
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 2004

OR

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

Commission File Number: 0-19756



PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

94-3023969

(I.R.S. Employer
Identification Number)

34801 Campus Drive

Fremont, CA 94555

(Address of principal executive offices)

Telephone Number **(510) 574-1400**

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 Act). Yes No

As of March 31, 2004 there were 94,140,950 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2004	2003
Revenues:		
Royalties	\$ 22,010	\$ 17,145
License and other	5,618	5,602
Total revenues	27,628	22,747
Costs and expenses:		
Research and development	33,029	15,973
General and administrative	8,068	5,309
Total costs and expenses	41,097	21,282
Operating income (loss)	(13,469)	1,465
Interest and other income, net	2,284	4,672
Interest expense	(1,385)	(1,886)
Impairment loss on investment	—	(150)
Income (loss) before income taxes	(12,570)	4,101
Provision for income taxes	(48)	(32)
Net income (loss)	\$ (12,618)	\$ 4,069
Net income (loss) per basic and diluted share	\$ (0.13)	\$ 0.05
Shares used in computation of net income (loss) per share:		
Basic	94,000	89,182
Diluted	94,000	90,150

See accompanying notes.

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PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS
(unaudited)
(In thousands, except per share data)

	March 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 358,593	\$ 341,768
Marketable securities, including \$6.8 million and \$7.4 million of restricted investments at March 31, 2004 and December 31, 2003, respectively	98,257	149,863
Other current assets	7,837	11,893
Total current assets	464,687	503,524
Land, property and equipment, net	185,724	155,513

Intangible assets, net	31,723	32,311
Restricted investments	10,007	13,362
Other assets	7,911	7,320
Convertible note receivable	30,000	30,000
Total assets	<u>\$ 730,052</u>	<u>\$ 742,030</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 5,204	\$ 3,576
Accrued compensation	6,258	5,903
Accrued clinical trial costs	1,386	1,759
Accrued interest	874	3,204
Other accrued liabilities	18,866	19,351
Deferred revenue	—	161
Current portion of long-term obligations	1,163	1,222
Total current liabilities	<u>33,751</u>	<u>35,176</u>

Convertible subordinated notes	250,000	250,000
Notes payable	401	595
Other long-term debt	7,795	7,928

Commitments and contingencies

Stockholders' equity:

Preferred stock, par value \$0.01 per share, 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.01 per share, 250,000 shares authorized; 94,141 and 93,886 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	941	939
Additional paid-in capital	669,328	666,793
Accumulated deficit	(232,909)	(220,291)
Accumulated other comprehensive income	745	890
Total stockholders' equity	<u>438,105</u>	<u>448,331</u>
Total liabilities and stockholders' equity	<u>\$ 730,052</u>	<u>\$ 742,030</u>

See accompanying notes.

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PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(In thousands)

	<u>Three Months Ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
Cash flows from operating activities:		
Net income (loss)	\$ (12,618)	\$ 4,069
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,611	1,423
Amortization of convertible notes offering costs	304	180
Consultant stock-based compensation expense	45	—
Amortization of intangible assets	588	—
Loss on disposal of fixed assets	397	—
Impairment loss on investment	—	150
Changes in assets and liabilities:		
Interest receivable	768	1,549
Other current assets	4,056	648
Other assets	(895)	156
Accounts payable	1,629	583
Accrued liabilities	(2,833)	(2,117)
Deferred revenue	(161)	(38)
Total adjustments	<u>6,509</u>	<u>2,534</u>
Net cash provided by (used in) operating activities	<u>(6,109)</u>	<u>6,603</u>
Cash flows from investing activities:		
Purchases of marketable securities	—	(30,084)
Maturities of marketable securities	50,000	110,000
Maturities of restricted investments	4,049	—
Purchases of land, property and equipment	(33,222)	(17,542)
Net cash provided by investing activities	<u>20,827</u>	<u>62,374</u>
Cash flows from financing activities:		
Proceeds from issuance of capital stock	2,493	27
Payments on other long-term obligations	(386)	(115)
Net cash provided by (used in) financing activities	<u>2,107</u>	<u>(88)</u>
Net increase in cash and cash equivalents	<u>16,825</u>	<u>68,889</u>

Cash and cash equivalents at beginning of period	341,768	287,730
Cash and cash equivalents at end of period	<u>\$ 358,593</u>	<u>\$ 356,619</u>

Supplemental Disclosure of Cash Flow Information

Cash paid during the period for interest	\$ 3,411	\$ 4,294
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See accompanying notes.

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PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
March 31, 2004
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. (we, us, our, PDL or the Company) is a biotechnology company engaged in the development of humanized antibodies to prevent or treat various disease conditions. We currently have antibodies under development for autoimmune and inflammatory conditions, asthma and cancer. We hold fundamental patents for our antibody humanization technology.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The accompanying consolidated condensed financial statements are unaudited, but include all adjustments (consisting only of normal recurring adjustments), which we consider necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in our financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

The information included in this quarterly report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2003. The Consolidated Condensed Balance Sheet as of December 31, 2003 is derived from our audited consolidated financial statements.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim consolidated condensed financial statements may not be indicative of results for any other interim period or for the entire year. For example, we receive royalty revenues on sales of the product Synagis. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters.

Principles of Consolidation

The consolidated condensed financial statements include the accounts of Protein Design Labs, Inc. and its wholly-owned subsidiaries after elimination of inter-company accounts and transactions.

Reclassifications

Certain reclassifications of prior year amounts have been made to conform to the current year presentation.

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Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition

We currently recognize revenues resulting from the licensing and use of our technology and from services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 101, "Revenue Recognition," as amended by SAB No. 104 (SAB 101). These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use as drugs, in drug development and production. Revenues, and their respective treatment for financial reporting purposes, are as follows:

Upfront and License Maintenance Fees

We generally recognize revenue from upfront fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Revenues recognized from upfront fees typically relate to patent license and patent rights agreements.

- Under patent license agreements, the licensee typically obtains a non-exclusive license to one or more of our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization

of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements. Consideration that we receive for patent license agreements is recognized upon execution and delivery of the patent license agreement and when payment is reasonably assured.

- Under patent rights agreements, the licensee purchases a research patent license in exchange for an upfront fee and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. The licensee performs all of the research, and therefore, upon delivery of the patent rights agreement, the earnings process is complete and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses. Subsequent to execution of the agreement, the licensee has the right to purchase patent licenses to certain designated targets, for which the licensee pays separate consideration at a later date. Such consideration is recognized upon exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.
- Under our humanization agreements, the licensee typically pays an upfront fee for us to humanize an antibody. These upfront fees are recognized as the humanization work is performed, which is typically over three to six months.
- Under patent license agreements and humanization agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in

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effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

Royalties

Under some of our patent license agreements, we receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from such licensees approximately one quarter in arrears; that is, generally at the end of the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we recognize royalty revenue in the quarter it is reported to us (i.e., generally royalty revenue is recognized one quarter following the quarter in which sales occurred).

Milestones

We enter into patent license and humanization agreements that may contain milestones related to reaching particular stages in product development. We recognize revenues from milestones when we have no further obligation with respect to the activities under the agreement and when we have confirmed that the milestone has been achieved. Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones generally include delivery of a humanized antibody meeting a certain binding affinity and, at the customer's election, delivery of a cell line meeting certain criteria described in the original agreement.
- Patent license agreements and humanization agreements sometimes require our customers to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the customer's product.
- We may also receive certain milestone payments in connection with licensing technology to or from our partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when they or we achieve certain levels of development with respect to the licensed technology.

Multiple Element Arrangements

If we determine that separate elements exist under Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

Stock-Based Compensation

At March 31, 2004, we had six stock-based employee compensation plans. We account for our plans under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations. No stock-based employee compensation cost is reflected in net income as all options granted under our

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plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income (loss) and net income (loss) per share if we had applied the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement No. 123, "Accounting for Stock-Based Compensation," as amended by FASB Statement No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," to stock-based employee compensation.

<u>(In thousands, except per share data)</u>	<u>Three Months Ended</u>	
	<u>March 31,</u>	
	<u>2004</u>	<u>2003</u>

Net income (loss), as reported	\$	(12,618)	\$	4,069
Deduct: Total stock-based employee compensation expense determined under the fair value method for all awards		(5,755)		(4,028)
Pro forma net income (loss)	\$	(18,373)	\$	41
Basic and diluted net income (loss) per share:				
As reported	\$	(0.13)	\$	0.05
Pro forma	\$	(0.20)	\$	0.00

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in the periods ended March 31, 2004 and 2003, respectively: (a) no dividends; (b) expected volatility of 69% and 78%; (c) weighted-average risk-free interest rates of 3.0% and 2.9%; and (d) expected lives of 5 years. These assumptions are subjective, and changes in these assumptions would materially affect the fair value estimates.

On March 31, 2004, the FASB issued the Exposure Draft "Share Based Payment," which would require all equity-based awards to employees to be recognized in the income statement based on their fair values. We expect that the final standard will be issued in late 2004, and we would be required to adopt the standard on January 1, 2005. Therefore, we expect that our accounting policy for employee stock-based compensation will change significantly in 2005.

We account for stock options granted to non-employees at fair value using the Black-Scholes Option Valuation Model in accordance with EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Stock options granted to non-employees are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense over the service period in which the non-employee provides services to the Company.

Segment and Concentrations Disclosure

In accordance with FASB Statement No. 131, "Disclosure About Segments of an Enterprise and Related Information," we are required to report operating segments and related disclosures about our products, services, geographic areas and major customers. We have no product revenue and have only one segment with facilities located primarily within the United States. The majority of our revenues are earned in the United States.

Revenues from Genentech in the first quarters of 2004 and 2003 accounted for 33% and 25% of total revenues, and revenues from MedImmune in the first quarters of 2004 and 2003 accounted for 42%

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and 43% of total revenues, respectively. Revenues from Seattle Genetics, Inc. accounted for 11% of total revenues in the first quarter of 2004. No other revenue from any other source exceeded 10% of total revenues for either period presented.

Capitalized Software

During the first quarter of 2004, we adopted Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use" (SOP 98-1). Pursuant to SOP 98-1, we recognize costs incurred in the preliminary planning phase of software development as expense as the costs are incurred. Software development costs incurred in the application development phase are capitalized and are included in property and equipment. Once the developed software is placed into service, these costs are amortized into expense over the estimated useful life of the software.

2. Net Income (Loss) Per Share

In accordance with FASB Statement No. 128, "Earnings Per Share," basic and diluted net income (loss) per share amounts have been computed using the weighted average number of shares of common stock outstanding during the periods presented. For the quarter ended March 31, 2004, we incurred a net loss, and as such, we did not include the effect of outstanding stock options or outstanding convertible notes in the diluted net loss per share calculations, as their effect would be anti-dilutive. For the quarter ended March 31, 2003, the calculation of diluted net income per share also includes the effect of dilutive outstanding stock options, but does not include the effect of outstanding convertible notes because the assumed conversion of these notes would be anti-dilutive.

The following is a reconciliation of the denominators used in the basic and diluted net income (loss) per share computations for the periods presented below:

	Three Months Ended	
	2004	2003
	(In thousands, except per share amounts)	
Numerator:		
Net income (loss)	\$ (12,618)	\$ 4,069
Denominator:		
Basic net income (loss) per share—Weighted-average shares	94,000	89,182
Dilutive potential common shares—Stock options	—	968
Denominator for diluted net income (loss) per share	94,000	90,150
Basic and diluted net income (loss) per share	\$ (0.13)	\$ 0.05

The total number of shares excluded from the calculations of diluted net income (loss) per share for outstanding convertible notes was 12,415,450 and 3,974,000 for the quarters ended March 31, 2004

and 2003, respectively. The total number of shares excluded from the calculation of diluted net loss per share for outstanding stock options was approximately 4,289,000 for the quarter ended March 31, 2004.

3. Comprehensive Income (Loss)

For the three months ended March 31, 2004, comprehensive loss was \$12.8 million as compared to comprehensive income of \$2.5 million for the three months ended March 31, 2003. Comprehensive income (loss) is comprised of net income (loss) and the change in unrealized gains and losses on our available-for-sale securities.

4. Other Accrued Liabilities

At March 31, 2004 and December 31, 2003, other accrued liabilities consisted of the following:

(In thousands)	March 31, 2004	December 31, 2003
Construction-in-process	\$ 13,020	\$ 14,568
Consulting and services	2,520	2,409
Other	3,326	2,374
	<u>\$ 18,866</u>	<u>\$ 19,351</u>

5. Collaborations

In January 2004, we entered into certain agreements with Seattle Genetics, Inc. (SGI) in which we granted patent rights and a patent license to SGI under our humanization patents and paid \$500,000 in cash in exchange for expanded access to SGI's drug conjugate and linker technology. Under the patent rights agreement, SGI also has the right to obtain additional patent licenses upon payment of additional fees, and upon the future commercialization of the products, SGI will pay us royalties on product sales.

In accordance with APB Opinion No. 29, "Accounting for Nonmonetary Transactions" (APB 29), we established the value of the drug conjugate and linker technology that we acquired from SGI based on the fair value of the consideration given to SGI, which included the patent rights and patent license granted to SGI and cash consideration of \$500,000. Based on the vendor-specific objective evidence of fair value of the patent rights and patent license granted to SGI, which is based on the terms of similar agreements that we have signed with third parties, we deemed the fair value of the patent rights and patent license to be \$3.0 million. Therefore, the fair value of the drug conjugate and linker technology acquired from SGI was \$3.5 million. As this early-stage technology has not reached technological feasibility and has no alternative future use in our research and development programs, in accordance with FASB Statement No. 2, "Accounting for Research and Development Costs," we recognized the \$3.5 million as research and development expense in the first quarter of 2004.

In accordance with EITF 00-21, we deemed the fair value of the patent rights and patent license granted to SGI to be \$3.0 million. As we have culminated the earnings process as proscribed under APB 29 and have satisfied revenue recognition criteria under SAB 101, we recognized revenue of \$3.0 million in the first quarter of 2004 upon the execution of the agreements.

6. Postretirement Benefit Plan

In June 2003, we established a postretirement health care plan, which covers medical, dental and vision coverage for certain of our former officers and their dependents. During the quarter ended March 31, 2004, we recognized net periodic benefit cost of approximately \$62,000. This expense includes service cost, interest cost, and amortization of prior service cost.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

OVERVIEW

We are a recognized leader in the discovery and development of humanized monoclonal antibodies for the treatment of disease. All of our revenues are derived from licensing, humanization and royalty arrangements. During the first quarter of 2004, we received royalties on six marketed products, with approximately 86% of our royalty revenues derived from the Herceptin antibody product marketed by Genentech and the Synagis antibody product marketed by MedImmune. We do not currently anticipate having proprietary marketed products prior to 2007. Accordingly, our revenues and related cash flows continue to depend substantially on the success of our licensees and our ability to enter into new licensing and royalty arrangements.

Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of March 31, 2004, we had an accumulated deficit of approximately \$232.9 million. We expect that our expenses will increase over the next several years because of the extensive resource commitments required to identify and develop antibody candidates, to achieve regulatory approval and to market potential products for commercial success for any individual product. Over the next several years, we also expect to incur substantial additional expenses as we continue to identify, develop and manufacture our potential products, invest in research and improve and expand our development, manufacturing, marketing and sales capabilities. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. Although we have had some profitable reporting periods, we do not expect to achieve sustained profitability until we are able to market and sell products. Since our goal is to launch our first product or products into

the North American market by 2007, our ability to achieve this cash-flow positive position would not occur sooner than that, even if we were successful.

Our commitment of resources to research and the continued development of our products will require significant additional funds. Our operating expenses may also increase as some of our earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as we invest in additional manufacturing capacity, as we defend or prosecute our patents and patent applications, and as we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new corporate collaborations or patent rights or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses and may require additional capital to fully execute our business strategy.

In January 2004, we entered into certain agreements with Seattle Genetics, Inc. (SGI) in which we granted patent rights and a patent license to SGI under our humanization patents and paid \$500,000 in cash in exchange for expanded access to SGI's drug conjugate and linker technology. Under the patent rights agreement, SGI also has the right to obtain additional patent licenses upon payment of additional fees, and upon the future commercialization of the products, SGI will pay us royalties on product sales. As the drug conjugate and linker technology that we acquired from SGI has not reached technological feasibility and has no alternative future uses in our research and development programs, we recognized the fair value of the technology, or \$3.5 million, as research and development expense in the first quarter of 2004. Additionally, we recognized \$3.0 million, the fair value of the patent rights and patent license granted to SGI, as license revenue.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

We believe there have been no significant changes in our critical accounting policies during the three months ended March 31, 2004 as compared to what was previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission on March 8, 2004.

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition

We currently recognize three types of revenues resulting from the licensing and use of our technology, and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the development, use, sale and importation of humanized antibodies.

We enter into patent license and humanization agreements that may contain other elements, such as royalties and milestones related to the achievement of particular stages in product development. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element. We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement and when payment is reasonably assured. Changes in the allocation of the contract value between deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract.

Under our humanization agreements, the licensee typically pays an upfront fee for us to "humanize" an antibody. These upfront fees are recognized as the humanization work is performed, which is typically over three to six months. We follow this method because we can reliably estimate the progress of each project based on information from our scientists. Due to our extensive experience in humanizing antibodies, coupled with the short-term nature of the humanization contracts, the likelihood that the actual progress is materially different than that reflected in our revenues at the end of any particular reporting period is low. Historically, revenues recognized have approximated actual progress under each humanization agreement.

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, direct expenses related to each patient enrolled in a clinical trial are recognized on an estimated cost-per-patient basis as services are performed. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from contract research organizations (CROs), such as estimated costs per-patient, to calculate our accrual for direct clinical expenses at the end of each reporting period. For indirect expenses, which relate to site and other administrative costs to manage our clinical trials, we rely on information provided by the CRO, including costs incurred by the CRO as of a particular reporting date, to calculate our indirect clinical expenses. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial, which we confirm directly with the CRO. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred, however, our experience has been that our estimates at the end of any particular reporting period have been materially accurate.

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Intangible Assets

The valuation in connection with the initial purchase and the ongoing evaluation for impairment of intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. For example, we estimate future probability-adjusted cash flows and certain discount rates as well as assumed commercialization dates for future potential products. These estimations affect the allocation between charges to acquired in-process research and development and capitalization of intangible assets. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for intangible assets.

Once the values for intangible assets are established, we must test intangible assets with definite useful lives for impairment in accordance with Financial Accounting Standards Board (FASB) Statement No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." When we conduct our impairment tests for intangibles, factors that are considered important in determining whether impairment might exist include significant changes in our underlying business and product candidates or other factors specific to each asset being evaluated. Any changes in key assumptions about the business and its prospects, or changes in market conditions or other externalities, could result in an impairment charge and such a charge could have a material adverse effect on our consolidated results of operations.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2004 and 2003

Revenues

(In thousands)	Three Months Ended March 31,		% Change
	2004	2003	
Royalties	\$ 22,010	\$ 17,145	28%
License and other	5,618	5,602	0%
Total revenues	\$ 27,628	\$ 22,747	21%

Royalties

Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth increased during the first quarter of 2004 compared to the comparable period in 2003 due primarily to the increase in reported product sales of MedImmune's Synagis and Genentech's Herceptin humanized antibody products. To a lesser extent, the increase from the prior-year period relates to royalties recognized on sales of two additional products, Genentech's Xolair and Raptiva products, which were launched in the second half of 2003. Royalty payments from sales of Synagis and Herceptin accounted for 53% and 33% of our royalty revenues for the three months ended March 31, 2004 as compared to 57% and 33% in the comparable period in 2003.

Beginning in the second quarter of 2004, we will recognize royalty revenue from sales of Genentech's Avastin humanized antibody product. We expect that royalty revenues will continue to increase as the number of drugs from which we receive royalty revenue has increased from four

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to seven over the past three quarters. Further, we expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of Synagis, which results in higher royalty revenues reported to us in the first and second quarters of the year as compared to the third and fourth quarters.

License and Other

License and other revenues recognized primarily consisted of upfront patent licensing and patent rights fees, milestones, and license maintenance fees. License and other revenues were relatively flat from the comparable period in 2003 due to increased patent rights and licensing revenues offset by lower milestone revenues.

License and other revenues recognized in the first quarter of 2004 included an upfront license fee from Genentech for its Avastin product following approval by the US Food and Drug Administration, two milestone payments and license maintenance fees. In addition, in connection with certain agreements signed

with Seattle Genetics, Inc. (SGI) in which we granted patent rights and a patent license as partial consideration for expanded access to SGI's drug conjugate and linker technology, we recognized license revenue of \$3.0 million, which we determined to be the fair value of the patent rights and patent license.

License and other revenues recognized in the first quarter of 2003 primarily consisted of an upfront licensing fee from Actinium Pharmaceuticals, Inc. for certain development rights to our SMART M195 (Zamyl) antibody conjugated to alpha-emitting radioisotopes, a milestone payment associated with a product licensing agreement and license maintenance fees.

Costs and Expenses

(In thousands)	Three Months Ended March 31,		% Change
	2004	2003	
Research and development	\$ 33,029	\$ 15,973	107%
General and administrative	8,068	5,309	52%
Total costs and expenses	\$ 41,097	\$ 21,282	93%

Research and Development

Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. The increase in the first quarter of 2004 when compared to the comparable prior-year period was primarily due to an increase in research and development personnel headcount of approximately 49 employees and associated costs of approximately \$5.6 million, in-licensing fees of \$3.5 million for expanded rights to certain drug conjugate and linker technology acquired from SGI, contract manufacturing services of \$2.4 million, an increase in facility-related costs of \$2.0 million, and higher clinical development expenses for our major research and development projects of approximately \$1.5 million. We expect our research and development expenses will increase further as we continue to advance our product candidates into later stages of development and add new product candidates.

Below is a summary of products and the related stages of development for each product in clinical development, including the research and development expenses recognized in connection with each product.

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Three Months Ended March 31,	
					2004	2003
Current Product Candidates						
Daclizumab					\$ 6,323	\$ 2,898
	Asthma	Phase IIa	—	2004		
	Ulcerative colitis	Phase II	—	2004		
HuZAF	Crohn's disease	Phase IIa		2004	3,497	4,474
Nuvion	Severe steroid-refractory Ulcerative colitis	Phase I/II	—	2004	4,602	1,736
Anti-a5b1 integrin Mab (1)	Solid tumors	Phase I	—	2004	5,297	—
Other (2)			—		13,310	6,865
	Total Research and Development Expenses				\$ 33,029	\$ 15,973

(1) Product acquired from Eos in April 2003.

(2) No single clinical product included in "other" constitutes more than 5% of the total research and development expenses for the periods presented.

The information in the column labeled "Estimated Completion of Phase" is our current estimate of the timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates provided in the table. The clinical development portion of these programs may span as many as seven to ten years and any further estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing biopharmaceutical products, including significant and changing government regulation, the uncertainty of future preclinical and clinical study results and uncertainties associated with process development and manufacturing as well as marketing. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the "Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we can not accurately predict the timing and level of such expenses," "If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products," "Our clinical trial strategy may increase the risk of clinical trial difficulties," "If we do not attract and retain key employees, our business could be impaired," and "We may be unable to obtain or maintain regulatory approval for our products" sections of our Risk Factors.

Acquired In-Process Research and Development

In connection with the April 2003 acquisition of Eos, we recorded charges for acquired in-process research and development of \$37.8 million due to Eos' incomplete research and development programs that had not yet reached technological feasibility as of April 4, 2003 and had no alternative future use as of that date. A summary and the status of these programs follows:

Program	Description	Status of Development	Value Assigned (in thousands)
Anti-angiogenesis (M200, Anti-a5b1 Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including pancreatic, non-small lung and colorectal cancers	Phase I clinical trials initiated in June 2003, and Phase II clinical trials are expected to commence by the end of 2004	\$ 24,067
Ocular Neovascularization (F200, Anti-a5b1 Integrin Antibody)	Fab fragment of Anti-a5b1 Integrin Antibody for ocular indications, including age-related macular degeneration	IND filing expected in 2005*	\$ 13,767

* Development progress may be affected by potential partnering discussions or commitment of resources to more advanced programs.

In addition, in 2003 we recorded a charge to acquired in-process research and development totaling approximately \$48.2 million in connection with the amendment to our collaboration agreement with Roche in October 2003, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell Zenapax® (daclizumab) in all disease indications other than transplantation. This amount relates to the rights to autoimmune indications for daclizumab that are currently being developed and tested in clinical studies, specifically to treat asthma and ulcerative colitis. Significant changes to the acquired in-process research and development daclizumab projects since December 31, 2003 are as follows:

In March 2004, we reported positive results from the initial clinical study of daclizumab in patients with chronic, persistent asthma whose disease is not well controlled with high doses of inhaled corticosteroids. We currently expect that the next trial of daclizumab in asthma will be a Phase II trial in which daclizumab is administered subcutaneously, expected to commence in late 2004 or early 2005.

General and Administrative Expenses

General and administrative costs include costs of personnel, professional services, consulting and other expenses related to our administrative functions and an allocation of facility costs. General and administrative expenses for the three months ended March 31, 2004 increased from the comparable period in 2003 primarily due to increased personnel-related expenses of approximately \$1.3 million, increased facilities-related costs of approximately \$0.4 million, increased outside services expenses of approximately \$0.9 million, and increased legal costs related to our intellectual property, licensing and other contractual matters of approximately \$0.2 million. We expect that general and administrative expenses will continue to increase as we continue to expand our organization to support our efforts to advance and manufacture products in development.

Interest and Other Income, Interest Expense and Impairment Loss on Investment

(In thousands)	Three Months Ended March 31,		% Change
	2004	2003	
Interest and other income, net	\$ 2,284	\$ 4,672	(105%)
Interest expense	(1,385)	(1,886)	(27%)
Impairment loss on investment	—	(150)	(100%)

Interest Income and Expense

Interest income for the three months ended March 31, 2004 decreased due to the reduced interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates and to a lesser extent, lower invested balances.

Interest expense for the three months ended March 31, 2004 decreased as a result of capitalizing approximately \$0.8 million of our interest cost in connection with the development activities for our future manufacturing facilities, compared to capitalization of such costs of \$0.5 million in the comparable period of 2003. Further, interest expense decreased slightly from the same period in the prior year due to a lower interest rate on our outstanding 2.75%, \$250 million convertible subordinated notes that were issued in July 2003, as compared to our 5.50%, \$150 million convertible notes that were outstanding during the first quarter of 2003 but redeemed in the fourth quarter of 2003, offset by the amortization of slightly higher issuance costs associated with our 2.75%, \$250 million convertible subordinated notes.

Impairment Loss on Investment

During the first quarter of 2003, we recorded an impairment charge of \$150,000 related to a complete write-down of shares of Signature BioScience, Inc. convertible preferred stock that we acquired during 2002 in exchange for the sale of the assets of our small molecule group.

Income Taxes

We have recorded a tax provision of approximately \$48,000 for the three months ended March 31, 2004 primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee, compared to \$32,000 for the comparable period in 2003. We do not expect to record any tax provision for federal income taxes based upon our projected tax loss for fiscal 2004.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have financed our operations primarily through public and private placements of equity and debt securities, revenue under agreements with third parties and interest income on invested capital. At March 31, 2004, we had cash, cash equivalents, marketable securities and restricted investments in the

aggregate of \$466.9 million, compared to \$505.0 million at December 31, 2003.

Net cash used in operating activities for the three months ended March 31, 2004 was \$6.1 million compared to net cash provided by operating activities of \$6.6 million for the three months ended March 31, 2003. The change from the 2003 period was primarily due to a net loss position in the 2004 period as compared to a net income position in the 2003 period, which was the result of higher research and development spending, offset by higher non-cash expenses, including depreciation and amortization, amortization of debt issuance costs from the issuance of our 2.75%, \$250 million convertible notes in July 2003, and the amortization of intangible assets acquired in the second and fourth quarters of 2003. In addition, we had higher amortization of prepaid and other current assets during the first quarter of 2004.

Net cash provided by investing activities for the three months ended March 31, 2004 was \$20.8 million compared to \$62.4 million in the comparable period in 2003. The change from the 2003 period was primarily the result of fewer maturities of our marketable securities and higher capital expenditures in the first quarter of 2004. Capital expenditures in the first quarters of 2004 and 2003 were primarily related to the development and construction activities for our manufacturing facility in Brooklyn Park, Minnesota.

Net cash provided by financing activities for the three months ended March 31, 2004 was \$2.1 million compared to net cash used in financing activities of \$0.1 million in the comparable period in 2003. In both periods, financing activities primarily related to the exercise of employee stock options offset by payments on our long-term obligations.

We estimate that our existing capital resources will be sufficient to fund our current level of operations for at least the next four years. Our future capital requirements will depend on numerous factors, including, among others, interest income, royalties from sales of products by third party licensees, including Synagis, Herceptin, Xolair, Raptiva, Avastin, Zenapax and Mylotarg; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; investment in existing and new research and development programs; time required to gain regulatory approvals; significant resources we will devote to constructing our manufacturing facilities; our ability to obtain and retain funding from third parties under collaborative arrangements; our continued development of internal marketing and sales capabilities; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. In order to develop and commercialize our potential products we may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders.

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Our material contractual obligations under lease, debt and construction agreements have not changed significantly from those at December 31, 2003, as disclosed in our Annual Report on Form 10-K filed on March 8, 2004.

In addition, as of March 31, 2004, we have made payments totaling \$1.6 million to ICOS Corporation pursuant to a manufacturing agreement for the manufacture of supplies of clinical trial materials for one of our products. The aggregate amount of all potential future payments that we may make under that agreement is \$4.8 million.

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RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Quarterly Report on Form 10-Q, including the risk factors listed below. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock.

Keep these risk factors in mind when you read forward-looking statements contained in this Quarterly Report on Form 10-Q and the documents incorporated by reference herein. These statements relate to our expectations about future events and time periods. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “intends,” “plans,” “believes,” “anticipates,” “expects,” “estimates,” “predicts,” “potential,” “continue” or “opportunity,” the negative of these words or words of similar import. Similarly, statements that describe our reserves and our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Forward-looking statements involve risks and uncertainties, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements.

We have a history of operating losses and may not achieve sustained profitability.

In general, our expenses have exceeded revenues. As of March 31, 2004, we had an accumulated deficit of approximately \$232.9 million. We expect our expenses to increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We may be unable to achieve sustained profitability.

Our commitment of resources to the continued development of our products will require significant additional funds for development. Our operating expenses may also increase as:

- some of our earlier stage potential products move into later stage clinical development;
- additional potential products are selected as clinical candidates for further development;

- we pursue clinical development of our potential products in new indications;

- we invest in additional manufacturing capacity;
- we build commercial infrastructure to market our products in North America;
- we defend or prosecute our patents and patent applications; and
- we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new agreements with third-party business partners, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses and may require additional capital to fully execute our business strategy.

We have substantial outstanding indebtedness, which could adversely affect our financial condition and prevent us from fulfilling our obligations under our 2.75% \$250 million convertible notes.

In connection with our sale of the 2.75% convertible notes, referred to as the Notes, in July 2003, we incurred \$250.0 million of indebtedness, set to mature in August 2023, although callable as early as 2010. Our total consolidated long-term debt as of March 31, 2004 was \$258.2 million and constituted approximately 37% of our total pro forma capitalization as of such date. The indenture relating to the Notes does not restrict our ability to incur additional indebtedness, including debt that is senior to the Notes.

The degree to which we are leveraged could have important consequences, because:

- it could affect our ability to satisfy our obligations under the Notes;
- a substantial portion of our cash flow from operations will be required to be dedicated to interest and principal payments and may not be available for operations, working capital, capital expenditures, expansion, acquisition or general corporate or other purposes;
- our ability to obtain additional financing in the future may be impaired;
- we may be more highly leveraged than some of our competitors, which may place us at a competitive disadvantage;
- our flexibility in planning for, or reacting to, changes in our business and industry may be limited; and
- it may make us more vulnerable in the event of a downturn in our business, our industry or the economy in general.

Our ability to make payments on and, if necessary, to refinance our debt, including the Notes, will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, business, financial, competitive, legislative, regulatory and other factors that are beyond our control.

We cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available in an amount sufficient to enable us to pay our debt, including the Notes, or to fund our other liquidity needs. We may need to refinance all or a portion of our debt, including the Notes, on or before maturity. We cannot assure you that we would be able to refinance any of our debt, including the Notes, on commercially reasonable terms or at all.

Our revenues, expenses and operating results will likely fluctuate in future periods.

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon:

- the seasonality of sales of licensed products;
- the existence of competing products;
- the market launch of recently licensed products;
- the marketing efforts of our licensees;
- potential reductions in royalties receivable due to credits for prior payments to us;
- the timing of royalty reports, some of which are required quarterly and others semi-annually; and
- our ability to successfully defend and enforce our patents.

We receive royalty revenues on sales of the product Synagis. This product has higher sales in the fall and winter, which to date have resulted in much higher royalties paid to us in our first and second quarters than in other quarters. The seasonality of Synagis sales will contribute to fluctuation of our revenues from quarter to quarter.

License and other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees, payments for manufacturing and clinical development services, and payments for the achievement of milestones under new and existing agreements with third-party business partners. Revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

Our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, including clinical trial expenses as well as payments owed by us and to us under collaborative agreements for reimbursement of expenses and which are recorded under our policy during the quarter in which such expenses are reported to us or to our partners and agreed to by us or our partners.

In addition, our expenses or other operating results may fluctuate due to the accounting treatment of securities we own or may purchase or securities we have issued or may issue. For example, if we are required to recognize expense for stock options, we will incur significantly higher losses. In addition, we hold a \$30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and

accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the change in the value of the Exelixis stock in our financial statements such that changes in the Exelixis stock price contribute to fluctuations of our operating results from quarter to quarter.

Our humanization patents are being opposed and a successful challenge or refusal to take a license could limit our future revenues.

Most of our current revenues are related to our humanization patents and the related licenses that third parties enter into with us for rights to those patents. If our rights are successfully challenged or third parties decline to take licenses for the patents, our future revenues would be adversely affected.

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European humanization patent. We appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if the opponents are successful, our ability to collect royalties on European sales of antibodies humanized by others would depend on: the scope and validity of our second European patent; and, whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents, and if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to our related patents in other jurisdictions, including the United States. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents.

With respect to our second European antibody humanization patent, eight notices of opposition were filed. We have filed a response with the European Patent Office. Oral hearings, originally scheduled to take place in October 2003, were postponed by the European Patent Office. The European Patent Office recently notified us that the new oral hearing dates are scheduled for the end of June and early July 2004.

In Japan, three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a

final determination from the Japanese Patent Office examiner affirming the Opposition Board's earlier decision. We have appealed this decision to the Tokyo High Court. A hearing was held in April 2003. We expect that the Tokyo High Court will render a decision within one to two years. The patent remains valid and enforceable during the appeal process. If this appeal is unsuccessful, we will then have an opportunity to appeal to the Japanese Supreme Court.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

Our ability to maintain and increase our revenues from licensing is dependent upon third parties entering into new patent licensing arrangements, exercising rights under existing patent rights agreements, and paying royalties under existing patent licenses with us. To date, we have been successful in obtaining such licensing arrangements, and in receiving royalties on product sales, from parties whose products may be covered by our patents. However, we have experienced challenges in our licensing efforts, including the disagreement we had with Genentech in 2003 over whether its Xolair antibody product was

covered under our humanization patents. There can be no assurance that we will continue to be successful in our licensing efforts in the future. Additionally, although we have reached an amicable settlement with Genentech that is intended to resolve such disagreements, Genentech or other companies may, in the future, seek to challenge our U.S. patents through litigation or patent office proceedings, such as re-examinations or interferences. If we experience difficulty in enforcing our patent rights through licenses, or if our licensees, or prospective licensees, challenge our antibody humanization patents, our revenues and financial condition could be adversely affected, and we could be required to undertake additional actions, including litigation to enforce our rights. Such efforts would increase our expenses and could be unsuccessful.

If we are unable to protect our patents and proprietary technology, we may not be able to compete successfully.

Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology. A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents. For example, BTG International Limited (successor in interest to the Medical Research Council) recently has been issued a U.S. patent, to which we have a license, with claims that might be construed to overlap with our issued humanization patents. While the significance of this new U.S. patent is unclear, if it is determined to conflict with our U.S. patents or patent applications, we may become involved in patent office or legal proceedings to determine which company was the first to invent the technology and processes contained in each of the respective patents. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation in claim scope could reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

We may require additional patent licenses in order to manufacture or sell our potential products.

Other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or may not be able to market our products at all.

Celltech has been granted a European patent covering humanized antibodies, which we have opposed. At an oral hearing in September 2000, the Opposition Division of the European Patent Office decided to revoke this patent. Celltech appealed that decision, but the Technical Board of Appeal recently rejected the appeal. As a result, the decision revoking the patent is final; no further appeals are available. However, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. In addition, Celltech has a third divisional application currently drafted with broad claims directed towards humanized antibodies. We cannot predict whether Celltech's second European patent will be modified or revoked in any future opposition proceedings, or whether it will be able to obtain the grant of a patent from the pending divisional application with claims broad enough to generally cover humanized antibodies. Celltech has also been issued a corresponding U.S. patent that contains claims that may be considered broader in scope than their first European patent. In addition, Celltech was recently issued a second U.S. patent with claims that may be considered broader than its first U.S. patent. We have entered into an agreement with Celltech providing each company with the right to obtain nonexclusive licenses for up to three antibody targets under the other company's humanization patents. This agreement expires in December 2004. Notwithstanding this agreement, if our humanized antibodies were covered by Celltech's European or U.S. patents and if we need more than the three licenses under those patents currently available to us under the agreement, or we are unable to negotiate an extension of this agreement beyond December 2004 on terms that are acceptable to us, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

In addition, if the Celltech U.S. patent or any related patent applications conflict with our U.S. patents or patent applications, we may become involved in proceedings to determine which company was the first to invent the products or processes contained in the conflicting patents. These proceedings could

be expensive, last several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation would reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

Lonza Biologics, Inc. has a patent issued in Europe to which we do not have a license that may cover a process that we use to produce our potential products. In addition, we do not have a license to an issued U.S. patent assigned to Stanford University and Columbia University, which may cover a process we use to produce our potential products. We have been advised that an exclusive license has been previously granted to a third party, Centocor, Inc., under this patent. If our processes were found to be covered by either of these patents, we might be required to obtain licenses or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflicts with these patents or to obtain licenses on acceptable terms.

We are also aware of issued patents that could apply to one or more of our specific products. For example, a U.S. patent issued to Advanced Biotherapy, Inc. has claims to the use of anti-gamma interferon antibodies to treat certain autoimmune diseases. The claims issued to Advanced Biotherapy, Inc., however, do

not cover treatment of Crohn's disease, the indication currently being investigated in our HuZAF (fontolizumab, anti-gamma interferon antibody) clinical trials. However, a European patent issued to Genentech in 1998 and a U.S. patent issued in 2003 do have claims to the use of anti-gamma interferon inhibitors, including antibodies, for treatment of inflammatory bowel disease, including Crohn's disease. As a result, we might be required to obtain licenses from others. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or we may not be able to market our products at all.

If our research efforts are not successful, we may not be able to effectively develop new products.

We are engaged in research activities intended to identify antibody product candidates that we may enter into clinical development. These research activities include efforts to discover and validate new targets for antibodies in our areas of therapeutic focus. We obtain new targets through our own drug discovery efforts and through in-licensing targets from institutions or other biotechnology or pharmaceutical companies. Our success in identifying new antibody product candidates depends upon our ability to discover and validate new targets, either through our own research efforts, or through in-licensing or collaborative arrangements. In order to increase the possibilities of identifying antibodies with a reasonable chance for success in clinical studies, part of our business strategy is to identify a number of potential targets. If we are unsuccessful in our research efforts to identify and obtain rights to new targets, our ability to develop new products could be harmed.

Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we cannot accurately predict the timing and level of such expenses.

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products, and the majority of our expenses are to support these activities. The completion of clinical trials often depends significantly upon the rate of patient enrollment, and our expense levels will vary depending upon the rate of enrollment. In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and is difficult to predict. The expenses associated with each phase of development depend upon the design of the trial. The design of each phase of trials depends in part upon results of prior phases, and additional trials may be needed at each phase. As a result the

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expense associated with future phases can not predicted in advance. Further, we may decide to terminate or suspend ongoing trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to unacceptable risks. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future.

If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products.

To obtain regulatory approval for the commercial sale of any of our potential products or to promote these products for expanded indications, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in indications for which approval is requested. We have had, and may in the future have, clinical setbacks that prevent us from obtaining regulatory approval for our potential products. Most recently, in May 2003, we announced that we have discontinued additional clinical studies of the humanized anti-IL-4 antibody after data from a Phase IIa clinical trial of the antibody in steroid-naïve, mild/moderate asthma indicated that the anti-IL-4 antibody did not demonstrate clinical benefit compared to placebo at either of the dose levels tested. Earlier clinical trials such as Phase I and II trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed.

Larger or later stage clinical trials may not produce the same results as earlier trials. Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials. As an example, in June 2003 we announced the discontinuance of studies aimed at the treatment of steroid-refractory graft-versus-host-disease following bone marrow transplantation with Nuvion after partial, preliminary results in a Phase II trial showed that Nuvion was not, on average, associated with a significant prolongation of survival relative to historic controls.

Even when a drug candidate shows evidence of efficacy in a clinical trial, it may be impossible to further develop or receive regulatory approval for the drug if it causes an unacceptable incidence or severity of side effects, or further development may be slowed down by the need to find dosing regimens that do not cause such side effects. For example, while Nuvion had shown biological activity in some patients in a Phase I/II trial for psoriasis, it has also caused a level of side effects that would be unacceptable in this patient population. Enrollment in this trial has been terminated and our current plan is not to further develop Nuvion for psoriasis. Development for Nuvion in severe steroid-refractory ulcerative colitis is ongoing.

In addition, we may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise because we have a relatively large number of potential products in clinical development. Additionally, regulatory review of our clinical trial protocols may cause us in some cases to delay or abandon our planned clinical trials. Our potential inability to commence or continue clinical trials, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of our potential products, further adds to the uncertainty of regulatory approval for our potential products.

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Our clinical trial strategy may increase the risk of clinical trial difficulties.

Research, preclinical testing and clinical trials may take many years to complete and the time required can vary depending on the indication being pursued and the nature of the product. We may at times elect to use aggressive clinical strategies in order to advance potential products through clinical development as rapidly as possible. For example, we may commence clinical trials without conducting preclinical animal efficacy testing where an appropriate animal

efficacy testing model does not exist, or we may conduct later stage trials based on limited early stage data. We anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

We may be unable to enroll sufficient patients in a timely manner in order to complete our clinical trials.

The rate of completion of our clinical trials, and those of our collaborators, is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population;
- perceived risks and benefits of the drug under study;
- availability of competing therapies, including those in clinical development;
- availability of clinical drug supply;
- availability of clinical trial sites;
- design of the protocol;
- proximity of and access by patients to clinical sites;
- patient referral practices of physicians;
- eligibility criteria for the study in question; and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

Our revenues from licensed technologies depend on the efforts and successes of our licensees.

In those instances where we have licensed rights to our technologies, the product development and marketing efforts and successes of our licensees will determine the amount and timing of royalties we may receive, if any. We have no assurance that any licensee will successfully complete the product development, regulatory and marketing efforts required to sell products. The success of products sold

by licensees will be affected by competitive products, including potential competing therapies that are marketed by the licensee or others.

Our lack of experience in sales, marketing and distribution may hamper market introduction and acceptance of our products.

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with partners. To market products directly, we must establish an internal marketing and sales group, contract for these services, or obtain the assistance of another company. Pursuant to the terms of our revised collaboration agreement with Hoffmann-La Roche Inc. (Roche), we have a reversion right, exercisable in 2006, but effective in 2007, to repurchase all rights, including marketing rights, in transplant indications, unless earlier elected by Roche. If we elect to exercise this right, or Roche elects to transfer such rights to us, we will be responsible for the marketing and commercialization of Zenapax in all indications worldwide. While Roche must notify us at least six months prior to a transfer of Zenapax to us, there can be no assurance that we will be able to establish marketing, sales and distribution capabilities for Zenapax in a timely manner. Further, we may not be able to establish such capabilities for our other products or succeed in gaining market acceptance for our products. If we were to enter into co-promotion or other marketing arrangements with pharmaceutical or biotechnology companies, our revenues would be subject to the payment provisions of these arrangements and could largely depend on these partners' marketing and promotion efforts.

If we do not attract and retain key employees, our business could be impaired.

To be successful we must attract additional and retain qualified clinical, manufacturing, scientific and management personnel. If we are unsuccessful in attracting and retaining qualified personnel, our business could be impaired.

Manufacturing difficulties could delay commercialization of our products.

Of the products that we currently have in clinical development, Roche and its affiliates are responsible for manufacturing Zenapax. In connection with the restructuring of our collaboration agreement with Roche, we obtained the rights to manufacture Zenapax. We are responsible for manufacturing our other products for our own development, and will begin manufacturing clinical supplies of Zenapax following a transition period that we expect will extend to 2005. Our ability to successfully market and develop Zenapax, in particular in transplantation, depends upon our success in manufacturing Zenapax at commercial scale. We have not manufactured this product in the past and we will need to show comparability with material used by Roche. There can be no assurance that we will successfully and in a timely manner be capable of manufacturing Zenapax following the transfer of Zenapax to us by Roche.

We intend to continue to manufacture potential products for use in preclinical and clinical trials using our manufacturing facility in accordance with standard procedures that comply with appropriate regulatory standards. The manufacture of sufficient quantities of antibody products that comply with these standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays and/or the inability to produce sufficient quantities of such products in a commercially viable manner. Our collaborative partners and we have experienced some manufacturing difficulties. Product

supply interruptions could significantly delay clinical development of our potential products, reduce third-party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization and sales of these products.

Manufacturing difficulties can even interrupt the supply of marketed products, thereby reducing revenues and risking loss of market share.

We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture all of our potential products on a commercial scale. To obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to improve and expand our existing manufacturing capabilities. We have recently completed improvements to our existing manufacturing plant in order to manufacture initial commercial supplies of certain products, including Nuvion and Zenapax. Our ability to file for, and to obtain, regulatory approvals for such products, as well as the timing of such filings, will depend on our ability to successfully operate our existing manufacturing plant. We may be unable to do so, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis. Failure to do so could delay commercialization of our products.

In addition, we are constructing a new commercial manufacturing plant. As we implement these plans, we will incur substantial costs. Any construction or other delays could impair our ability to obtain necessary regulatory approvals and to produce adequate commercial supplies of our potential products on a timely basis. Failure to do so could delay commercialization of some of our products and could impair our competitive position.

Our revenue may be adversely affected by competition and rapid technological change.

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our antibody technology platform. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

Any product that our collaborative partners or we succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, markets Simulect® (basiliximab), a product competitive with Zenapax, in the United States and Europe. Novartis has acquired a significant interest in Roche.

We may be unable to obtain or maintain regulatory approval for our products.

All of our products in development are subject to risks associated with applicable government regulations. The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and non-clinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within

this regulatory framework requires a number of years and the expenditure of substantial resources. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process and quality control procedures must conform to rigorous guidelines in order to receive FDA approval. Pharmaceutical product manufacturing establishments are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the United States, foreign manufacturing establishments must comply with these FDA approved guidelines. These foreign manufacturing establishments are subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, pharmaceutical product manufacturing facilities may also be regulated by state, local and other authorities.

In addition, during 2003 the FDA completed the transfer of regulatory responsibility, review and continuing oversight for many biologic therapeutic products, including antibody therapeutics, from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This transfer of responsibility could result in new regulatory standards, which could result in delays in development or regulatory approvals for our potential products. In addition, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured by Roche is comparable to the material we produce at our manufacturing facilities. New regulations resulting from the transfer of regulatory responsibility from CBER to CDER could make it more difficult for us to show comparability which could delay development and regulatory approval of Zenapax in new indications or reduce or interrupt commercial sales of Zenapax for the prevention of acute kidney transplant rejection.

For the marketing of pharmaceutical products outside the United States, our collaborative partners and we are subject to foreign regulatory requirements and, if the particular product is manufactured in the United States, FDA and other U.S. export provisions. Requirements relating to the manufacturing, conduct of clinical trials, product licensing, promotion, pricing and reimbursement vary widely in different countries. Difficulties or unanticipated costs or price controls may be encountered by us or our licensees or marketing partners in our respective efforts to secure necessary governmental approvals. This could delay or prevent us, our licensees or our marketing partners from marketing potential pharmaceutical products.

Both before and after approval is obtained, a biologic pharmaceutical product, its manufacturer and the holder of the BLA for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA if applicable regulatory criteria are not satisfied. Moreover, even if

regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which the pharmaceutical product may be marketed. Further, regulatory approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA, the manufacturer continues to be subject to facility inspection and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or regulatory approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holder.

Manufacturing changes may result in delays in obtaining regulatory approval or marketing for our products.

Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. If we make changes in the manufacturing process, we may be required to demonstrate to the FDA and corresponding foreign authorities that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. Additionally, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured by Roche does not differ significantly from the material we produce at our manufacturing facilities. Showing comparability between the material we produce before and after manufacturing changes, and in the case of Zenapax, between the material produced by Roche and the drug material produced by us, is particularly important if we want to rely on results of prior preclinical studies and clinical trials performed using the previously produced drug material. Depending upon the type and degree of differences between the newer and older drug material, and in the case of Zenapax, between the our material and the Roche material, we may be required to conduct additional animal studies or human clinical trials to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material. We have made manufacturing changes and are likely to make additional manufacturing changes for the production of our products currently in clinical development. These manufacturing changes or an inability to immediately show comparability between the Roche material and our material could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

Our business may be harmed if we cannot obtain sufficient quantities of raw materials.

We depend on outside vendors for the supply of raw materials used to produce our product candidates. Once a supplier's materials have been selected for use in our manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

We may be subject to product liability claims, and our insurance coverage may not be adequate to cover these claims.

We face an inherent business risk of exposure to product liability claims in the event that the use of products during research and development efforts or after commercialization results in adverse effects. This risk will exist even with respect to any products that receive regulatory approval for commercial sale. While we have obtained liability insurance for our products, it may not be sufficient to satisfy any liability that may arise. Also, adequate insurance coverage may not be available in the future at acceptable cost, if at all.

We may incur significant costs in order to comply with environmental regulations or to defend claims arising from accidents involving the use of hazardous materials.

We are subject to federal, state and local laws and regulations governing the use, discharge, handling and disposal of materials and wastes used in our operations. As a result, we may be required to incur significant costs to comply with these laws and regulations. We cannot eliminate the risk of

accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities which exceed our resources. In addition, we cannot predict the extent of the adverse effect on our business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

Changes in the U.S. and international health care industry could adversely affect our revenues.

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. Cost containment measures, whether instituted by health care providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payors may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

We may not be able to obtain or maintain our desired price for our products. Our products may not be considered cost effective relative to alternative therapies. As a result, adequate third-party reimbursement may not be available to enable us to maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborative partners.

Our common stock price is volatile and an investment in our company could decline in value.

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile so that investment in our securities involves substantial risk. Additionally, the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The following are some of the factors that may have a significant effect on the market price of our common stock:

- developments or disputes as to patent or other proprietary rights;
- disappointing sales of approved products;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in obtaining regulatory approvals or unfavorable FDA advisory panel recommendations;

- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- disputes or disagreements with collaborative partners;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- initiation, termination or modification of agreements with our collaborative partners;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the common stock would likely drop significantly. A significant drop in the price of a company's common stock often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

We may not have the ability to raise the funds to repurchase the 2.75% \$250 million convertible notes on the repurchase date or to finance any repurchase offer required by the indenture.

In August 2010, August 2013 and August 2018, respectively, holders of our \$250 million convertible notes (the Notes) may require us to repurchase all or a portion of their notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of notes to be repurchased in August 2013 and August 2018, at our option, in cash, shares of our common stock or a combination of cash and shares of our common stock. In addition, if a repurchase event occurs (as defined in the indenture), each holder of the Notes may require us to repurchase all or a portion of the holder's notes. We cannot assure you that there will be sufficient funds available for any required repurchases of these securities. In addition, the terms of any agreements related to borrowing which we may enter into from time to time may prohibit or limit our repurchase of notes or make our repurchase of notes an event of default under certain circumstances. If a repurchase event occurs at a time when a credit agreement prohibits us from purchasing the Notes, we could seek the consent of the lender to purchase the Notes or could attempt to refinance the debt covered by the credit

agreement. If we do not obtain a consent, we may not purchase the Notes. Our failure to purchase tendered notes would constitute an event of default under the indenture, which might also constitute a default under the terms of our other debt. In such circumstances, our financial condition and the value of our securities could be materially harmed.

Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards, including proposed changes in accounting for stock options, may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty for companies such as ours and insurance costs are increasing as a result of this uncertainty and other factors. We are

committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Prior and future acquisitions could be difficult to integrate, disrupt our business, dilute stockholder value and harm our operating results.

In April 2003, we completed the acquisition of a privately owned company, Eos Biotechnology, Inc. We expect to continue to review opportunities to acquire other businesses, products or technologies that would complement our current products, expand the breadth of our markets or enhance our technical capabilities, or that may otherwise offer growth opportunities. In our acquisition of Eos, we issued stock as all of the consideration, and we may be obligated to release additional shares from escrow. The issuance of stock in these and any future transactions will dilute stockholders' percentage ownership.

Other risks associated with acquiring the operations of other companies include:

- problems assimilating the purchased operations, technologies or products;
- unanticipated costs associated with the acquisition;
- diversion of management's attention from our existing business;
- the potential loss of key collaborators of the acquired companies;
- lack of synergy, or the inability to realize expected synergies, resulting from the acquisition;
- adverse effects on existing relationships with other third-party business partners;
- risks associated with entering markets in which we have no, or limited, prior experience; and

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- potential loss of key employees of acquired organizations.

We cannot assure that we would be successful in overcoming problems encountered in connection with such acquisitions, and our inability to do so could significantly harm our business. In addition, to the extent that the economic benefits associated with such acquisitions diminish in the future, we may be required to record write downs of goodwill, intangible assets or other assets associated with such acquisitions.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We maintain a non-trading investment portfolio of investment grade, highly liquid, debt securities, which limits the amount of credit exposure to any one issue, issuer, or type of instrument. We do not use derivative financial instruments for speculative or trading purposes. We hold a \$30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the value of the Exelixis stock in our financial statements. Such a requirement could cause changes in the Exelixis stock price to contribute to fluctuation of our operating results from quarter to quarter. The securities in our investment portfolio are not leveraged and are classified as available-for-sale and therefore are subject to interest rate risk. We do not currently hedge interest rate exposure. As of March 31, 2004, there has been no material change in our interest rate exposure from that described in the Company's Annual Report on Form 10-K for the year ended December 31, 2003.

Because we translate foreign currencies into United States dollars for reporting purposes, currency fluctuations can have an impact on our results. For the three months ended March 31, 2004 and 2003, there was no material currency exchange impact on our Consolidated Condensed Statements of Operations from our intercompany transactions. As of March 31, 2004, we did not engage in foreign currency hedging activities.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation as of March 31, 2004, our chief executive officer and chief financial officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q.

Changes in internal controls. There were no changes in our internal controls over financial

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reporting during the quarter ended March 31, 2004, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Item 3 of our Annual Report on Form 10-K for the period ended December 31, 2003. No significant changes in the status of disclosed items have occurred since December 31, 2003.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

- 10.1** Amendment No. 1 to Special Compensation and Employment Agreement Dated May 1, 2002 Between Laurence Jay Korn and Protein Design Labs, Inc.
- 31.1** Certification required by Rule 13a-14(a) or Rule 15d-14(a).
- 31.2** Certification required by Rule 13a-14(a) or Rule 15d-14(a).
- 32.1** Certification by the Chief Executive Officer and the Chief Financial Officer of Protein Design Labs, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

(b) Reports filed on Form 8-K during the quarter ended March 31, 2004.

On February 26, 2004, we announced our financial results for the year and quarter ended December 31, 2003.

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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.

Dated: April 30, 2004

PROTEIN DESIGN LABS, INC.
(Registrant)

/s/ Mark McDade
Mark McDade
Chief Executive Officer
(Principal Executive Officer)

/s/ Glen Sato
Glen Sato
Senior Vice President and Chief
Financial Officer
(Principal Accounting Officer)

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**AMENDMENT NO. 1 TO
SPECIAL COMPENSATION AND EMPLOYMENT AGREEMENT
DATED MAY 1, 2002
BETWEEN LAURENCE JAY KORN AND PROTEIN DESIGN LABS, INC.**

This Amendment (the "Amendment") to the Special Compensation and Continued Employment Agreement (the "Agreement") is made effective as of March 26, 2004 (the "Effective Date") by and between Laurence Jay Korn, Ph.D. ("Dr. Korn") and Protein Design Labs, Inc. (the "Company").

WHEREAS, Dr. Korn has been nominated as a candidate for re-election to the Company's Board of Directors (the "Board") at the next Annual Meeting of Stockholders, scheduled to be held on June 30, 2004; and

WHEREAS, Dr. Korn has agreed to resign as Chairman of the Company effective immediately following the 2004 Annual Meeting .

NOW, THEREFORE, the parties agree as follows:

1. Resignation as Employee and Officer. As used in this Amendment, the term "2004 Annual Meeting" shall mean the next Annual Meeting of Stockholders of the Company (currently scheduled to be held June 30, 2004) at which Dr. Korn is nominated as a candidate for re-election to the Company's Board by the Company (and provided that the number of nominees by the Company does not exceed the number of directors being elected at that meeting), which nomination is presented to the Company's Stockholders in the Company's Proxy Statement, and which nomination of Dr. Korn is not withdrawn by the Company. Immediately following the adjournment of the 2004 Annual Meeting, Dr. Korn will resign as Chairman and as an employee of the Company (the "Resignation"). Effective as of such Resignation, Dr. Korn will cease to be an *ex officio* member of all Board committees. From the Effective Date until such Resignation, Dr. Korn will wind down from his current level of activity and transition to the appropriate Company employee(s) the activities outlined in Paragraph 2(a) through (d) of the Agreement. The winding down of activities contemplated by this Amendment shall not constitute "Good Reason" under the Agreement. Dr. Korn's salary and benefits under the Agreement will continue through the date of Resignation.

2. Compensation and Benefits Upon Resignation.

(a) Salary and Vacation Pay. On the date of Resignation, Dr. Korn shall deliver to the Company a signed general release in the form attached as Exhibit "A" (the "Release"). Promptly following the seven (7) day period within which Dr. Korn may revoke the Release (as provided in Section 5 of the Release), the Company shall pay to Dr. Korn by Company check the amount of \$515,000.00, less applicable withholding taxes. On the date of Resignation, the Company shall pay to Dr. Korn by Company check an amount equal to his accrued but unused vacation time, calculated in accordance with Company policy, less applicable withholding taxes. Upon his Resignation, Dr. Korn shall be entitled only to the compensation provided for in this Amendment and not the benefits described in Section 6 of the Agreement.

(b) Stock Option Vesting. Automatically upon delivery of the Release, and without any further action being required by the Company, Dr. Korn shall become vested in an additional 12 months of unvested stock options previously granted to him under the Company's 1991 and 1999 Stock Option Plans (the "Plans"). All of Dr. Korn's options under the Plans shall continue to vest in accordance with their terms so long as he continuously serves as a member of the Board, despite the termination of his employment, and shall not terminate until the earlier of (i) three months after termination of service as a member of the Board or (ii) the expiration of the ten-year term of each option.

(c) Employee Fringe Benefits. Subject to delivery of the Release, Dr. Korn will continue to receive all employee fringe benefits identified in Paragraph 3(c) of the Agreement for 1 year from the date of Resignation, to the extent such fringe benefits can be made generally available to directors or former employees of the Company pursuant to the terms of the applicable fringe benefit or policy. In addition, upon the date of Resignation, Dr. Korn shall immediately become a participant in the Company's retiree medical insurance plan, subject to the terms and conditions of such plan, whether or not he delivers the Release.

(d) Office Space. The Company will continue to provide Dr. Korn with the office space at 545 Middlefield Road, Suite 175, Menlo Park, California 94025 (the "Facility") without charge until February 28, 2005. Dr. Korn will give 30 days' written notice to the Company if he decides to vacate the Facility before February 28, 2005. Dr. Korn may retain, without charge, furniture owned by the Company and currently in, or on order for, Dr. Korn's office and his executive assistant's office. Office equipment (including, copier, fax, personal computer) and furniture currently in the conference room in the Facility may be used by Dr. Korn without charge until February 28, 2005, and thereafter shall be returned to the Company. Furniture on order for the conference room in the Facility shall be delivered to the Company's facilities in Fremont and retained by the Company. To the extent required by law, the Company may report amounts equal to monthly rent of the Facility at current fair market value and the fair market value of any equipment and furniture transferred or leased to Dr. Korn as ordinary income to Dr. Korn, on Form 1099, and/or any other reports required by law.

3. Termination of Specific Terms of the Agreement; Survival of Remaining Terms.

(a) the following provisions in the Agreement shall terminate as of the Effective Date:

Section 2(a)-(d)
Section 3(d), paragraph two; sentence two

(b) the following provisions in the Agreement shall terminate immediately following the 2004 Annual Meeting:

Section 1
Section 2(e)
Section 3(a)
Section 3(c), last sentence

Section 3(d), paragraph one, sentences one, two and three
Section 3(d), paragraph two, first sentence
Section 6, except paragraph five, final sentence
Section 8

(c) the following provision in the Agreement shall terminate one year after the date of Resignation:

Section 3(c), third sentence

Except as specifically amended or terminated hereby, all terms of the Agreement which, by their terms, survive the termination of his employment, shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have signed this Amendment effective as of the date set forth above.

PROTEIN DESIGN LABS, INC.

**LAURENCE JAY KORN,
Ph.D.**

By: /s/ Mark McDade

/s/ Laurence Jay Korn

Mark McDade
Chief Executive Officer

EXHIBIT A

GENERAL RELEASE OF CLAIMS

In exchange for the termination benefits described in the Special Compensation and Employment Agreement dated May 1, 2002, as amended (the "Agreement"), between me and Protein Design Labs, Inc. (the "Company"), I hereby agree as set forth below:

1. I and my successors and assigns release the Company, its parents, subsidiaries and affiliated entities, and each of their respective shareholders, investors, directors, officers, employees, agents, attorneys, insurers, legal successors and assigns, of and from any and all claims, actions and causes of action, whether now known or unknown, which I now have, or at any other time had, or shall or may have against those released parties based upon or arising out of any matter, cause, fact, thing, act or omission whatsoever occurring or existing at any time up to and including the date on which I am signing this General Release of Claims (the "Release"), including, but not limited to, any claims that are based upon or arise out of my employment with the Company or the termination of that employment, and any claims of breach of contract, wrongful termination, retaliation, fraud, defamation, infliction of emotional distress or national origin, race, age, sex, sexual orientation, disability or other discrimination or harassment under the Civil Rights Act of 1964, the Age Discrimination In Employment Act of 1967, the Americans with Disabilities Act, the Fair Employment and Housing Act or any other applicable law or statute.

2. I acknowledge that I have read section 1542 of the Civil Code of the State of California, which states in full:

A general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor.

I waive any rights that I have or may have under section 1542 to the full extent that I may lawfully waive such rights pertaining to this Release, and I affirm that I am releasing all known and unknown claims that I have or may have against the parties listed above.

3. I agree that I will not, for a period of 5 years, directly or indirectly solicit any of the Company's employees (other than Jeanne Mager), contractors, vendors, strategic partners or customers to terminate their employment, contractor, vendor, strategic partner, or customer relationships with the Company.

4. I agree that I will not, at any time, make any critical or disparaging statements to any person or entity regarding the Company, or any of its directors, employees, products, and/or services, except to the extent that such statements are necessary to respond truthfully to a subpoena or other compulsory legal process.

5. This Release cannot be modified or amended except by a supplemental written agreement signed by an authorized representative of the Company and me.

I UNDERSTAND THAT I SHOULD CONSULT WITH AN ATTORNEY PRIOR TO SIGNING THIS AGREEMENT AND THAT I AM GIVING UP ANY LEGAL CLAIMS I HAVE AGAINST THE PARTIES RELEASED ABOVE BY SIGNING THIS RELEASE. I FURTHER UNDERSTAND THAT I MAY HAVE UP TO 21 DAYS TO CONSIDER THIS RELEASE, THAT I MAY REVOKE IT AT ANY TIME DURING THE 7 DAYS AFTER I SIGN IT, AND THAT IT SHALL NOT BECOME EFFECTIVE UNTIL THAT 7-DAY PERIOD HAS PASSED. I ACKNOWLEDGE THAT I AM SIGNING THIS RELEASE KNOWINGLY, WILLINGLY AND VOLUNTARILY IN EXCHANGE FOR THE COMPENSATION AND BENEFITS DESCRIBED IN THE AGREEMENT.

Dated: _____, 2004

Laurence Jay Korn, Ph.D.

CERTIFICATIONS

I, Mark McDade, certify that:

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

Date: April 30, 2004

/s/ Mark McDade
Mark McDade
Chief Executive Officer

CERTIFICATIONS

I, Glen Sato, certify that:

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

Date: April 30, 2004

/s/ Glen Sato

Glen Sato
Chief Financial Officer

CERTIFICATIONS

Mark McDade, Chief Executive Officer and Glen Sato, Chief Financial Officer of Protein Design Labs, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- (1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

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

Dated: April 30, 2004

By:

/s/ Mark McDade

Mark McDade
Chief Executive Officer

/s/ Glen Sato

Glen Sato
Chief Financial Officer