payable	425	425	(3,440)	(3,554)
Accrued expenses	(1,408)	(1,408)	(1,296)	(1,312)
Accrued interest		118	(1)	19
Deferred revenue	(294)	(294)	(251)	(251)
Deferred research and development payments	1,484	1,484		
Net cash used in operating activities (previously reported as net cash used in continuing operations)	(35,669)	(35,660)	(52,918)	(53,914)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>				
Purchases of marketable securities	(72,539)	(72,539)	(49,667)	(49,667)
Proceeds from maturity or sale of marketable securities	49,969	49,969	109,649	109,649
Investments in patents and licensed technology	(5)	(5)	(27)	(27)
Purchases of property, plant and equipment	(941)	(941)	(1,299)	(1,364)
Net cash provided by (used in) investing activities	(23,516)	(23,516)	58,656	58,591
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>				
Net proceeds from issuance of common stock	44,864	44,864	50	50
Net cash provided by financing activities	44,864	44,864	50	50
Net cash provided by (used in) discontinued operations	30		(980)	

<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(14,291)	(14,312)	4,808	4,727
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	24,816	24,844	47,522	47,574
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<u>\$ 10,525</u>	<u>\$ 10,532</u>	<u>\$ 52,330</u>	<u>\$ 52,301</u>

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**ALEXION PHARMACEUTICALS, INC.**

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

*This report contains forward-looking statements which involve risks and uncertainties. Such statements are subject to certain factors which may cause our plans and results to differ significantly from plans and results discussed in forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in Risk Factors - Exhibit 99.1 to our Annual Report on Form 10-K for our fiscal year ended July 31, 2003. 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, 2003 and the related Management's Discussion and Analysis of Financial Conditions and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended July 31, 2003.*

**Overview**

We are engaged in the discovery and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including cardiovascular, hematologic and autoimmune disorders, inflammation and cancer. Since our inception 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. ( AAT ) we are engaged in the discovery and development of a portfolio of additional antibody therapeutics targeting severe unmet medical needs.

The purpose of this Form 10-Q/A is to amend and restate in its entirety Items 1 and 2 of our Quarterly Report on Form 10-Q for the quarter ended January 31, 2004 entitled Consolidated Financial Statements (Unaudited) and Management's Discussion and Analysis of Financial Condition and Results of Operations. For additional information regarding the restatement, please refer to Note 15 to the Consolidated Financial Statements (Unaudited) included in Item 1. All applicable financial information presented in this Item 2 has been restated to take into account the effects of the restatement described in Note 15 to the Consolidated Financial Statements (Unaudited).

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of January 31, 2004, we had an accumulated deficit of \$304.0 million. We expect to incur substantial and increasing operating losses for the next several years due to expenses associated with product research and development, pre-clinical studies and clinical testing, regulatory activities, manufacturing development, scale-up and commercial manufacturing and developing a sales and marketing force. We may 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 with major pharmaceutical companies for product development and commercialization, where we would still play a major role.

Our two lead product candidates are antibodies that address specific diseases that arise when the human immune system attacks the human body itself and produces undesired inflammation. We are currently examining our two lead antibody product candidates in a variety of clinical development programs.

One of our antibody product candidates, pexelizumab, is an antibody fragment under development in collaboration with Procter & Gamble Pharmaceuticals ( P&G ) for treatment of acute cardiovascular disorders. In 2003, we completed a Phase III clinical trial of pexelizumab, known as the PRIMO-CABG trial, in approximately 3000 patients undergoing coronary artery bypass graft surgery ( CABG ) with cardio-pulmonary bypass ( CPB ). In November 2003, at the Late-Breaking Clinical Trials Session of the 2003 Scientific Sessions Meeting of the American Heart Association, the results of the PRIMO-CABG study were presented. As we disclosed in August 2003, there was reduction in the primary endpoint, although it was not achieved with statistical significance. The

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**ALEXION PHARMACEUTICALS, INC.**

primary endpoint in this trial was a composite of the incidence of death or myocardial infarction, measured at 30 days post-procedure, in the subpopulation of patients undergoing CABG without concomitant valve surgery. However, key secondary endpoints were achieved, including the same death or myocardial infarction composite in the overall study population, which included all patients undergoing CABG with or without concomitant valve surgery. We, along with our partner P&G, are currently planning and expect to initiate a confirmatory pivotal Phase III trial in CABG patients this year to expand upon and confirm observations from the PRIMO-CABG trial. In September 2000 the FDA granted Fast Track status for the development of pexelizumab in CPB. Fast Track designation provides for expedited development and application review for approval of a drug through the FDA. In addition, we expect to advance pexelizumab into a pivotal Phase III clinical trial in acute myocardial infarct ( AMI ) patients receiving angioplasty.

Our other lead antibody product candidate, eculizumab, is in clinical development for the treatment of a variety of chronic inflammatory diseases. In particular, eculizumab is under evaluation in a Phase I extension study in paroxysmal nocturnal hemoglobinuria ( PNH ) patients. PNH is a rare chronic blood disease characterized by severe anemia and risk of blood clotting or thrombosis. Results from the twelve months of therapy in this open-label three month PNH pilot study performed in the United Kingdom were presented at the American Society of Hematology meeting in December 2003. The three month results were also published in the February 5, 2004 issue of the New England Journal of Medicine. In this PNH study, eculizumab was well-tolerated and associated with a 71% reduction in the need for blood transfusions, up to 81% reduction in biochemical parameters of hemolysis, or destruction of red cells, and 96% reduction in clinical paroxysms. An open-label extension trial that will help us evaluate long term-safety is ongoing in which all eleven PNH patients from the original Phase I trial are participating. We are currently in discussion with the FDA to determine the next steps required for the Phase III development of eculizumab in PNH. We are planning and expect to initiate this year a pivotal Phase III program with eculizumab in PNH patients.

During the quarter ended January 31, 2004, we announced preliminary results of our approximately 350 patient Phase IIb study of eculizumab in rheumatoid arthritis patients. The primary efficacy endpoint of the trial was the improvement in ACR20 score after a six month treatment period. Results of the current trial indicate that the primary endpoint was achieved with statistical significance in the monthly dosing arm but not in the bimonthly dosing arm. Eculizumab treatment appeared to be safe and well tolerated, with the most common adverse events being upper respiratory tract infection, headache and nausea. The most common serious adverse events were myocardial infarction, accidental injury and cerebral infarction. Serious and common adverse event rates appeared to be similar between placebo and eculizumab in the study population. After completing the analysis of this Phase IIb rheumatoid arthritis trial, we anticipate presenting the results at an upcoming scientific conference and determining our plans for eculizumab in rheumatoid arthritis.

In December 2003, we and XOMA (U.S.) LLC ( XOMA ) entered into a collaborative agreement for the development and commercialization of a rationally designed human c-MPL agonist antibody to treat chemotherapy-induced thrombocytopenia. Thrombocytopenia is an abnormal blood condition in which the number of platelets is reduced, potentially leading to bleeding complications. The compound was discovered at AAT and is in pre-clinical development. The c-MPL antibody was designed to mimic the activity of human thrombopoietin ( TPO ), a naturally occurring protein responsible for platelet production. Under the terms of the agreement, we and XOMA will share development and commercialization expenses, including clinical development, manufacturing and marketing costs world-wide, as well as revenues, on generally a 70 : 30 basis, with us retaining the larger portion. In addition, we received a \$1.5 million upfront non-refundable payment upon initiation of the collaboration and will receive a similar sized payment tied to achievement of a regulatory milestone. We are recognizing the \$1.5 million upfront payment as a reduction of research and development expenses over 8 years, which represents the estimated length of time to achieve commercial viability. XOMA will be entitled to royalty payments and milestones from Alexion related to its bacterial cell expression technology.

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*Critical Accounting Policies and Changes*

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent liabilities. On an on-going basis, we evaluate our estimates, including those related to intangible assets; collaborative, royalty and license arrangements; and other contingencies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. Different assumptions might cause our estimates to differ.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

**Revenues** - We record contract research revenues from research and development support payments, license fees and milestone payments under collaboration with third parties, and amounts received from various government grants. We evaluate all deliverables in our collaborative agreements to determine whether they represent separate units of accounting. Deliverables qualify for separate accounting treatment if they have standalone value to the customer and if there is objective evidence of fair value. Up-front, non-refundable license fees received in connection with a collaboration are deferred and amortized into revenue over the life of the agreement or underlying technologies. Revenues derived from the achievement of milestones are recognized when the milestone is achieved, provided that the milestone is substantive and a culmination of the earnings process has occurred. Research and development support revenues are recognized as the related work is performed and expenses are incurred under the terms of the contracts for development activities. Revenues derived from the achievement of milestones or recognition of related work when performed under terms of a contract may cause our operating results to vary considerably from period to period. Deferred revenue results from cash received or amounts receivable in advance of revenue recognition under research and development contracts.

**Research and development expenses** - We record research and development expenses when they are incurred unless recoverable under contract. Research and development expenses include the following major types of costs: salaries and benefit costs, research license fees and various contractor costs, depreciation and amortization of lab facilities and leasehold improvements, building and utilities costs related to research space, and lab supplies. Research and development expenses can fluctuate significantly from milestone payments due to third parties upon the attainment or triggering of contractual milestones such as the grant of a patent, FDA filing, FDA approval, or achieving a manufacturing or sales objective. Accrued research and development expenses are comprised of amounts owed to suppliers for research and development work performed on behalf of us. At each period end we evaluate the accrued expense balance related to these activities based upon information received from the supplier and estimated progress toward completion of the research or development objectives to ensure that the balance is appropriately stated. Such estimates are subject to changes as additional information becomes available.

**Goodwill, net** At January 31, 2004, we carry \$20.0 million of goodwill, net, acquired in connection with our acquisition of Prolifaron, representing the excess cost over fair value of the net assets acquired. On a prospective basis, this goodwill or any long-lived investment asset is subject to annual impairment reviews. Impairment charges, if any, will be recorded as a component of operating expenses in the period in which the impairment is determined, if any.

**Prepaid manufacturing costs** At January 31, 2004, we carry \$10.0 million of prepaid manufacturing costs for cash remitted to Lonza pursuant to a large-scale product supply agreement for the long-term commercial manufacture of our C5 inhibitor antibody, eculizumab. We expect to



amortize this advance over the large-scale manufacture of the product. We evaluate the prepaid manufacturing costs, which will be amortized over the large-scale manufacture of eculizumab, against estimated net

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realizable value ( NRV ). If estimated NRV is not positive, then all or a portion of the prepaid manufacturing cost may have to be recognized as an expense. If we terminate the agreement, we could be required to complete the purchase of product scheduled for manufacture up to 18 months following termination, or at our election to make a termination payment of up to \$25 million, less partial return of the unused portion of prepaid manufacturing costs. Any portion of the prepaid manufacturing cost that becomes unusable, due to amendment or termination of the agreement, may have to be recognized as an expense at such time.

**Results of Operations**

Certain reclassifications have been made to prior year operating expenses for the three and six months ended January 31, 2003 to conform prior year expense classifications to current year expense classifications.

A summary of revenues generated from contract research collaboration, milestone payment, and grant awards is as follows for the three and six months ended January 31 (dollars in thousands):

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>January 31,</b>		<b>January 31,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
<b><u>Collaboration/Grant Awards</u></b>				
P&G	\$ 147	\$ 170	\$ 294	\$ 339
U.S. government grants		50		204
<b>Contract Research Revenues</b>	<b>\$ 147</b>	<b>\$ 220</b>	<b>\$ 294</b>	<b>\$ 543</b>

**Three Months Ended January 31, 2004****Compared with Three Months ended January 31, 2003**

We earned contract research revenues of \$147,000 for the three months ended January 31, 2004 and \$220,000 for the same period ended January 31, 2003. The revenue for the current three month period is a non-cash item representing the amortization of the \$10 million upfront fee paid by P&G in February 1999. The \$50,000 decrease in revenues associated with U.S. government grants as compared to the same period a year ago resulted primarily from the reduction in grant reimbursable billings from our various government grants as a result of our completion of the related research.

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We incurred research and development expenses of \$14.5 million for the three months ended January 31, 2004 and \$18.7 million for the three months ended January 31, 2003. The \$4.2 million decrease resulted primarily from lower clinical trial costs of approximately \$6.7 million due principally to the completion of the pexelizumab Phase III PRIMO-CABG clinical trial and to the shift to P&G of CABG Phase III clinical trial costs, as well as lower clinical trial costs for eculizumab. As part of our collaboration with P&G, we and P&G agreed that we would bear the first 50% of the projected PRIMO-CABG Phase III clinical trial costs and P&G would bear the second 50%. We completed our portion of the 50% of the projected cost of this arrangement for the PRIMO-CABG trials in the second quarter of fiscal year 2003, while P&G completed their portion of the 50% of the projected cost of this arrangement in the first quarter of fiscal year 2004. Per the collaboration, in the second quarter of fiscal year 2004, additional costs incurred over the original projected costs were shared equally by us and P&G. Additionally, Columbus Farming Corporation ( CFC ) did not incur research and development expenses in the second quarter of fiscal 2004 because its activities were suspended due to the abandonment of our UniGraft xenotransplantation program in the prior year. CFC did incur \$0.4 million of research and development expenditures in the second quarter of fiscal 2003. Partially offsetting the decrease in clinical costs and CFC costs were increased manufacturing development and activity costs of \$2.5 million and headcount and compensation cost increases of approximately \$0.4 million.

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Our general and administrative expenses were \$3.3 million for the three months ended January 31, 2004 and \$2.8 million for the three months ended January 31, 2003. The increase of \$500,000 resulted principally from growth of our operations and increased headcount and compensation cost increases of approximately \$300,000, and increased costs associated with our pre-marketing and business development activities of approximately \$200,000.

Total operating expenses were \$17.8 million and \$21.2 million for the three months ended January 31, 2004 and 2003, respectively.

Investment income was \$1.0 million for the three months ended January 31, 2004 and \$1.7 million for the three months ended January 31, 2003. The decrease in investment income of \$0.7 million resulted primarily from lower principal and lower market interest rates. Interest expense, primarily on our \$120 million convertible subordinated notes, was \$1.9 million for the quarters ended January 31, 2004 and 2003.

For the three months ended January 31, 2004, we recorded a state tax benefit of approximately \$62,000. The benefit is the result of legislation reinstated in August 2003 by the State of Connecticut that allows for the research and development tax credit exchange program for 2004. The legislation allows companies to exchange research and development tax credits earned in the tax year for a cash refund from the state at the rate of 65% of the research tax credit, as defined.

As a result of the above factors, we incurred a net loss of \$18.5 million, or \$0.85 basic and diluted net loss per common share, for the three months ended January 31, 2004, compared to a net loss of \$21.5 million, or \$1.18 basic and diluted net loss per common share, for the three months ended January 31, 2003.

**Six Months Ended January 31, 2004**

**Compared with Six Months ended January 31, 2003**

We earned contract research revenues of \$294,000 for the six months ended January 31, 2004 and \$543,000 for the same period ended January 31, 2003. The revenue for this six month period is a non-cash item representing the amortization of the \$10 million upfront fee paid by P&G in February 1999. The \$204,000 decrease in revenues associated with U.S. government grants as compared to the same period a year ago resulted primarily from the reduction in grant reimbursable billings from our various government grants as a result of our completion of the related research.

We incurred research and development expenses of \$31.2 million for the six months ended January 31, 2004 and \$38.4 million for the six months ended January 31, 2003. The \$7.2 million decrease resulted primarily from lower clinical trial costs of \$12.9 million due principally to the completion of the pexelizumab Phase III PRIMO-CABG clinical trial and to the shift to P&G of CABG Phase III clinical trial costs as stated above. Additionally, CFC did not incur research and development expenses during the first six months of fiscal 2004 because its activities were suspended. CFC did incur \$1.0 million of research and development expenditures in the first six months of fiscal 2003. Partially offsetting the decrease in clinical costs and CFC costs were increased manufacturing development and activity costs of \$5.8 million and increased headcount and compensation costs of approximately \$0.9 million. We believe research and development expenses will increase due to the preparation and expected initiation of a confirmatory pivotal Phase III clinical trial with pexelizumab in CABG patients, a pivotal Phase III clinical trial with

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pexelizumab in AMI patients receiving angioplasty, and a pivotal Phase III program with eculizumab in PNH patients.

Our general and administrative expenses were \$6.1 million for the six months ended January 31, 2004 and \$4.9 million for the six months ended January 31, 2003. The increase of \$1.2 million resulted principally from growth of our operations and increased headcount and compensation cost increases of approximately \$660,000, increased costs associated with our pre-marketing and business development activities of approximately \$320,000, as well as an increase in directors and officers liability insurance of approximately \$230,000.

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**ALEXION PHARMACEUTICALS, INC.**

Total operating expenses were \$37.3 million and \$43.3 million for the six months ended January 31, 2004 and 2003, respectively.

Investment income was \$2.0 million for the six months ended January 31, 2004 and \$3.5 million for the six months ended January 31, 2003. The decrease in investment income of \$1.5 million resulted primarily from lower principal and lower market interest rates. Interest expense, primarily on our \$120 million convertible subordinated notes, was \$3.9 million for the six months ended January 31, 2004 and 2003.

For the six months ended January 31, 2004, we recorded a state tax benefit of approximately \$133,000. The benefit is the result of legislation reinstated in August 2003 by the state of Connecticut that allows for the research and development tax credit exchange program for 2004. The legislation allows companies to exchange research and development tax credits earned in the tax year for a cash refund from the state at the rate of 65% of the research tax credit, as defined.

As a result of the above factors, we incurred a net loss of \$38.8 million, or \$1.85 basic and diluted net loss per common share, for the six months ended January 31, 2004 compared to a net loss of \$43.1 million, or \$2.37 basic and diluted net loss per common share, for the six months ended January 31, 2003.

**Liquidity and Capital Resources**

As of January 31, 2004, cash, cash equivalents, and marketable securities were \$223.2 million compared with \$215.4 million at July 31, 2003. The increase was primarily due to selling additional shares of our common stock in September 2003, partially offset by funding operating activities.

Net cash used in operating activities for the six months ended January 31, 2004 was \$35.7 million. This consisted primarily of our net loss of \$38.8 million partially offset by increase deferred research and development payments and the add back of non-cash expenses such as depreciation. The increase in deferred research and development payments is due to the \$1.5 million non-refundable payment received from XOMA.

Net cash used in investing activities for the six months ended January 31, 2004 was \$23.5 million. This included \$22.6 million of net purchases of marketable securities and \$0.9 million of property, plant, and equipment additions.

Net cash provided by financing activities for the six months ended January 31, 2004 was \$44.9 million, which includes proceeds from stock option exercises and the sale of common stock. In September 2003, we sold 3.6 million shares of our common stock at a price of \$13.00 per share resulting in net proceeds of approximately \$43.9 million, net of underwriting discounts, fees and other expenses of approximately \$2.9 million related to the transaction. We expect to use the net proceeds of the sale of common stock to fund working capital and other general corporate purposes, including additional clinical trials of pexelizumab and eculizumab, as well as other research and product development activities.

We anticipate that our existing capital resources together with the anticipated funding from our revised collaboration with P&G, as well as the addition of our interest and investment income earned on available cash and marketable securities should provide us adequate resources to fund our operating activities and capital equipment requirements as currently planned for at least the next twenty-four months. This should also provide us adequate funding for the clinical testing and manufacturing of our C5 Inhibitor product candidates and support for our broad research and development of our additional product candidates.

Our contractual obligations include our \$120 million of convertible subordinated notes due March 2007, along with interest payments, our annual payments of approximately \$2.2 million for operating leases, principally for

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facilities and equipment, and an open letter of credit of \$200,000 which serves as a security deposit on our facility in Cheshire, Connecticut. In addition, CFC is the payer under a \$3.9 million note, which is classified as a current liability as of January 31, 2004.

Our commercial commitments consist of cancelable research and development, clinical development and manufacturing cost commitments along with anticipated supporting arrangements, subject to certain limitations and cancellation clauses. The timing and level of our commercial scale manufacturing costs (assuming we utilize our long-term commercial scale product manufacturing capacity), which may or may not be realized, are contingent upon our clinical development programs' progress as well as our commercialization plans.

Under terms of the agreement for Lonza to manufacture commercial supplies of eculizumab, we could owe penalties for failure to purchase a minimum volume of product or if we terminate the agreement prior to its expiration. On a quarterly basis, we evaluate our plans to proceed with production under the agreement which depends upon our clinical development programs' progress as well as commercialization plans. In addition, we evaluate the prepaid manufacturing costs, which will be amortized over the large-scale product manufacturing production, against estimated net realizable value (NRV). If estimated NRV is not positive, then all or a portion of the prepaid manufacturing cost may have to be recognized as an expense. If we terminate the agreement, we could be required to complete the purchase of product scheduled for manufacture up to 18 months following termination, or at our election to make a termination payment of up to \$25 million, less partial return of the unused portion of prepaid manufacturing costs. We currently are negotiating with Lonza to amend the large-scale product supply agreement. These negotiations may result in our having to pay a non-refundable, non-creditable fee to secure certain modified manufacturing capacity. The future realization of such fee would be assessed based on our NRV analysis as described above. Any portion of the prepaid manufacturing cost that becomes unusable, due to amendment or termination of the agreement, may have to be recognized as an expense at such time.

These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change. Further, under terms of our collaboration with P&G, we may be obligated to reimburse P&G for 50% of cancellation costs under P&G's third-party pexelizumab manufacturing contract. Our portion of those cancellation costs could amount to as much as \$9.8 million.

Additional payments, aggregating up to \$49 million, would be required if we elect to continue development under our current pre-clinical development programs and if specified development milestones are reached (including achievement of commercialization). Approximately \$3 million of these costs may be incurred in the next three years.

The following table summarizes our current contractual obligations as of January 31, 2004 and the effect such obligations and projected commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. This assumes non-termination of agreements and does not include the aforementioned milestone payments (\$ amounts in millions):

	Total for remainder of fiscal					2009 and
	2004	2005	2006	2007	2008	thereafter
<b>Contractual obligations:</b>						
Convertible subordinated notes	\$	\$	\$	\$ 120.0	\$	\$



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Note payable	3.9					
Interest payments	3.5	6.9	6.9	6.9		
Operating leases	1.1	2.3	2.4	2.5	2.1	6.1
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total contractual obligations	\$ 8.5	\$ 9.2	\$ 9.3	\$ 129.4	\$ 2.1	\$ 6.1
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
<u>Commercial commitments:</u>						
Clinical and manufacturing development	\$ 6.5	\$ 19.7	\$ 21.9	\$ 20.7	\$ 20.7	\$
Licenses	0.4	0.4	0.5	0.6	0.8	
Research and development	0.3	0.1				
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total commercial commitments	\$ 7.2	\$ 20.2	\$ 22.4	\$ 21.3	\$ 21.5	\$
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

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

#### **Note Payable**

In February 1999, CFC purchased substantially all of the assets of the UniGraft xenotransplantation program, including principally, land, buildings and laboratory equipment, from its then partner in the program, U.S. Surgical Corporation, now a division of Tyco International, Ltd. ( Tyco ). The purchase was financed through the issuance by CFC of a \$3.9 million note payable to Tyco. Interest on the \$3.9 million note payable, at 6% per annum, is payable quarterly by CFC. The xenotransplantation manufacturing assets of CFC that were purchased from Tyco, including the real estate, are pledged as security for this note. The principal balance under the note is due in May 2005, and accordingly was classified as a long-term obligation as of July 31, 2003. However, upon CFC's failure to make its quarterly interest payment due to Tyco in August 2003, CFC defaulted on the note. As a result of the event of default, the note is classified as a current liability as of January 31, 2004.

In the quarter ended October 31, 2003, in conjunction with the event of default, we notified Tyco that the UniGraft xenotransplantation program has been abandoned and CFC activities have been suspended. CFC is seeking to liquidate itself to fulfill its debt obligation in whole or in part. CFC further notified Tyco that it does not have the funds or assets to satisfy the \$3.9 million note. During the quarter ended January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. We expect the sale or liquidation of the assets to take place within one year. If CFC's assets, consisting of property, plant and equipment with a current estimated fair value of \$1.2 million, are insufficient to satisfy the \$3.9 million note and other obligations of CFC, then the unpaid amount of the note may be discharged debt, recognized as other income in a future period to CFC.

#### **Long-term Debt    Convertible Subordinated Notes**

Interest on our \$120 million 5.75% convertible subordinated notes due March 15, 2007 is payable semi-annually in September and March of each year. The holders may convert all or a portion of the notes into common stock any time on or before March 15, 2007 at a conversion price of \$106.425 per common share. Beginning March 20, 2003, we may redeem some or all of the notes per the declining redemption prices listed for the notes. We may also elect to pay the repurchase price for some or all the notes in cash or common stock. Our 5.75% convertible subordinated notes due March 2007 are trading at a discount to their face amounts. Accordingly, in order to reduce future cash interest payments, as well as future payments due at maturity; we may, from time to time, depending on market conditions, repurchase some of our outstanding convertible debt for cash, exchange debt for shares of our common stock, preferred stock, debt or other consideration, or a combination of any of the foregoing. If we exchange shares of our capital stock, or securities convertible into or exercisable for our capital stock, for outstanding convertible debt, the number of shares that we might issue as a result of such exchanges would significantly exceed that number of shares originally issuable upon conversion of such debt and, accordingly, such exchanges could result in material dilution to holders of our common stock. There can be no assurance that we will repurchase or exchange any outstanding convertible debt.

#### **P&G Pharmaceuticals Collaboration**

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



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**ALEXION PHARMACEUTICALS, INC.**

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

We agreed to bear the first 50% of projected costs associated with the Phase III clinical trial in coronary artery bypass graft surgery ( CABG ) (called PRIMO-CABG ) and P&G agreed to bear the second 50% as part of our revised collaboration. As of January 31, 2004, we and P&G both completed each of our obligations with respect to the originally projected costs. Additional costs incurred over the original projected costs are shared equally by us and P&G. Reimbursements received by us from P&G in connection with P&G 's 50% share of our services and related personnel are recorded as a reduction of research and development expense. As part of the revised collaboration per the MOU, P&G funded 100% of the costs for the two acute myocardial infarction ( AMI ) Phase II clinical trials in myocardial infarction, or heart attack, patients.

We and P&G have agreed, as per the MOU, that each will share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any future AMI or CABG Phase III clinical trial costs.

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

**Liquidity**

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

the progress, timing and scope of our research and development programs;

the progress, timing and scope of our preclinical studies and clinical trials;

the time and cost necessary to obtain regulatory approvals;

the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;

the time and cost necessary to develop sales, marketing and distribution capabilities;

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**ALEXION PHARMACEUTICALS, INC.**

changes in applicable governmental regulatory policies; and

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

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

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

**PART II. OTHER INFORMATION**

Item 6. Exhibits

(a) Exhibits

31.1 Certification by Leonard Bell, M.D., Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Amendment No. 1 to Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.

31.2 Certification by Carsten Boess, Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Amendment No. 1 to Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.

32.1 Certification by Leonard Bell, M.D., Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Amendment No. 1 to Alexion Pharmaceuticals, Inc.'s

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Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.

32.2 Certification by Carsten Boess, 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 Amendment No. 1 to Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.

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**SIGNATURES**

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

**ALEXION PHARMACEUTICALS, INC.**

Date: March 30, 2004

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

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

Date: March 30, 2004

By: /s/ David W. Keiser

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David W. Keiser  
President and Chief Operating Officer

Date: March 30, 2004

By: /s/ Carsten Boess

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Carsten Boess  
Vice President and Chief Financial Officer (principal financial officer)

Date: March 30, 2004

By: /s/ Barry P. Luke

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