

ALEXION PHARMACEUTICALS INC
Form 10-K/A
May 06, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to
FORM 10-K/A

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

For the fiscal year ended July 31, 2003

or

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

For the transition period from to

Commission file number: 0-27756

ALEXION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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Delaware
(State or Other Jurisdiction of

13-3648318
(I.R.S. Employer

Incorporation or Organization)

Identification No.)

352 Knottter Drive, Cheshire Connecticut 06410

(Address of Principal Executive Offices) (Zip Code)

203-272-2596

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value \$0.0001

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the National Association of Securities Dealers Automated Quotation (NASDAQ) National Market System on January 31, 2003, was approximately \$229,249,000.

The number of shares of Common Stock outstanding as of January 31, 2003 was 18,208,796.

Explanatory Note

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The purpose of this amendment is to amend and restate in its entirety Item 7 of our Form 10-K for the fiscal year ended July 31, 2003 entitled Management's Discussion and Analysis of Financial Condition and Results of Operations in response to comments received from the Securities and Exchange Commission. This amendment to our Form 10-K does not reflect events occurring after the filing of our original Form 10-K or modify or update those disclosures affected by subsequent events. No other modifications or changes have been made to our Form 10-K as originally filed or the exhibits filed therewith.

Item 7. 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 Important Factors Regarding Forward-Looking Statements attached hereto as Exhibit 99.1.

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, autoimmune and hematologic disorders, inflammation 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 are therapeutic antibodies that address specific diseases that arise when the human immune system produces inflammation in the human body. Antibodies are proteins that bind specifically to selected targets, or antigens, in the body. After the antibody binds to its target, it may activate the body's immune system against the target, block activities of the target or stimulate activities of the target. We are currently examining our two lead antibody product candidates in a variety of clinical development programs. We are developing pexelizumab in collaboration with Procter & Gamble Pharmaceuticals, or P&G, and rely on P&G for the timely development and potential commercialization of pexelizumab

Currently, none of our drug product candidates is available for commercial sale. All of our potential products are in clinical or pre-clinical development and the status of each of our lead product candidates is set forth, by indication, in Item 1 of this Report under the heading Product Development Programs.

Successful completion of development of a product candidate is contingent on numerous risks, uncertainties and other factors which are described in detail in the risk factors which are attached as Exhibit 99.1 to this Report. These factors include:

completion of pre-clinical and clinical trials of the product candidate with scientific results that support further development and/or regulatory approval

receipt of necessary regulatory approvals

obtaining adequate supplies of product candidates on commercially reasonable terms

obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials

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performance of third-party collaborators, particularly Procter & Gamble Pharmaceuticals, on whom we rely heavily for the co-development and commercialization of one of our lead product candidates

performance of third-party manufacturers, particularly Lonza Biologics, on whom we rely heavily for the manufacture of one of our lead product candidates

obtaining manufacturing, sales and marketing capabilities for which we presently have limited resources

As a result of the amount and nature of these factors, many of which are outside of our control, the success, timing of completion, and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things,

slow patient enrollment;

long treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product candidate;

adverse medical events or side effects in treated patients;

lack of effectiveness of the product candidate being tested; and

lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our drug products. If we do not obtain and maintain regulatory approval for our products, we will not generate any revenues from the sale of our products and the value of our company and our financial condition and results of operations will be substantially harmed.

To date, we have not received any revenues from the sale of products. We have incurred operating losses since our inception. As of July 31, 2003, we had an accumulated deficit of approximately \$265 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, pre-commercialization activities, developing a sales and marketing force, and increasing administrative personnel and professional services to support growth of our operations, and 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 will play a major role.

Critical Accounting Policies and the Use of Estimates

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

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,

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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 the Company. 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. These evaluations are subject to changes in estimate in subsequent periods.

Goodwill At July 31, 2003, we carried \$20.0 million of goodwill, net, acquired in connection with our acquisition of Prolifaron (see Financial Note No. 3), 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.

Long-lived assets and prepaid manufacturing costs We evaluate the recoverability of our long-lived assets and prepaid manufacturing costs based upon planned usage and projected cash flows. These plans are subject to periodic revisions dependent on the success of our research and development programs and product candidate development. Accordingly, impairment charges may periodically occur if these revisions result in a change in planned asset use or cash flow generation. We record cash advances paid to secure future long term manufacturing production at third-party contract manufacturers as prepaid manufacturing costs. These costs will be amortized over the period of manufacturing production. These cash advances are subject to a refund, if the manufacturing facility is unavailable as scheduled or forfeiture if we terminate the scheduled manufacturing production pursuant to contractual terms. We currently anticipate that we will proceed with production under the contract.

Results of Operations

Fiscal Years Ended July 31, 2003, 2002, and 2001

We earned contract research revenues of \$0.9 million, \$6.5 million, and \$11.8 million for the fiscal years ended July 31, 2003, 2002, and 2001, respectively. The decrease in revenues in fiscal year 2003 as compared to fiscal year 2002 was principally due to decreased research payments from Procter & Gamble Pharmaceuticals, or P&G, resulting from our December 2001 agreement per a binding memorandum of understanding, or MOU, to revise our 1999 collaboration agreement with P&G. The decrease in revenues in fiscal year 2002 as compared to 2001 was primarily due to decreased research payments from P&G, resulting from our revised 1999 collaboration agreement and the completion of the Phase II pexelizumab CPB study.

During fiscal year 2003, we incurred research and development expenses of \$71.0 million. For fiscal years 2002 and 2001, we incurred research and development expenses of \$60.0 million and \$38.9 million, respectively. We track our research and development costs by category incurred rather than by project. Our research and development costs consist primarily of personnel, benefits, clinical trial costs and other clinical related costs, manufacturing development and manufacturing costs, discovery research costs, depreciation expense, and occupancy related facility operating costs. The following table summarizes the major research and development expense categories for fiscal years 2003, 2002, and 2001. (\$ in thousands):

	2003	2002	2001
	(\$ in thousands)		
Research and Development Expenses:			
Payroll and benefits	\$ 13,613	\$ 11,044	\$ 9,385
Clinical development	25,122	19,778	10,049
Manufacturing development and manufacturing	17,405	13,017	7,745
Discovery research	8,242	10,339	6,979
Operating and occupancy	3,911	3,126	2,722
Depreciation and amortization	2,749	2,701	1,991
Total Research and Development	\$ 71,042	\$ 60,005	\$ 38,871

The increase in research and development expenses for fiscal year 2003 as compared to 2002 was due to greater clinical trial costs while sustaining greater manufacturing costs for our two lead product candidates pexelizumab and eculizumab. Our agreement with P&G to bear the first 50% of the Phase III pexelizumab PRIMO-CABG trial costs, along with our concurrent clinical trials with eculizumab in PNH, rheumatoid arthritis, and membranous nephritis patients, resulted in higher clinical trial costs in fiscal 2003 as compared to 2002, although we had completed in January 2003 our obligations associated with incurring the first 50% of the projected PRIMO-CABG trial costs. In addition, we incurred higher payroll and benefit costs, higher operating and occupancy costs, and higher depreciation costs due to the continued growth of our company in personnel, increased space and equipment, and higher rent and occupancy costs. These increases were partially offset by lower discovery costs as we concentrated more of our resources on our two lead product candidates pexelizumab and eculizumab as well as our decision to terminate the Unigraft xenotransplantation program. The increase in research and development expenses for fiscal year 2002 as compared to 2001 was attributable to higher clinical trial costs associated primarily with the Phase III pexelizumab PRIMO-CABG trial (enrollment began in January 2002) as a result of the revised collaboration agreement with P&G which required us to share in the pexelizumab development costs and greater clinical manufacturing costs associated with our two lead product candidates. In addition, we had increased payroll and benefit costs, higher operating and occupancy costs, and higher depreciation costs due to the continued growth of our company in personnel, increased space and equipment, and higher rent and occupancy costs. Discovery costs were higher for 2002 as compared to 2001 due to the fact that we funded a greater amount of external research as well as increased costs associated with the Unigraft xenotransplantation program prior to the decision to terminate the program.

We expect that subject to the outcome of discussions regarding potential further clinical development requirements for pexelizumab, our overall research and development expenses in fiscal 2004 will decrease due to lower clinical trial study costs resulting from the Phase III PRIMO-CABG clinical trial completion. This will, however, be offset by increased manufacturing development, scale-up and manufacturing activities costs associated with our two lead C5 inhibitor candidates, pexelizumab and eculizumab. However, clinical and manufacturing activities costs are highly dependent upon the initiation, performance and enrollment of clinical trials.

Our general and administrative expenses were \$10.6 million, \$8.0 million and \$7.1 million for fiscal years 2003, 2002, and 2001, respectively. The increase in general and administrative expenses in fiscal year 2003 as compared to 2002 was principally due to increased costs associated with our pre-marketing and business development activities and increased personnel and professional services to support growth of our operations. The increase in general and administrative expenses in fiscal year 2002 as compared to 2001 was principally due to higher payroll related costs. We expect our general and administrative expenses to increase with our pre-marketing and business development activities and increased personnel to support growth of our operations.

We concluded that further investment in the UniGraft program by us did not meet sufficient criteria for continued development with our own resources, as compared to other internal programs; consequently, we have suspended our financial commitment to this program. This termination of our UniGraft program, following our inability to secure a collaboration to share in future funding of this program, resulted in an impairment to our UniGraft manufacturing assets, principally the real estate, building, building improvements and capital lab and farm equipment at our subsidiary, Columbus Farming Corporation, or CFC, resulting in a write down of approximately \$2.7 million of those assets. As of July 31, 2003, the carrying value of those assets was approximately \$1.2 million after the write down. These assets will continue to be classified as held for use until such time that we have the ability to dispose of them. CFC had purchased the assets relating to the UniGraft program in 1999 from our then partner in the xenotransplantation program, U.S. Surgical Corporation, now a division of Tyco Healthcare, or Tyco. The purchase price was paid through the issuance of a \$3.9 million note. All of these assets are pledged to secure CFC's obligations under the note. CFC failed to make the August 2003 interest payment due under the note. Accordingly, CFC and Tyco are in discussions regarding the sale of these assets and the application of the proceeds to CFC's obligations under the note.

The acquisition of Prolifaron in fiscal 2001 resulted in a one-time, non-cash charge of \$21 million allocated to in-process research and development projects. In addition, we recognized approximately \$23 million of the purchase price as goodwill which was being amortized over the seven years following purchase. The amortization of this goodwill resulted in a charge of \$2.90 million in the twelve months ended July 31, 2001. Effective August 1, 2001, our adoption of SFAS No. 142 caused the amortization of goodwill to cease.

Total operating expenses were \$84.2 million, \$68.0 million, and \$69.9 million for fiscal years 2003, 2002, and 2001, respectively. Total operating expenses in the twelve months ended July 31, 2001 included the one-time non-cash in-process research and development charge and the non-cash amortization of goodwill related to the acquisition of Prolifaron.

Other income (expense), net, was an expense of \$(1.9 million) in fiscal year 2003 and income of \$4.2 million and \$10.2 million for fiscal years 2002, and 2001, respectively, and represents interest expense offset by investment income. The other expense, net, in fiscal year 2003 as compared to 2002 was due to interest expense offset by lower investment income from lower market interest rates and lower cash balances. The decrease in fiscal year 2002, other income, net, as compared to 2001 was due to decreased investment income from lower cash balances and lower market interest rates. A state tax benefit of \$0.8 million and \$0.7 million was recognized in each of fiscal year 2003 and 2002 resulting from our exchange of our fiscal 2003, 2002 and 2001 incremental research and development tax credits.

During fiscal year 2001, we recorded a \$9.1 million non-cash charge that is related to the cumulative effect of a change in accounting principle per the adoption of Staff Accounting Bulletin No. 101 or SAB 101. We adopted SAB 101 in fiscal year 2001 and therefore changed our revenue recognition policy for up front non-refundable

payments from immediate recognition to deferral of the revenue with the up front fee amortized into revenue over the life of the agreement. We recognized the non-cash cumulative effect adjustment of \$9.1 million as of August 1, 2000. Included in each of fiscal years 2003, 2002 and 2001 were contract revenues of \$0.6 million related to the SAB 101 amortization of the up front, non-refundable payment over the life of the agreement.

As a result of the above factors, we incurred net losses of \$84.5 million, \$56.5 million, and \$57.0 million or \$4.64, \$3.12, and \$3.28 basic and diluted net loss per share for fiscal years ended July 31, 2003, 2002, and 2001, respectively. Shown below are our statements of operations for fiscal years ended 2003, 2002, and 2001.

The following table displays the results of our operations relative to our 2001 results.

	Twelve months ended July 31,		
	2003	2002	2001
	(\$ in thousands, except per share data)		
Contract Research Revenues	\$ 877	\$ 6,536	\$ 11,805
Operating Expenses:			
Research and development	71,042	60,005	38,871
General and administrative	10,621	7,993	7,135
Impairment of fixed assets	2,560		
In-process research development (IPRD)			21,000
Amortization of goodwill (GW)			2,901
Total operating expenses	84,223	67,998	69,907
Operating loss	(83,346)	(61,462)	(58,102)
Other income (expense), net	(1,885)	4,220	10,177
State tax benefit, net	764	700	
Loss before cumulative effect of SAB 101	(84,467)	(56,542)	(47,925)
Cumulative effect of adoption of SAB 101			(9,118)
Net loss	\$ (84,467)	\$ (56,542)	\$ (57,043)
Basic and diluted net loss per share	\$ (4.64)	\$ (3.12)	\$ (3.28)

Liquidity and Capital Resources

Since our inception in January 1992, we have financed our operations and capital expenditures principally through private placements of our common and preferred stock, an initial public offering of our common stock and subsequent follow-on offerings, the sale of convertible subordinated notes, other debt financing, payments received under corporate collaborations and grants, and equipment and leasehold improvements financing.

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As of July 31, 2003, our cash, cash equivalents, and marketable securities totaled \$215.4 million compared to \$308.6 million as of July 31, 2002. At July 31, 2003, our cash and cash equivalents consisted of \$24.8 million that we hold in short-term highly liquid investments with original maturities of less than three months. The decrease in cash, cash equivalents and marketable securities as compared to July 31, 2002 was due to the use of funds to fund our operations, including prepaid manufacturing costs to reserve commercial manufacturing capacity, and capital equipment investments. During the year ended July 31, 2003, we invested \$3.1 million in property, plant and equipment to support our research and development efforts. We anticipate our research and

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

Our contractual obligations include our \$120 million of convertible subordinated notes due March 2007, our annual payments of approximately \$2.2 million for operating leases, principally for facilities and equipment, and, an open letter of credit of \$200,000 which serves as a security deposit on our facility in Cheshire, Connecticut. In addition, CFC is the payer under a \$3.9 million note.

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 the terms of our agreement for Lonza Biologics plc, or Lonza, to manufacture commercial supplies of eculizumab, we could owe penalties for failure to purchase a minimum manufacturing capacity volume or if we terminate the agreement prior to its expiration. If we terminate the agreement, we could be required to pay for unused contracted or scheduled manufacturing capacity usage for up to 18 months following termination, or at our election to make a termination payment of up to \$25 million, less partial return of any unused portion of prepaid manufacturing costs. These obligations, commitments and supporting arrangements represent payments based on current operating forecast, which are subject to change. Further, under terms of our Memorandum of Understanding with Procter & Gamble Pharmaceuticals, we may be obligated to reimburse P&G 50% of cancellation costs under P&G's third-party pexelizumab manufacturing contract. Our portion of those cancellation costs could amount up to \$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 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 contractual obligations and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. These do not include the aforementioned milestones and assume non-termination of agreements (\$ amounts in millions):

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009 and thereafter</u>
Contractual obligations:						
Subordinated convertible notes	\$	\$	\$	\$ 120.0	\$	\$
Note payable		3.9 ^(a)				
Operating leases	2.2	2.3	2.4	2.5	2.1	6.1
Total contractual obligations	\$ 2.2	\$ 6.2	\$ 2.4	\$ 122.5	\$ 2.1	\$ 6.1
Commercial commitments:						
Clinical and manufacturing development	\$ 15.7	\$ 25.6	\$ 23.4	\$ 23.7	\$ 24.1	\$
Licenses	0.4	0.4	0.5	0.6	0.8	
Research and development	0.3	0.1				
Total commercial commitments	\$ 16.4	\$ 26.1	\$ 23.9	\$ 24.3	\$ 24.9	\$

(a) In August, 2003 the Note Payable will be classified as a current liability based upon the default in August, 2003 (see discussion below).

In February 1999, our wholly owned subsidiary Columbus Farming Corporation, or CFC, purchased substantially all of the assets of the xenotransplantation program, including principally, land, buildings and laboratory equipment, from our then partner in the program, U.S. Surgical Corporation, now a division of Tyco Healthcare, or 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. In August 2003, CFC was unable to make a scheduled quarterly interest payment under the note. The principal balance under the note is stated to be due in May 2005, but will be classified as a current liability when the note is deemed in default since CFC was unable to make the quarterly interest payment due to Tyco. The xenotransplantation manufacturing assets of CFC that were purchased from U.S. Surgical, including the real estate, are pledged as security for this note.

We have notified Tyco that CFC operations have been suspended and that CFC is seeking to liquidate itself to fulfill its debt obligation as best as possible. CFC has further notified Tyco that it does not have the funds or assets to satisfy the \$3.9 million note, and was unable to make the quarterly interest payment due to Tyco in August 2003. CFC has had discussions with Tyco regarding the sale of the CFC assets and application of the proceeds to CFC's obligations under the note, as well as with regard to satisfaction of the note generally. The event of default under the note requires the note to be classified as a current liability at the time of default. 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.

We lease our headquarters and research and development facility in Cheshire, Connecticut that we relocated to in November 2000. The lease has an initial term of ten years and six months, expiring in December 2010. At this site, we lease a total of 89,000 square feet of space, which includes approximately 69,000 square feet related to research and laboratories. We have incurred initial leasehold improvements aggregating approximately \$7.4 million. In addition, we are paying a pro rata percentage of real estate taxes and operating expenses. Our pilot

manufacturing plant, which may be used for producing compounds for some of our current and anticipated clinical trials, is expected to remain in New Haven, Connecticut and encompasses approximately 33,000 square feet of labs and offices. The lease in New Haven has an initial term of approximately 5 years, ending in October 2007 with three options to extend of one year each. We believe our research and development facilities and our pilot manufacturing facility, together with third party manufacturing facilities, will be adequate for our current ongoing activities. Alexion Antibody Technologies, Inc., our wholly-owned subsidiary, leases approximately 25,000 square feet of labs, office space and unimproved storage in San Diego, California. The lease has a term of ten years, expiring in August 2012.

In January 1999, we entered into a collaboration with P&G with respect to the joint development of pexelizumab. In December 2001, we and P&G entered into a binding memorandum of understanding, or MOU, pursuant to which we and P&G revised our January 1999 collaboration. Under the revised structure per the MOU, we and P&G will 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, P&G was generally funding all clinical development and manufacturing costs for pexelizumab. 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 to the rest of the world, if any. We are responsible for paying royalties and licensing fees 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, but not for previously agreed sales milestones and we will generally forego further research and development support payments from P&G.

We agreed to bear the first 50% of projected costs associated with the U.S. Phase III PRIMO-CABG clinical trials and P&G will bear the second 50% of such costs, with a final adjustment to make even the 50% sharing of costs. As of January 31, 2003, we had completed our obligation associated with the first 50% of the projected costs. It is expected that by the end of our first fiscal quarter of fiscal year 2004, P&G will complete its obligation with respect to the second 50% of projected costs. With the Phase III PRIMO-CABG completion, a final adjustment to make even the 50% sharing costs will occur in fiscal 2004. Reimbursements received from P&G in connection with Alexion services and related personnel and P&G's 50% cost share are recorded as a reduction of research and development and market research expense.

As part of the revised collaboration per the MOU, P&G agreed to continue to fund 100% of the costs for the two Phase II clinical trials in acute myocardial infarction, AMI, or heart attack, patients. We and P&G have agreed 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-Phase III clinical trial costs. P&G has the right to terminate the collaboration or sublicense its collaboration rights at any time. If P&G terminates the collaboration, P&G is required to contribute its share of agreed to obligations and costs incurred prior to termination, but may not be required to contribute towards costs incurred after termination. In the event that P&G were to terminate the collaboration, under the MOU, all rights and the exclusive license to our intellectual property related to pexelizumab would revert back to us. The MOU does not contemplate any payments to P&G in the event P&G were to terminate the collaboration; however, P&G might seek to negotiate such a payment or might seek to sublicense its MOU rights, rather than terminate the collaboration. We rely heavily on P&G for the development, manufacture and potential commercialization of pexelizumab. Termination of our agreement by

P&G or sublicense of its collaboration rights could cause significant delays in the development, manufacture and potential commercialization of pexelizumab and result in substantial additional cost to us.

For tax reporting purposes, as of July 31, 2003, we had approximately \$245.6 million of federal net operating loss carryforwards, which expire through 2022 (of which approximately \$18.2 million resulted from the exercise of nonqualified stock options) and \$9.5 million of tax credit carryforwards, which expire commencing in fiscal 2008. Provisions of the Tax Reform Act of 1986 may limit our ability to utilize net operating loss and tax credit carryforwards in any given year if certain events occur, including a provision relating to cumulative changes in ownership interests in excess of 50% over a three-year period. We believe that we have triggered these limitation provisions.

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 discount, 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.

Recently issued accounting standards

In June 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 146, Accounting for Costs Associated with Exit or Disposal Activities. This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The adoption of this new standard did not have a material impact on either our operating results or financial position.

In November 2002, the EITF issued abstract No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF No. 00-21 addresses certain aspects of the accounting for arrangements under which a vendor will perform multiple revenue-generating activities. The guidance in this issue is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We do not believe that the adoption of EITF No. 00-21 will be material to our operating results or financial position.

In November 2002, the FASB issued FASB Interpretations No. (FIN) 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB interpretation No. 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. The adoption of FIN 45 did not have a material impact on either our operating results or financial position. We have complied with the disclosure provisions of FIN 45.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS No. 150 establishes standards for how an issuer classifies and measures financial instruments. The standard is effective for new or modified contracts after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. We do not believe that the adoption of SFAS No. 150 will be material to our operating results or financial position.

