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 June 30, 2004

OR

o **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	**94-3023969**
(State or other jurisdiction of incorporation or organization)	(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 o

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

As of July 19, 2004 there were 95,122,446 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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Revenues:				
Royalties	$ 24,731	$ 17,905	$ 46,741	$ 35,050
License and other	1,052	3,096	6,670	8,698
Total revenues	25,783	21,001	53,411	43,748
Costs and expenses:				
Research and development	32,009	20,538	65,038	36,511
General and administrative	7,450	7,193	15,518	12,502
Acquired in-process research and development	—	37,834	—	37,834
Total costs and expenses	39,459	65,565	80,556	86,847
Operating loss	(13,676)	(44,564)	(27,145)	(43,099)
Interest and other income, net	2,583	4,188	4,867	8,861
Interest expense	(1,351)	(1,755)	(2,736)	(3,641)
Impairment loss on investment	—	—	—	(150)
Loss before income taxes	(12,444)	(42,131)	(25,014)	(38,029)
Provision for income taxes	8	18	56	49
Net loss	$ (12,452)	$ (42,149)	$ (25,070)	$ (38,078)
Net loss per basic and diluted share	$ (0.13)	$ (0.45)	$ (0.27)	$ (0.42)
Shares used in computation of net loss per basic and diluted share:	94,587	93,301	94,294	91,242

See accompanying notes.

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

	June 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 137,087	$ 341,768
Marketable securities, including $6.8 million and $7.4 million of restricted investments at June 30, 2004 and December 31, 2003, respectively	291,880	149,863
Other current assets	6,445	11,893
Total current assets	435,412	503,524

Land, property and equipment, net	208,412	155,513
Intangible assets, net	31,135	32,311
Restricted investments	10,046	13,362
Other assets	6,804	7,320
Convertible note receivable	30,000	30,000
Total assets	$ 721,809	$ 742,030
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,998	$ 3,576
Accrued compensation	6,486	5,903
Accrued clinical trial costs	1,734	1,759
Accrued interest	2,593	3,204
Other accrued liabilities	12,552	19,351
Deferred revenue	—	161
Current portion of long-term obligations	1,089	1,222
Total current liabilities	30,452	35,176
Convertible subordinated notes	250,000	250,000
Notes payable	245	595
Other long-term debt	7,658	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; 95,118 and 93,886 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	951	939
Additional paid-in capital	679,241	666,793
Accumulated deficit	(245,361)	(220,291)
Accumulated other comprehensive income (loss)	(1,377)	890
Total stockholders' equity	433,454	448,331
Total liabilities and stockholders' equity	$ 721,809	$ 742,030

See accompanying notes.

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

	Six Months Ended June 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	$ (25,070)	$ (38,078)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Acquired in-process research and development	—	37,834
Depreciation and amortization	5,528	3,298
Amortization of convertible notes offering costs	605	360
Stock-based compensation expense	560	199
Amortization of intangible assets	1,176	176
Loss on disposal of fixed assets	514	—
Impairment loss on investment	—	150
Changes in assets and liabilities:		
Interest receivable	407	2,425
Other current assets	5,448	859
Other assets	(88)	790
Accounts payable	2,422	3,775
Accrued liabilities	(6,852)	(1,576)
Deferred revenue	(161)	—
Total adjustments	9,559	48,290
Net cash provided by (used in) operating activities	(15,511)	10,212
Cash flows from investing activities:		
Purchases of marketable securities	(235,353)	(50,084)
Maturities of marketable securities	90,000	172,000
Cash acquired in acquisition of Eos	—	2,453
Maturities of restricted investments	3,913	—
Purchases of land, property and equipment	(58,877)	(35,762)
Net cash provided by (used in) investing activities	(200,317)	88,607
Cash flows from financing activities:		
Proceeds from issuance of capital stock	11,900	2,062

Payments on other long-term obligations	(753)	(447)
Net cash provided by financing activities	11,147	1,615
Net increase (decrease) in cash and cash equivalents	(204,681)	100,434
Cash and cash equivalents at beginning of period	341,768	287,730
Cash and cash equivalents at end of period	$ 137,087	$ 388,164

See accompanying notes.

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
June 30, 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 a substantial portion of our royalty revenues on sales of the product *Synagis*® marketed by MedImmune. 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.

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. 104, "Revenue Recognition." 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. Generally there are three types of collaboration arrangements PDL enters into under which we provide access to our proprietary patent portfolio covering the humanization of antibodies.

- 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. In addition, the licensee has the 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 we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses; therefore, upon delivery of the patent rights agreement, the earnings process is complete. When a licensee exercises its right to obtain patent licenses to certain designated drug targets for commercial purposes, we recognize the related consideration as revenue upon the licensee's 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 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 licensees to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the licensee'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

As of June 30, 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. During the quarter ended June 30, 2004, we recognized approximately $363,000 in stock-based compensation expense with respect to modifications to certain employee stock option awards. The tables below illustrate the effect on net loss and net 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" (SFAS 123), as amended by FASB Statement No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," to our stock-based employee compensation plans.

During the preparation of the notes to the consolidated condensed financial statements for the quarter ended June 30, 2004, we determined that the calculation of our pro forma net loss reported under SFAS 123 for the years ended December 31, 2001, 2002 and 2003, as previously reported, was understated primarily as a result of our having inadvertently excluded the fair value of (and, therefore, the amortization expense related to) options granted during 1998 through 2001. In addition, we found that amortization expense was incorrectly calculated in 2001, 2002 and 2003 due primarily to inaccuracies in the computation of the weighted-average expected life used to calculate the fair value of stock options granted during 2000 through 2003. Accordingly, pro forma net loss reported under SFAS 123 for the years ended December 31, 2001, 2002 and 2003, for the three months ended March 31, 2003 and 2004 and for the three and

six months ended June 30, 2003, presented in the tables below, has been revised. These revisions had no effect on our previously reported consolidated results of operations or financial condition.

(In thousands, except per share data)	Three Months Ended June 30, 2004	Three Months Ended June 30, 2003 (Revised)	Six Months Ended June 30, 2004	Six Months Ended June 30, 2003 (Revised)
Net loss, as reported	$ (12,452)	$ (42,149)	$ (25,070)	$ (38,078)
Add: Stock-based employee compensation expense included in reported net loss	363	—	363	—
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards	(4,216)	(7,139)	(9,504)	(14,290)
Pro forma net loss	$ (16,305)	$ (49,288)	$ (34,211)	$ (52,368)
Basic and diluted net loss per share:				
As reported	$ (0.13)	$ (0.45)	$ (0.27)	$ (0.42)
Pro forma	$ (0.17)	$ (0.53)	$ (0.36)	$ (0.57)
Impact of revision on previously reported:				
Pro forma net loss		$ (2,584)		$ (5,724)
Pro forma net loss per share		$ (0.03)		$ (0.06)

(In thousands, except per share data)	Three Months Ended March 31, 2004	Three Months Ended March 31, 2003 (Revised)	Year Ended December 31, 2003	Year Ended December 31, 2002 (Revised)	Year Ended December 31, 2001
Net income (loss), as reported	$ (12,618)	$ 4,069	$ (129,814)	$ (14,554)	$ 2,647
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards	(5,289)	(7,152)	(25,220)	(31,462)	(40,867)
Pro forma net loss	$ (17,907)	$ (3,083)	$ (155,034)	$ (46,016)	$ (38,220)
Basic and diluted net income (loss) per share:					
As reported	$ (0.13)	$ 0.05	$ (1.40)	$ (0.16)	$ 0.03
Pro forma	$ (0.19)	$ (0.03)	$ (1.68)	$ (0.52)	$ (0.44)
Impact of revision on previously reported:					
Pro forma net loss	$ 466	$ (3,124)	$ (5,965)	$ (19,620)	$ (1,928)
Pro forma net loss per share	$ 0.01	$ (0.04)	$ (0.06)	$ (0.22)	$ (0.02)

For the periods presented in the table below, 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:

	Three Months Ended June 30, 2004	Three Months Ended June 30, 2003	Six Months Ended June 30, 2004	Six Months Ended June 30, 2003	Year Ended December 31, 2003	Year Ended December 31, 2002	Year Ended December 31, 2001
Expected life, in years (revised, except 2004 periods)	2.7	2.8	2.7	2.8	2.8	2.7	3.0
Risk-free interest rate	3.0%	2.8%	2.4%	2.9%	2.9%	3.9%	4.2%
Volatility	67%	72%	70%	73%	72%	87%	98%
Dividend yield	0	0	0	0	0	0	0

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 statement of operations based on their fair values. We will adopt the final standard upon its issuance from the FASB.

We account for stock options granted to non-employees at fair value using the Black-Scholes option-pricing 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 second quarters of 2004 and 2003 accounted for 38% and 26% of total revenues, respectively, and revenues from Genentech in the first half of 2004 and 2003 accounted for 33% and 26% of total revenues, respectively. Revenues from MedImmune in the second quarters of 2004 and 2003 accounted for 52% and 56% of total revenues, respectively, and revenues from MedImmune in the first half of 2004 and 2003 accounted for 47% and 50% of total revenues, respectively. 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 loss per share amounts have been computed using the weighted-average number of shares of common stock outstanding during the periods presented. For all periods presented, 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.

The total number of shares excluded from the calculations of diluted net loss per share for outstanding convertible notes was 12,415,450 for the three and six months ended June 30, 2004 and 3,974,000 for the three and six months ended June 30, 2003. The total number of shares excluded from the calculation of diluted net loss per share for stock options was 4,251,000 and 1,743,000 for the three months ended June 30, 2004 and 2003 and 4,335,000 and 1,363,000 for the six months ended June 30, 2004 and 2003, respectively.

3. Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and the change in unrealized gains and losses on our available-for-sale securities. The following table presents the calculation of our comprehensive loss, in thousands:

(In thousands)	Three Months Ended June 30, 2004	Three Months Ended June 30, 2003	Six Months Ended June 30, 2004	Six Months Ended June 30, 2003
Net loss	$ (12,452)	$ (42,149)	$ (25,070)	$ (38,078)
Other comprehensive income (loss):				
Increase (decrease) in unrealized gains on marketable securities	(2,122)	(1,321)	(2,267)	(2,870)
Total comprehensive loss	$ (14,574)	$ (43,470)	$ (27,337)	$ (40,948)

4. Other Accrued Liabilities

At June 30, 2004 and December 31, 2003, other accrued liabilities consisted of the following:

(In thousands)	June 30, 2004	December 31, 2003
Construction-in-process	$ 6,417	$ 14,568
Consulting and services	3,679	2,409
Other	2,456	2,374
	$ 12,552	$ 19,351

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 or 2004 upon the execution of the agreements.

6. Restructuring and Other Charges

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials, in June 2004 management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased office facility. As a result of the restructuring plan and in accordance FASB Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," we incurred a charge of approximately $288,000, included in research and development expenses in the Statement of Operations, in the quarter ended June 30, 2004. The restructuring charge included approximately $97,000 of severance-related amounts, $169,000 of committed cost for our New Jersey leased facility, primarily related to lease expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned at the facility. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005. The workforce reductions were completed by the end of the second quarter of 2004.

As of June 30, 2004, we had made payments totaling approximately $31,000 for severance-related restructuring charges. We expect to pay the balance of the severance costs during the third quarter of 2004, and we currently expect to pay the facility-related costs through October 2005. Actual future cash requirements may differ materially from the accrual at June 30, 2004, particularly if we sublease the facility.

Also in the second quarter of 2004, we completed the first phase of a physical inventory of substantially all of our laboratory equipment at our Fremont facilities. As a result, we recorded a charge to research and development expenses of $300,000, which

represents the estimated amount of net book value of assets that are no longer in use. We plan to complete the physical inventory of these assets by the end of 2004.

7. 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 three and six months ended June 30, 2004, we recognized net periodic benefit cost of approximately $62,000 and $124,000, respectively. This expense includes service cost, interest cost, and amortization of prior service cost.

8. Related-Party Transaction

Pursuant to an agreement with Dr. Laurence Korn regarding his resignation as an officer of the Company, Dr. Korn resigned on June 30, 2004 as Chairman of the Company's Board and as an employee of the Company. Dr. Korn remains a member of the Board. Under the agreement, Dr. Korn received a severance payment of $515,000 in addition to the acceleration of an additional 12 months' of vesting of certain stock options previously granted to him. During the second quarter of 2004, we recognized $515,000 for his severance payment, which was paid in July 2004, and approximately $40,000 in stock-based compensation expense in connection with the accelerated vesting of stock options. Additionally, Dr. Korn will continue to receive certain fringe benefits for a period of one year from his resignation date and 112,500 of his unvested, outstanding stock options as of June 30, 2004 will continue to vest under the terms of the original stock option agreements. As this represents a change in the status in grantee status under FASB Statement No. 44, "Accounting for Certain Transactions Involving Stock Compensation," we expect to recognize stock-based compensation expense over the next two years as these stock options vest under the fair value method of accounting as proscribed by SFAS 123.

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 "believes," "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 second quarter of 2004, we received royalties on seven marketed products, with approximately 85% 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 June 30, 2004, we had an accumulated deficit of approximately $245.4 million. We expect that our expenses will increase over the next several years because of the extensive resource commitments required to identify, develop and manufacture antibody candidates, to achieve regulatory approval and to market potential products for commercial success. 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 profitability or a 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.

Significant Events

In January 2004, we entered into certain agreements with Seattle Genetics, Inc. (SGI) in which we granted patent rights and patent licenses 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 and six months ended June 30, 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 on-going 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.

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 and Six Months Ended June 30, 2004 and 2003

Revenues

	Three Months Ended June 30,			Six Months Ended June 30,		
(In thousands)	2004	2003	% Change	2004	2003	% Change
Royalties	$ 24,731	$ 17,905	38%	$ 46,741	$ 35,050	33%
License and other	1,052	3,096	(58)%	6,670	8,698	(20)%
Total revenues	$ 25,783	$ 21,001	24%	$ 53,411	$ 43,748	23%

Royalties

Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth increased during the first and second quarters of 2004 compared to the comparable periods 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 periods relates to royalties recognized on sales of three additional products, Genentech's Xolair, Raptiva and Avastin products, which were launched in the second half of 2003 and the first quarter of 2004. Royalty payments from sales of Synagis and Herceptin accounted for 54% and 31% of our royalty revenues for the three months ended June 30, 2004 as compared to 66% and 31% in the comparable period in 2003. Royalty payments from sales of Synagis and Herceptin accounted for 54% and 32% of our royalty revenues for the six months ended June 30, 2004 as compared to 62% and 32% in the comparable period in 2003.

We expect that royalty revenues will continue to increase as the number of drugs from which we receive royalty revenues has increased from four to seven over the past year. 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 decreased from the comparable periods in 2003 due to fewer license fees and milestone payments received during the first and second quarters of 2004. During the second quarter of 2003, we recognized revenue related to the exercise of an option by Wyeth to acquire a patent license and a milestone payment associated with a patent license agreement, with no such comparable revenue in the second quarter of 2004.

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 FDA, 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

	Three Months Ended June 30,			Six Months Ended June 30,		
(In thousands)	2004	2003	% Change	2004	2003	% Change
Research and development	$ 32,009	$ 20,538	56%	$ 65,038	$ 36,511	78%
General and administrative	7,450	7,193	4%	15,518	12,502	24%

Acquired in-process research and development	—	37,834	—	—	37,834	—
Total costs and expenses	$ 39,459	$ 65,565	(40)%	$ 80,556	$ 86,847	(7)%

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 second quarter of 2004 compared to the second quarter of 2003 was primarily due to an increase in research and development personnel headcount of approximately 97 employees from June 30, 2003 to June 30, 2004 and associated costs of approximately $4.2 million, contract manufacturing services of $3.2 million, and an increase in facility-related costs of $2.1 million. In addition, during the second quarter of 2004 we incurred approximately $0.3 million in restructuring charges related to the closure of our New Jersey facility and $0.3 million for the write-off of certain assets (see Restructuring and Other Charges below), and approximately $0.5 million related to stock-based compensation for non-employees and modifications to certain employee stock options, all of which was included in research and development expenses.

The increase in research and development costs during the first six months of 2004 compared to the same period in 2003 was primarily due to an increase in research and development personnel headcount with associated costs of approximately $10.4 million, contract manufacturing services of $5.6 million, an increase in in-licensing costs of $4.5 million, an increase in facility-related costs of $4.1 million, and higher clinical development expenses for our major research and development projects of approximately $1.7 million. We expect our research and development expenses will increase further as we 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 Six Months Ended June 30, 2004	2003
Current Product Candidates						
Daclizumab					$ 15,612	$ 6,579
	Asthma	Phase IIa	—	2004		
	Ulcerative colitis **(1)**	Phase II	—	2004		
HuZAF	Crohn's disease	Phase IIa		2004	5,523	10,325
Nuvion	Severe steroid-refractory ulcerative colitis	Phase I/II	—	2004	10,611	3,943
M200 (2)	Solid tumors	Phase I	—	2004	11,400	677
***Other* (3)**			—		21,892	14,987
	Total Research and Development Expenses				**$ 65,038**	$ 36,511

(1) Clinical trial for daclizumab in ulcerative colitis was discontinued during the second quarter of 2004.

(2) Anti-$\alpha_5\beta_1$ integrin product acquired as part of Eos acquisition in April 2003.

(3) 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 7 to 10 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.

Restructuring and Other Charges included in Research and Development Expenses

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials in June 2004, management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, we incurred a charge of approximately $288,000, included in research and development expenses in the Statement of Operations, in the quarter ended June 30, 2004. The restructuring charge included approximately $97,000 of severance-related amounts, $169,000 of committed cost for our New Jersey leased facility, primarily related to lease expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned at the facility. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in

October 2005. The workforce reductions were completed by the end of the second quarter of 2004. We expect to pay the balance of the severance costs during the third quarter of 2004, and we expect to pay the facility-related costs through October 2005. Actual future cash requirements may differ materially from the accrual at June 30, 2004, particularly if we sublease the facility.

Also in the second quarter of 2004, we completed the first phase of a physical inventory of substantially all of our laboratory equipment at our Fremont facilities. As a result, we recorded a charge to research and development expenses of $300,000, which represents the estimated amount of net book value of assets that are no longer in use. We plan to complete the physical inventory of these assets by the end of 2004.

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 June 30, 2004 increased slightly from the comparable period in 2003 primarily due to increased personnel-related expenses of approximately $0.6 million, primarily resulting from the resignation of Dr. Laurence Jay Korn as Chairman of the Board and an employee of the Company (see below). We expect that general and administrative expenses will increase slightly for the second half of 2004, as compared to the first six months of 2004.

The increase in general and administrative expenses for the six months ended June 30, 2004 as compared to the 2003 period was primarily due to increased personnel-related expenses of approximately $1.8 million, increased facilities-related costs of approximately $0.5 million, increased outside services expenses of approximately $0.8 million, and increased legal costs related to our intellectual property, licensing and other contractual matters of approximately $0.3 million.

In connection with Dr. Laurence Korn's resignation as Chairman of the Board and an employee of the Company, Dr. Korn received a severance payment of $515,000 in addition to the acceleration of an additional 12 months' of vesting of certain stock options previously granted to him. During the second quarter of 2004, we recognized $515,000 for his severance payment, which was paid in July 2004, and approximately $40,000 in stock-based compensation expense in connection with the accelerated vesting of stock options as provided under the amended Agreement. Additionally, Dr. Korn will continue to receive certain fringe benefits for a period of one year from his resignation date and 112,500 of his unvested, outstanding stock options as of June 30, 2004 will continue to vest under the terms of the original stock option agreements. As this represents a change in the status in grantee status under FASB Statement No. 44, "Accounting for Certain Transactions Involving Stock Compensation," we expect to recognize stock-based compensation expense over the next two years as the stock options vest under the fair value method of accounting as proscribed by SFAS 123.

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-α5β1 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-α5β1 Integrin Antibody)	Fab fragment of Anti-α5β1 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 were then 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 follow-on trial in which daclizumab is administered subcutaneously, expected to commence by the first quarter of 2005.

- In May 2004, we reported results from a Phase II clinical study of daclizumab in patients with moderate-to-severe ulcerative colitis. Daclizumab did not meet primary or secondary endpoints in the trial, and we do not intend to develop it further for this indication.

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

	Three Months Ended June 30,			Six Months Ended June 30,		
(In thousands)	2004	2003	% Change	2004	2003	% Change
Interest and other income, net	$ 2,583	$ 4,188	(44)%	$ 4,867	$ 8,861	(48)%
Interest expense	(1,351)	(1,755)	(23)%	(2,736)	(3,641)	(25)%
Impairment loss on investment	—	—	—	—	(150)	—

Interest and Other Income and Expense

Interest income for the three and six months ended June 30, 2004 decreased from the comparable periods in 2003 due to the reduced interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates and lower invested balances.

Interest expense for the three and six months ended June 30, 2004 decreased from the comparable periods in 2003 as a result of capitalizing more interest costs in connection with the development activities for our future manufacturing facilities. We capitalized approximately $0.9 million and $1.7 million of our interest cost in the three and six months ended June 30, 2004, compared to $0.7 million and $1.2 million in the three and six months ended June 30, 2003, respectively. Further, interest expense decreased slightly from the same periods 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, partially 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 second 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 research group.

Income Taxes

We have recorded a tax provision of approximately $56,000 for the six months ended June 30, 2004, compared to $49,000 for the comparable period in 2003. Taxes during both periods primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee. 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 June 30, 2004, we had cash, cash equivalents, marketable securities and restricted investments in the aggregate of $439.0 million, compared to $505.0 million at December 31, 2003.

Net cash used in operating activities for the six months ended June 30, 2004 was approximately $15.5 million, compared to net cash provided by operating activities of $10.2 million in the comparable 2003 period. The change from the 2003 period was primarily due to a higher research and development expenses in the 2004 period as compared to the 2003 period, which was primarily the result of higher spending to support our ongoing preclinical and clinical efforts, including an approximate 25% increase in research and development personnel from June 30, 2003 to June 30, 2004.

Net cash used in investing activities was $200.3 million for the six months ended June 30, 2004, compared to net cash provided by investing activities of $88.6 million in the comparable period in 2003. The change from the 2003 period was primarily the result of fewer maturities of our marketable securities, a larger number of purchases of marketable securities, and higher capital expenditures in the first two quarters of 2004. Capital expenditures in the first six months 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 six months ended June 30, 2004 was $11.1million compared to $1.6 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 debt 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.

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 June 30, 2004, we have made payments totaling $2.4 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 $4.0 million, payable in 2004.

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 June 30, 2004, we had an accumulated deficit of approximately $245.4 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 June 30, 2004 was $257.9 million. 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. The European Patent Office has scheduled oral hearings for February 2005.

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 affirming the Opposition Board's earlier decision. We appealed this decision to the Tokyo High Court. A hearing was held in April 2003, and the Tokyo High Court recently notified us that the Opposition Board's decision was upheld. We have appealed this decision 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. 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 claim scope 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. An Oral Hearing is scheduled to take place in January 2005. 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.

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.

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 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 2004, we announced that daclizumab, our humanized antibody that binds to the interleukin-2 (IL-2) receptor, did not meet the primary endpoint in a Phase II clinical trial in patients with moderate-to-severe ulcerative colitis. As a result, we terminated further development of daclizumab in this indication. Further development of daclizumab in asthma is ongoing.

Early 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, the daclizumab Phase II clinical trials in moderate-to-severe ulcerative colitis, which did not meet the primary endpoint in May 2004, were based on earlier Phase I physician-sponsored clinical trials that indicated safety and biological activity for a small number of patients in this indication.

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.

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.

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 result in our being unable to successfully achieve our projected development timelines, or potentially even 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 (daclizumab). 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 manufacturing capabilities. Our current plans are to validate and use our new manufacturing plant in Brooklyn Park, Minnesota in order to manufacture initial commercial supplies of Nuvion and daclizumab. 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, as we implement construction and validation of our new Brooklyn Park, Minnesota manufacturing facility, we are implementing an enterprise resource management software platform to support the operations of the Company, including our new manufacturing facility. These efforts will involve substantial costs and resource commitments. Any construction, validation 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. 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
- 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 June 30, 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 six months ended June 30, 2004 and 2003, there was no material currency exchange impact on our Consolidated Condensed Statements of Operations from our intercompany transactions. As of June 30, 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 June 30, 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 reporting during the quarter ended June 30, 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company's 2004 Annual Meeting of Stockholders was held on June 30, 2004 at the Company's principal offices in Fremont, California. Of the 94,472,181 shares of common stock outstanding as of the record date, 81,289,398 shares were present at the meeting or represented by proxy, representing approximately 86% of the total votes eligible to be cast.

At the meeting, the stockholders voted to re-elect the Class II members of the Company's Board of Directors as follows:

Nominee	For	Withheld

Laurence Jay Korn, Ph.D.	77,486,040	3,803,358
Max Link, Ph.D.	74,299,494	6,989,904

Additionally, the stockholders did not approve a proposal for the 2004 Equity Incentive Plan, as follows:

For	Against
13,055,874	53,089,681

Finally, the stockholders voted to ratify the appointment of Ernst & Young LLP as the Company's independent auditors for the fiscal year ending December 31, 2004 as follows:

For	Against
80,692,767	596,631

ITEM 5. OTHER INFORMATION

Our Trading Compliance Policy allows stock trading plans pursuant to Rule 10b5-1 promulgated under the Securities Exchange Act of 1934 ("Rule 10b5-1). Rule 10b5-1 trading plans specify the trading period, the number of shares of common stock to be sold, and prices and conditions under which shares held by directors, officers and employees may be sold. Under the trading plan, an independent broker will execute the trades pursuant to specific selling instruction provided by the relevant individual at the time the plan was established. During the quarter ended June 30, 2004, all of our executive officers and two directors adopted trading plans ranging in duration from a minimum of one year up to three years.

Under his trading plan, Mark McDade, Chief Executive Officer and director, may sell up to an aggregate of 400,000 shares, but in any event no more than 100,000 shares per year, which are acquirable under stock option grants, through December 2007. Dr. Laurence Jay Korn, a director, may sell up to an aggregate of 540,000 shares, which shares principally are acquirable under stock option grants, through the period ending on April 2005. Dr. Cary Queen, a director, may sell up to an aggregate of 95,000 shares, which shares principally are acquirable under stock option grants, through December 2007.

We believe that additional directors and officers may establish trading plans under Rule 10b5-1. We do not undertake any obligation to update or revise our disclosure regarding plans currently in effect or to identify other individuals who may enter into trading plans under Rule 10b5-1 in the future.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

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 or furnished on Form 8-K during the quarter ended June 30, 2004.

On May 6, 2004, Protein Design Labs, Inc. (the "Company") announced its financial results for the fiscal quarter ended March 31, 2004.

SIGNATURES

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

Dated: August 9, 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)

EXHIBIT 31.1

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: August 9, 2004

/s/ Mark McDade

Mark McDade
Chief Executive Officer

EXHIBIT 31.2

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: August 9, 2004

/s/ Glen Sato
Glen Sato
Chief Financial Officer

EXHIBIT 32.1

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: August 9, 2004

By:

/s/ Mark McDade
Mark McDade
Chief Executive Officer

/s/ Glen Sato
Glen Sato
Chief Financial Officer