

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 2003

OR

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

Commission File Number: 0-19756



PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

94-3023969  
(I.R.S. Employer  
Identification Number)

34801 Campus Drive  
Fremont, CA 94555  
(Address of principal executive offices)  
Telephone Number (510) 574-1400

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and, (2) has been subject to such filing requirements for the past 90 days:

Yes ☒

No ☐

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

As of April 30, 2003 there were 93,345,184 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)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
<i>(In thousands, except per share data)</i>	<b>2003</b>	<b>2002</b>
Revenues:		
Royalties	\$ 17,145	\$ 13,676
License and other	5,602	651
Total revenues	<u>22,747</u>	<u>14,327</u>
Costs and expenses:		
Research and development	16,392	13,178
General and administrative	5,070	4,155
Total costs and expenses	<u>21,462</u>	<u>17,333</u>
Operating income (loss)	<u>1,285</u>	<u>(3,006)</u>
Interest income	4,672	7,138
Interest expense	(1,706)	(2,240)
Impairment loss on investment	(150)	--
Income before income taxes	<u>4,101</u>	<u>1,892</u>
Provision for income taxes	32	11
Net income	<u><u>\$ 4,069</u></u>	<u><u>\$ 1,881</u></u>
Net income per share:		
Basic	<u><u>\$ 0.05</u></u>	<u><u>\$ 0.02</u></u>
Diluted	<u><u>\$ 0.05</u></u>	<u><u>\$ 0.02</u></u>
Weighted average number of shares:		
Basic	<u>89,182</u>	<u>88,645</u>
Diluted	<u><u>90,150</u></u>	<u><u>91,750</u></u>

See accompanying notes

PROTEIN DESIGN LABS, INC.  
CONSOLIDATED CONDENSED BALANCE SHEETS  
(unaudited)

<i>(In thousands, except per share data)</i>	<b>March 31, 2003</b>	<b>December 31, 2002</b>
	<hr/>	<hr/>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 356,619	\$ 287,730
Marketable securities	235,599	318,680
Other current assets	6,784	7,432
Total current assets	<hr/> 599,002	<hr/> 613,842
Property, plant and equipment, net	86,988	70,802
Other assets	2,688	3,174
Convertible note receivable	30,000	30,000
Total assets	<hr/> <hr/> \$ 718,678	<hr/> <hr/> \$ 717,818
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,211	\$ 1,628
Accrued compensation	2,022	2,520
Accrued clinical trial costs	2,055	2,327
Accrued interest	1,008	3,071
Other accrued liabilities	5,292	4,576
Deferred revenue	--	38
Current portion of other long-term debt	474	466
Total current liabilities	<hr/> 13,062	<hr/> 14,626
Convertible subordinated notes	150,000	150,000
Other long-term debt	8,303	8,426
Total liabilities	<hr/> 171,365	<hr/> 173,052
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; 89,184 and 89,179 shares issued and outstanding at March 31, 2003 and December 31, 2002, respectively	892	892
Additional paid-in capital	628,319	628,292
Accumulated deficit	(86,408)	(90,477)
Accumulated other comprehensive income	4,510	6,059
Total stockholders' equity	<hr/> 547,313	<hr/> 544,766
Total liabilities and stockholders' equity	<hr/> <hr/> \$ 718,678	<hr/> <hr/> \$ 717,818

See accompanying notes

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

	Three Months Ended	
	March 31,	
	2003	2002
<i>(In thousands)</i>		
Cash flows from operating activities:		
Net income	\$ 4,069	\$ 1,881
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,423	1,232
Amortization of convertible notes offering costs	180	180
Impairment loss on investment	150	--
Changes in assets and liabilities:		
Interest receivable	1,549	2,468
Other current assets	648	(1,273)
Other assets	156	(246)
Accounts payable	583	846
Accrued liabilities	(2,117)	(4,214)
Deferred revenue	(38)	--
Total adjustments	2,534	(1,007)
Net cash provided by operating activities	6,603	874
Cash flows from investing activities:		
Purchases of marketable securities	(30,084)	(19,954)
Maturities of marketable securities	110,000	140,000
Purchases of land, property, plant and equipment	(17,542)	(7,874)
Net cash provided by investing activities	62,374	112,172
Cash flows from financing activities:		
Proceeds from issuance of capital stock, net of issuance costs	27	1,055
Payments on other long-term debt	(115)	(107)
Net cash provided by (used in) financing activities	(88)	948
Net increase in cash and cash equivalents	68,889	113,994
Cash and cash equivalents at beginning of period	287,730	120,268
Cash and cash equivalents at end of period	\$ 356,619	\$ 234,262
Non-cash investing activities:		
Exchange of assets for third party preferred stock	\$ --	\$ 1,241
Supplemental cash flow data:		
Cash paid during the period for interest	\$ 4,294	\$ 4,302
Cash paid during the period for taxes	\$ 22	\$ 11

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS**  
**March 31, 2003**  
**(unaudited)**

**1. Summary of Significant Accounting Policies**

Organization and Business

Protein Design Labs, Inc. (PDL) is a biotechnology company engaged in the development of humanized antibodies to prevent or treat various disease conditions. Our key areas of disease focus include oncology, inflammatory and autoimmune diseases.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The accompanying 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 accompanying financial statements should be read in conjunction with our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2002. The Consolidated Balance Sheet as of December 31, 2002 is derived from our audited consolidated financial statements. Results for any interim period are not necessarily indicative of results for any other interim period or for the entire year. For example, we receive royalty revenues on sales of the product Synagis. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters.

Reclassifications

Certain reclassifications of prior year amounts have been made to conform to the current year presentation, including royalty revenue, license and other revenue and interest income.

Net Income (Loss) Per Share

In accordance with Financial Accounting Standards Board Statement No. 128, "Earnings Per Share" (FAS 128), basic and diluted net income (loss) per share amounts have been computed using the weighted average number of shares of common stock outstanding during the periods presented. Calculation of diluted net income (loss) per share also includes the effect of outstanding stock options, if dilutive, but does not include the effect of outstanding convertible notes because the assumed conversion of these notes would be anti-dilutive for the periods presented.

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

	Three Months Ended	
	March 31,	
	2003	2002
<i>(In thousands, except per share data)</i>		
Numerator:		
Net income	\$ 4,069	\$ 1,881
Denominator:		
Basic net income per share -		
weighted-average shares	89,182	88,645
Dilutive potential common shares -		
stock options	968	3,105
Denominator for diluted net income		
per share	90,150	91,750

The total number of shares excluded from the calculations of diluted net income per share for outstanding convertible notes was 3,974,000 in 2003 and 2002. The total number of shares excluded from the calculation of diluted net income per share for stock options was 9,991,000 and 5,553,000 for the periods ended March 31, 2003 and 2002, respectively. Such securities, had they been dilutive, would have been included in the computations of diluted net income per share.

#### Comprehensive Income (Loss)

For the three months ended March 31, 2003, total comprehensive income was \$2.5 million as compared to total comprehensive loss of \$1.7 million for the three months ended March 31, 2002. Total comprehensive income is comprised of net income and unrealized gains and losses on our available-for-sale securities.

#### Stock-Based Compensation

At March 31, 2003, we had six stock-based employee compensation plans. We account for our plans under the recognition and measurement principles of APB Opinion No. 25, "Accounting for Stock Issued to Employees", and related Interpretations. No stock-based employee compensation cost is reflected in net income as all options granted under our plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income and net income per share if we had applied the fair value recognition provisions of FASB Statement No. 123, "Accounting for Stock-Based Compensation", as amended by FAS 148, "Accounting for Stock-Based Compensation – Transition and Disclosure", to stock-based employee compensation.

(In thousands, except per share data)	<b>Three Months Ended March 31,</b>	
	<b><u>2003</u></b>	<b><u>2002</u></b>
Net income, as reported	\$ 4,069	\$ 1,881
Deduct: Total stock-based employee compensation expense determined under the fair value method for all awards, net of related tax effects	<u>(4,028)</u>	<u>(282)</u>
Pro forma net income	<u>\$ 41</u>	<u>\$ 1,599</u>
Net income per share:		
Basic—as reported	<u>\$ 0.05</u>	<u>\$ 0.02</u>
Basic—pro forma	<u>\$ 0.00</u>	<u>\$ 0.02</u>
Diluted—as reported	<u>\$ 0.05</u>	<u>\$ 0.02</u>
Diluted—pro forma	<u>\$ 0.00</u>	<u>\$ 0.02</u>

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in each of the periods ended March 31, 2003 and 2002, respectively: (a) no dividends; (b) expected volatility of 78% and 87%; (c) weighted-average risk-free interest rates of 2.93% and 4.40%; and (d) expected lives of 5 years.

#### 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. Our estimates and assumptions could differ significantly from the amounts which may actually be incurred.

#### Impairment Loss on Investment

In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately held drug discovery company, in exchange for 523,952 shares of Signature convertible preferred stock. The stock received was recorded at the net book value of the assets sold plus transaction costs incurred, which approximated \$1.3 million. In conjunction with this transaction, in December 2002, we accrued an additional \$0.2 million payable to Signature in connection with cash retention bonuses to designated key employees still employed by Signature after one year. Pursuant to the terms of the agreement, in exchange for these bonus payments we received in the first quarter of 2003 an additional 149,701 shares of Signature convertible preferred stock, which was recorded as an increase in the carrying value of the preferred stock. Since the shares we received are not publicly traded, the value of the shares is difficult to estimate. As of December 31, 2002, we estimated that the value of our investment in Signature had declined to \$150,000 and that an impairment of our investment had occurred and that such impairment was other than temporary. Accordingly, we recorded an impairment charge of \$1.4 million in December 2002. As of March 31, 2003, we estimated that our investment in Signature had become fully impaired and that such impairment was other than temporary. Accordingly, we recorded a further impairment charge of \$150,000 in March 2003.



### Recent Accounting Pronouncements

In June 2002, the FASB issued Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (FAS 146), which provides guidance related to accounting for costs associated with disposal activities covered by FAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", or with exit or restructuring activities previously covered by EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." FAS 146 supersedes EITF Issue No. 94-3 in its entirety. FAS 146 requires that costs related to exiting an activity or to a restructuring not be recognized until the liability is incurred. We adopted FAS 146 on January 1, 2003. Our adoption of FAS 146 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. Our adoption of FIN 45 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), "Revenue Arrangements with Multiple Deliverables." EITF 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. EITF 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. Finally, EITF 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting arrangement. The provisions of EITF 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company is currently evaluating the impact that the adoption of EITF 00-21 will have on its financial position and results of operations.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A variable interest entity is a corporation, partnership, trust, or any other structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was

established. Our adoption of FIN 46 did not have a material impact on our results of operations or financial position.

## **2. Subsequent Events**

In early April 2003, we announced that we had completed our acquisition of privately held Eos Biotechnology, Inc. (Eos), a South San Francisco antibody discovery company, in exchange for approximately 4.3 million shares of our common stock (approximately 177,000 of such shares were withheld from Eos shareholders to cover the shareholder tax liabilities incurred in connection with receipt of the shares issued in the acquisition). In connection with the acquisition, we currently anticipate recording a charge of approximately \$39.0 million related to acquired in-process research and development in the second quarter of 2003.

In May 2003, we announced that, based on our analysis of data from a Phase IIa clinical trial of our humanized anti-IL-4 antibody in steroid-naïve, mild/moderate asthma patients, we do not plan to conduct additional clinical studies of the antibody.

Also in May 2003, we announced that Glen Y. Sato was named as our new Senior Vice President and Chief Financial Officer.

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

*This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein 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**

In general, we have a history of operating losses and may not achieve sustained profitability. As of March 31, 2003, we had an accumulated deficit of approximately \$86.4 million. Our expenses will increase because of the extensive resource commitments required to identify and develop antibody candidates, achieve regulatory approval and market potential products for commercial success for any individual product. Over the next several years, we expect to incur substantial additional expenses as we continue to identify, develop and manufacture our potential products, invest in research and improve and expand our development, manufacturing, marketing and sales capabilities.

Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. Although we have had some profitable reporting periods, we do not expect to achieve sustained profitability until we are able to market and sell products.

In February 2003, we announced the signing of a definitive merger agreement with Eos Biotechnology, Inc., a privately held South San Francisco-based antibody discovery company, in exchange for 4.3 million shares of our common stock (approximately 177,000 of such shares were withheld from Eos shareholders to cover the shareholder tax liabilities incurred in connection with receipt of the shares issued in the acquisition). The acquisition closed in April

2003. The Eos acquisition expanded our research personnel and added new capabilities in antibody target identification and validation, particularly in oncology. We also obtained two pre-clinical antibody product candidates, one of which is expected to begin clinical development for potential treatment of solid tumors in the first half of 2003, and the second, for potential treatment of certain ocular indications, by mid-2004. In conjunction with the merger, we currently expect to record a charge of approximately \$39.0 million related to acquired in-process research and development in the second quarter of 2003.

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.

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 marketing efforts of our licensees, potential reductions in royalties payable to us due to credits for prior payments to us, the timing of royalty reports, some of which are required quarterly and others semi-annually, our method of accounting for royalty revenues from our licensees in the period reported to us, and our ability to successfully defend and enforce our patents. We receive royalty revenues on sales of the product Synagis. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters. We expect the seasonality of Synagis sales to contribute to future fluctuation of our royalty revenues from quarter to quarter.

License and other revenue may also be unpredictable and may fluctuate due to the timing of payments of upfront fees, payments for manufacturing and clinical development services and payments for the achievement of milestones under new and existing collaborative, humanization, and patent licensing agreements. Revenue historically recognized under our prior agreements may not be an indicator of revenue from any future collaborations.

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

#### CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

We believe there have been no significant changes in our critical accounting policies during the three months ended March 31, 2003 as compared to what was previously disclosed in our Annual

Report on Form 10-K for the year ended December 31, 2002 filed with the Securities and Exchange Commission on March 31, 2003.

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 humanization of antibodies for use in drug development and production. Revenues, and their respective treatment for financial reporting purposes, are as follows:

### *Upfront and License Maintenance Fees*

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

- Under patent license agreements, the licensee typically obtains a non-exclusive license to 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.
- Under patent rights agreements, licensees currently purchase a research patent license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. All of the research is performed by the licensee, and therefore, upon delivery of the patent rights agreement, the earnings process is complete and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses. Subsequent to execution of the agreement, the licensee has the right to purchase patent licenses to certain designated targets, for which the licensee pays separate consideration at a later date. Such consideration is recognized upon exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.
- Under our humanization agreements, at times referred to in our previous filings as research and development agreements, the licensee typically pays an upfront fee for us to “humanize” an antibody. These upfront fees are recognized on a percent completion basis, 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.

### *Milestone Payments*

Certain agreements include milestone payments which are recognized as revenue when earned as part of a multi-element arrangement. Each element of the contract represents a separate earnings process and as such we recognize milestone amounts 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. 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 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. We recognize these milestones when we have no further performance obligations with respect to that milestone and the funding party confirms that the milestone stipulated in the agreement has been met.
- Patent license agreements and humanization agreements sometimes require our customers to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the customer's product. Because we have no obligations with respect to any of this activity, we record these milestone payments as revenue when received and we have confirmed that the milestone has been achieved.
- 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 we or they achieve certain levels of development with respect to the licensed technology. These fees are recognized when we have no further performance obligations with respect to the applicable milestone and it is confirmed that the milestone stipulated in the agreement has been met.

### *Royalties*

Under some of our agreements, we also 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 have adopted an accounting policy of recording the royalty revenue in the quarter it is reported to us (i.e., generally revenue is recognized one quarter following the quarter in which sales occurred). We receive royalty revenues on sales of the product Synagis. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters. The seasonality of Synagis sales could contribute to future fluctuation of our royalty revenues from quarter to quarter.

## **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, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the patient's continued participation in the trial. 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. Our estimates and assumptions could differ significantly from the amounts which may actually be incurred.

## **Valuation of Financial Instruments**

We invest our excess cash balances primarily in short-term and long-term marketable debt securities. These securities are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Estimated fair value is based upon quoted market prices for these or similar instruments. All available-for-sale securities in our portfolio have readily determinable market prices.

In determining if and when a decline in market value below amortized cost is other than temporary, we evaluate the market conditions, offering prices, trends of earnings, price multiples, and other key measures for our investments in marketable debt securities. If such a decline in value is deemed to be other-than-temporary, we recognize an impairment loss in the current period operating results to the extent of the decline.

Historically, we have not recognized any impairment losses on our available-for-sale securities, nor have we realized gains or losses on the sale of available-for-sale securities, as all securities liquidated have been held to maturity.

## **Cost Method Investments**

In determining if and when a cost method investment's decline in estimated fair value below cost is other-than-temporary, we evaluate the general market conditions, the operating results and business prospects of our investees, and other key considerations. When such a decline in value is deemed to be other-than-temporary, we recognize an impairment loss on the investment in the current period operating results to the extent of the decline.

## **RESULTS OF OPERATIONS**

### ***Three Months Ended March 31, 2003 and 2002***

(In thousands)	<b>Three Months Ended March 31,</b>		
	<b><u>2003</u></b>	<b><u>2002</u></b>	<b><u>% Change</u></b>
Royalties	\$17,145	\$13,676	25%
License and other	<u>5,602</u>	<u>651</u>	761%
Total Revenues	<u>\$22,747</u>	<u>\$14,327</u>	59%

### **Royalties**

Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth were \$17.1 million in the first quarter of 2003, a 25% increase compared to \$13.7 million in the comparable period in 2002. The increase in 2003 was primarily due to higher third-party sales of Synagis reported by MedImmune and Herceptin reported by Genentech. Royalty payments from sales of Synagis and Herceptin accounted for 57% and 33% of our revenues for the three months ended March 31, 2003 as compared to 58% and 32% in the comparable period in 2002. We expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of Synagis.

### **License and Other Revenues**

License and other revenue was \$5.6 million in the first quarter of 2003, a 761% increase compared to \$0.7 million in the comparable period in 2002. License and other revenue recognized in the first quarter of 2003 primarily consists of an upfront licensing fee for certain development rights to our SMART M195 antibody conjugated to alpha-emitting radioisotopes, a milestone payment associated with a product licensing agreement and license maintenance fees. License and other revenue in the first quarter of 2002 primarily consisted of license maintenance fees.

(In thousands)	<b>Three Months Ended March 31,</b>		
	<b><u>2003</u></b>	<b><u>2002</u></b>	<b><u>% Change</u></b>
<b>Costs and Expenses</b>			
Research and development	\$16,392	\$13,178	24%
General and administrative	<u>5,070</u>	<u>4,155</u>	22%
Total costs and expenses	<u>\$21,462</u>	<u>\$17,333</u>	24%

### **Research and Development Expenses**

Research and development expenses for the three months ended March 31, 2003 increased to \$16.4 million, a 24% increase compared to \$13.2 million in the year-earlier quarter. Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. The increase in the first quarter of 2003 was primarily due to an increase in research and development personnel headcount of approximately 59 employees and associated costs of approximately \$1.9 million, higher clinical development expenses for our major research and development projects of approximately \$1.0 million and an increase in facility-related costs of \$0.3 million. We expect our research and development expenses will increase further as we integrate personnel and



operations from the Eos acquisition and 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. The information in the column labeled “Estimated Completion of Current Phase” is only our 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. 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 our collaborations are not successful, we may not be able to effectively develop and market some of our products,” “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 below. For further information on our products refer to our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2002.

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of	Three Months Ended	
				Current Phase	March 31,	
					2003	2002
<u>Current Product Candidates</u>					(In thousands)	
Daclizumab					\$ 2,898	\$ 1,879
	Asthma	Phase II	--	2004		
	Ulcerative Colitis	Phase II	--	2004		
HuZAF					4,474	2,301
	Crohn's Disease	Phase II		2004		
	Psoriasis	Phase I/II		2003		
Nuvion					1,736	636
	Steroid Refractory Graft Vs. Host Disease	Phase II		2004		
	Ulcerative Colitis	Phase I		2003		
<u>Out-license Candidates and Other</u>						
Anti-IL-4	Asthma	Phase IIa	GlaxoSmithKline	Completed (1)	724	787
Anti-IL-12	Autoimmune Diseases	Phase I		Completed (2)	118	809
Remitogen					144	859
	Non-Hodgkin's B-Cell Lymphoma	Phase II		Completed (3)		
	Solid Tumors	Phase I		2003		
Zamy1 (SMART M195)	Acute Myeloid Leukemia	Phase III		Completed (4)	121	1,506
Other (5)					<u>6,177</u>	<u>4,401</u>
	Total Research and Development Costs				\$ <u>16,392</u>	\$ <u>13,178</u>

- (1) Further development of this product is not currently expected.
- (2) Product returned to a preclinical status while further research is conducted.
- (3) Further development of this product is not currently expected.
- (4) Product candidate is available for out-license. No further internal development of this product is currently expected.
- (5) No single potential product included in "other" constitutes more than 5% of the total research and development costs for the specified period.

The overall completion dates or total costs incurred during the period presented for our major research and development programs are estimates based on current information. 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 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. These risks and uncertainties make reliably estimating overall completion dates and total costs incurred during the period presented highly speculative. For additional discussion of factors affecting overall completion dates and total costs, see the "Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we cannot accurately predict the timing and level of such expenses" section of our Risk Factors below.

### General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2003 increased to \$5.1 million, a 22% increase compared to \$4.2 million in the comparable period in 2002. 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. The \$0.9 million increase in general and administrative expenses for the three months ended March 31, 2003 as compared to the 2002 period was primarily due to increased personnel and recruiting costs and legal costs related to our intellectual property, licensing and other contractual matters. We expect that general and administrative expenses will continue to increase as we continue to build our organization.

(In thousands)	Three Months Ended March 31,		<u>% Change</u>
	<u>2003</u>	<u>2002</u>	
<b>Interest Income, Interest Expense and Investment Impairment</b>			
Interest income	\$4,672	\$7,138	(35%)
Interest expense	(1,706)	(2,240)	(24%)
Impairment loss on investment	(150)	--	100%

## **Interest Income and Expense**

Interest income for the three months ended March 31, 2003 decreased due to the reduced interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates and to a lesser extent, lower invested balances.

Interest expense for the three months ended March 31, 2003 decreased as a result of capitalizing \$0.5 million of our interest cost in connection with the renovation of our existing manufacturing facilities and the development activities for our future manufacturing facilities.

## **Impairment Loss on Investment**

In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately held drug discovery company, in exchange for 523,952 shares of Signature convertible preferred stock. The stock received was recorded at the net book value of the assets sold plus transaction costs incurred, which approximated \$1.3 million. In conjunction with this transaction, in December 2002, we accrued an additional \$0.2 million payable to Signature in connection with cash retention bonuses to designated key employees still employed by Signature after one year. Pursuant to the terms of the agreement, in exchange for these bonus payments we received in the first quarter of 2003 an additional 149,701 shares of Signature convertible preferred stock, which was recorded as an increase in the carrying value of the preferred stock. Since the shares we received are not publicly traded, the value of the shares is difficult to estimate. As of December 31, 2002, we estimated that the value of our investment in Signature had declined to \$150,000 and that an impairment of our investment had occurred and that such impairment was other than temporary. Accordingly, we recorded an impairment charge of \$1.4 million in December 2002. As of March 31, 2003, we estimated that our investment in Signature had become fully impaired and that such impairment was other than temporary. Accordingly, we recorded a further impairment charge of \$150,000 in March 2003.

## **Income Taxes**

We have recorded a tax provision of approximately \$32,000 for the three months ended March 31, 2003 primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee, compared to \$11,000 for the comparable period in 2002. We do not expect to record any tax provision for federal income taxes based upon our projected tax loss for fiscal 2003.

## **LIQUIDITY AND CAPITAL RESOURCES**

To date, we have financed our operations primarily through public and private placements of equity and debt securities, revenue under agreements with third parties and interest income on invested capital. At March 31, 2003, we had cash, cash equivalents and marketable securities in the aggregate of \$592.2 million, compared to \$606.4 million at December 31, 2002.

Net cash provided by operating activities for the three months ended March 31, 2003 and 2002 was approximately \$6.6 million and \$0.9 million, respectively. The change in the 2003 period was primarily due to an increase in net income for the three months ended March 31, 2003 and a smaller decrease in accrued liabilities.

Net cash provided by investing activities for the three months ended March 31, 2003 was \$62.4 million compared to \$112.2 million in the comparable period in 2002. The change in the 2003

period was primarily the result of decreased maturities of marketable securities and increased purchases of marketable securities and property, plant and equipment. Capital expenditures in 2003 were primarily related to the development and construction activities for our manufacturing facility in Brooklyn Park, Minnesota. Capital expenditures in the 2002 period primarily consisted of land and equipment purchases and renovation of our Plymouth, Minnesota manufacturing facility.

Net cash used in financing activities for the three months ended March 31, 2003 was \$0.1 million compared to net cash provided by financing activities of \$0.9 million in the comparable period in 2002. The change in 2003 from 2002 was primarily the result of a decrease in the exercise of stock options.

We estimate that our existing capital resources will be sufficient to fund our current level of operations for at least the next few 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, 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.

In Fremont, California; Menlo Park, California; Somerville, New Jersey; Plymouth, Minnesota and Paris, France, we occupy leased facilities under agreements that expire in 2006, 2005, 2005, 2009 and 2004, respectively. We also have leased certain office equipment under operating leases.

In September 1999, Fremont Holding L.L.C. (our wholly owned subsidiary) obtained a \$10.2 million term loan to purchase our Fremont, California facilities. The loan bears interest at the rate of 7.64% per year amortized over 15 years with principal and interest payable monthly. The loan is secured by our Fremont, California facilities and is subject to the terms and covenants of the loan agreement.

In February 2000, we issued 5.50% Convertible Subordinated Notes due February 15, 2007 with a principal amount of \$150 million (the Convertible Notes). The Convertible Notes are convertible at the holders' option into our common stock at a conversion price of \$37.75 per share, subject to adjustment as a result of certain events. Interest on the Convertible Notes is payable semiannually in arrears on February 15 and August 15 of each year. The Convertible Notes are unsecured and are subordinated to all our existing and future Senior Indebtedness (as defined in the indenture relating to the Convertible Notes). The Convertible Notes may be

redeemed at our option, in whole or in part, beginning on February 15, 2003 at the redemption prices set forth in the Convertible Notes indenture.

In May 2001, we signed a collaborative agreement with Exelixis, Inc. to discover and develop humanized antibodies for the diagnosis, prevention and treatment of cancer. We agreed to provide Exelixis with \$4.0 million in annual research funding through June 1, 2003, and we purchased a \$30.0 million five-year note, convertible at our option after the first year of the collaboration into Exelixis common stock. The research funding period will end in June 2003. During the funding period, Exelixis performs certain genetic screens and other research activities intended to identify and validate targets for antibody therapeutics in oncology. We received an exclusive, worldwide license to develop antibodies against certain targets identified by Exelixis that are involved in cell growth, cell death and proliferation. Exelixis has the right to co-fund development of antibodies resulting from the collaboration. Therefore, we recognize the expense of research funding ratably over the periods for which it was performed. For antibody products we develop that Exelixis elects not to co-fund, we have agreed to make specified milestone payments and royalty payments on any product sales.

In connection with the construction of our new commercial manufacturing facility in Brooklyn Park, Minnesota, we have entered into, and will continue to enter into, agreements with third parties for the design and construction of the facility. In July 2002, we engaged Fluor Daniel (a division of Fluor Enterprises) to handle the engineering and certain procurement services for the new facility. Under that agreement, we will owe an aggregate of approximately \$13.6 million to be paid in 2003 and 2004. The design and project management work to be completed under this agreement is scheduled for completion in the third quarter of 2003 and the construction support work is scheduled to be completed by the third quarter of 2004. In addition, we have entered into various commitments related to the manufacturing equipment required for the new facility of approximately \$21.7 million, which is to be paid in 2003. In May 2003, we signed agreements with McGough Construction for the construction management and certain construction services for the facility. Under those agreements, we will owe an estimated aggregate of approximately \$93.0 million to be paid in 2003 and 2004. The facility construction is scheduled to be completed in 2004.

Our material contractual obligations under lease, debt and construction agreements for the next five years, and thereafter, as of March 31, 2003 are as follows:

	PAYMENTS DUE BY PERIOD				
	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years	Total
<i>(In thousands)</i>					
CONTRACTUAL OBLIGATIONS (1)					
Operating leases (2)	\$ 4,986	\$ 3,170	\$ 1,621	\$ 702	\$ 10,479
Long-term debt	1,139	2,278	2,278	7,718	13,413
Convertible debentures	8,250	16,500	158,250	--	183,000
Construction contracts	74,450	32,079	--	--	106,529
Total contractual cash obligations	<u>\$ 88,825</u>	<u>\$ 54,027</u>	<u>\$ 162,149</u>	<u>\$ 8,420</u>	<u>\$ 313,421</u>

- (1) This table does not include (a) any milestone payments from us to third parties which may become payable under research collaborations or license agreements as the timing and likelihood of such payments are not known, (b) any royalty payments from us to third parties as the amounts

of such payments and / or likelihood of such payments are not known and (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

- (2) Includes lease obligations associated with the acquisition of Eos Biotechnology, Inc. subsequent to March 31, 2003.

## **RISK FACTORS**

*This Quarterly Report contains, in addition to historical information, forward-looking statements which involve risks and uncertainties. Our actual results may differ significantly from the results discussed in forward-looking statements. Factors that may cause such a difference include those discussed in the material set forth below and elsewhere in this document. Additional risks and uncertainties not presently known to us or that we currently see as immaterial may also impair our business. If any of these risks actually occurs, it could materially harm our business, financial condition or operating results.*

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

In general, our expenses have exceeded revenues. As of March 31, 2003, we had an accumulated deficit of approximately \$86.4 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 invest in additional manufacturing capacity
- 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.

### **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 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
- 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 could 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. In May 2002, we entered into an agreement with our Chairman of the Board under which vesting of his stock options may accelerate in certain events, and such acceleration would trigger an accounting expense.

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 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.

**Our humanization patents are being opposed and a successful challenge could limit our future revenues.**

Most of our current revenues are related to our humanization patents. 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 have appealed this decision. Until our appeal 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 our appeal is unsuccessful, 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, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, the Opposition Division's decision could encourage challenges of 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 appeals process with respect to our first European patent, if we were to commence an infringement action to enforce that patent, such an action would likely be stayed until the appeal 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. Eight notices of opposition have been filed with respect to our second European antibody humanization patent and we have filed our response with the European Patent Office. Oral hearings are scheduled to take place in October 2003. Also, three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a final determination from the Japanese Patent Office examiner affirming the Opposition Board's earlier decision. We have appealed this decision to the Tokyo High Court. The patent will remain valid and enforceable during this appeal process. If this appeal is unsuccessful, we will then have an opportunity to appeal to the Japanese Supreme Court.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings; however, we may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If our appeal with respect to our first European patent is unsuccessful or if the outcome of the other 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.

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



Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology.

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents. For example, BTG International Limited (successor in interest to the Medical Research Council) recently has been issued a U.S. patent, to which we have a license, with claims that might be construed to overlap with our issued humanization patents. While the significance of this new U.S. patent is unclear, if it conflicts with our U.S. patents or patent applications, we may become involved in patent office or legal proceedings to determine which company was the first to invent the technology and processes contained in 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.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation which 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 has appealed that decision. Also, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. In addition, Celltech has a third divisional application currently drafted with broad claims directed towards humanized antibodies. We

cannot predict whether Celltech will be able to successfully appeal the decision of the Opposition Division with respect to their first European patent or 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. 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. Nevertheless, if our humanized antibodies were covered by Celltech's European or U.S. patents and if we were to need more than the three licenses under those patents currently available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

In addition, if the Celltech U.S. patent or any related patent applications conflict with our U.S. patents or patent applications, we may become involved in proceedings to determine which company was the first to invent the products or processes contained in the conflicting patents. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of our patents. Any limitation would reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

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

We are also aware of issued patents that could apply to one or more of our specific products. For example, a U.S. patent recently issued to Advanced Biotherapy, Inc. has claims to the use of anti-gamma interferon antibodies to treat certain autoimmune diseases. The claims issued to Advanced Biotherapy, Inc., however, do not cover treatment of either Crohn's disease or psoriasis, the two indications currently being investigated in our HuZAF (Anti-Gamma Interferon Antibody) clinical trials. However, a European patent issued to Genentech in 1998 and a U.S. patent issued in 2003 do have claims to the use of anti-gamma interferon inhibitors, including antibodies, for treatment of inflammatory bowel disease, including Crohn's disease. Additional examples include issued U.S. and European patents to Genetics Institute (now a wholly-owned subsidiary of Wyeth) that may cover our anti-IL-12 antibody, and a recently issued U.S. patent to Genentech claiming humanized antibodies with certain framework region substitutions that may cover some of our antibodies in development. As a result, we might be required to obtain licenses from others. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or we may not be able to market our products at all.

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

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

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

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products, and the majority of our expenses are to support these activities. The completion of clinical trials often depends significantly upon the rate of patient enrollment, and our expense levels will vary depending upon the rate of enrollment. In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and is difficult to predict. The expenses associated with each phase of development depend upon the design of the trial. The design of each phase of trials depends in part upon results of prior phases, and additional trials may be needed at each phase. As a result the expense associated with future phases can not be 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 a relatively large number of potential products in clinical development. We may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise. 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.

Earlier clinical trials such as Phase I and II trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As

a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed.

Larger or later stage clinical trials may not produce the same results as earlier trials. Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials. As an example, in a Phase I trial, Remitogen produced partial clinical responses in several B-cell lymphoma patients. Partial, preliminary results in a Phase II trial of Remitogen, however, did not show a similar response rate. Consequently, the dosing regimen was amended in that trial to attempt to determine an effective dosing regimen. However, enrollment with this dosing regimen was progressing slowly. Therefore, in November 2002, we decided to terminate this study and we currently do not intend to conduct further clinical trials 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. For example, while Nuvion has shown biological activity in some patients in a Phase I/II trial for psoriasis, it has also caused a level of side effects that would be unacceptable in this patient population. Enrollment in this trial currently is suspended and our current plan is not to continue this trial and not to further develop Nuvion for psoriasis.

**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 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
- availability of clinical drug supply

- availability of clinical trial sites
- design of the protocol
- proximity of and access by patients to clinical sites
- patient referral practices of physicians
- eligibility criteria for the study in question, and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

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

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

In those instances where we have licensed rights to our technologies, the product development and marketing efforts and successes of our licensees will determine the amount and timing of royalties we may receive, if any. We have no assurance that any licensee will successfully complete the product development, regulatory and marketing efforts required to sell products. The success of products sold by licensees will be affected by competitive products, including potential competing therapies that are marketed by the licensee or others.

**If our collaborations are not successful, we may not be able to effectively develop and market some of our products.**

We have agreements with pharmaceutical and other companies to develop, manufacture and market certain of our potential products. In some cases, we are relying on our partners to manufacture such products, to conduct clinical trials, to compile and analyze the data received from these trials, to obtain regulatory approvals and, if approved, to market these licensed products. As a result, we may have little or no control over the manufacturing, development and marketing of these potential products and little or no opportunity to review clinical data prior to or following public announcement.

Our agreements can generally be terminated by our partners on short notice. A partner may terminate its agreement with us or separately pursue alternative products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by us or our collaborative effort. Even if a partner continues to contribute to the arrangement, it may nevertheless determine not to actively pursue the development or commercialization of any resulting products. In these circumstances, our ability to pursue potential products could be severely limited.

Continued funding and participation by partners will depend on the timely achievement of our research and development objectives, the retention of key personnel performing work under those

agreements and on each partner's own financial, competitive, marketing and strategic considerations. Such considerations include:

- the commitment of each partner's management to the continued development of the licensed products or technology
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts, and
- the relative advantages of alternative products or technology being marketed or developed by each partner or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

Our ability to enter into new relationships and the willingness of our existing partners to continue development of our potential products depends upon, among other things, our patent position with respect to such products. If we are unable to successfully maintain our patents we may be unable to collect royalties on existing licensed products or enter into additional agreements.

**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 either establish a marketing group and direct sales force or obtain the assistance of another company. We may not be able to establish marketing, sales and distribution capabilities 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 retain our qualified clinical, manufacturing, scientific and management personnel. If we are unsuccessful in 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, Hoffmann-La Roche Inc. and its affiliates (Roche) are responsible for manufacturing Zenapax. We are responsible for manufacturing our other products for our own development. 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. We and our collaborative partners 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. For example, in December 1999, Roche received a warning letter from the FDA regarding deficiencies in the manufacture of various products. Although the letter primarily related to products other than Zenapax, Roche has also experienced difficulties in the manufacture of Zenapax leading to interruptions in supply. If future manufacturing difficulties arise and are not corrected in a timely manner, Zenapax supplies could be interrupted, which could cause a delay or termination of our clinical trials of Zenapax in autoimmune disease and could force Roche to withdraw Zenapax from the market temporarily or permanently, resulting in loss of revenue to us. These occurrences could impair our competitive position.

We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture our potential products on a commercial scale. To obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to improve and expand our existing manufacturing capabilities. We are currently improving our existing manufacturing plant in order to manufacture initial commercial supplies of certain products. 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 improve our existing manufacturing plant. We may be unable to do so, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis. Failure to do so could delay commercialization of our products.

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

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

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our SMART antibody technology. 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 we or our collaborative partners 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, has received approval to market Simulect, a product competitive with Zenapax, in the U.S. and Europe. Novartis has acquired a significant interest in Roche. We cannot predict the impact, if any, that this relationship may have on Roche's efforts to market Zenapax.

**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.

For the marketing of pharmaceutical products outside the United States, we and our collaborative partners 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. This 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, 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 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.

**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 may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty for companies such as ours and insurance costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

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

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

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

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

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

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We maintain a non-trading investment portfolio of investment grade, highly liquid, debt securities which limits the amount of credit exposure to any one issue, issuer, or type of instrument. We do not use derivative financial instruments for speculative or trading purposes. We hold a \$30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the value of the Exelixis stock in our financial statements. Such a requirement could cause changes in the Exelixis stock price to contribute to fluctuation of our operating results from quarter to quarter. The securities in our investment portfolio are not leveraged and are classified as available-for-sale and therefore are subject to interest rate risk. We do not currently hedge interest rate exposure. As of March 31, 2003, 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, 2002.

### **ITEM 4. CONTROLS AND PROCEDURES**

(a) Under the supervision and with the participation of our management, including our principal executive officer and principal accounting officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), within 90 days of the filing date of this report. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures are effective.

(b) There have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referenced in paragraph (a) above.

## **PART II. OTHER INFORMATION**

### **ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

#### **(a) Exhibits**

**99.1** 906 Certification for Chief Executive Officer

**99.2** 906 Certification for Principal Accounting Officer

**(b)** No Reports on Form 8-K were filed during the quarter ended March 31, 2003.

## **SIGNATURE**

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

Dated: May 14, 2003

PROTEIN DESIGN LABS, INC.  
(Registrant)

/s/ Mark McDade

Mark McDade  
Chief Executive Officer  
(Principal Executive Officer)

/s/ Robert Kirkman

Robert L. Kirkman  
Vice President, Business  
Development and Corporate  
Communications  
(Principal Accounting Officer)

## CERTIFICATION

I, Mark McDade, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protein Design Labs, Inc.;
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a. Designed such disclosure controls and procedures 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 the periodic reports are being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report ("Evaluation Date"); and
  - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ Mark McDade

Mark McDade

Chief Executive Officer

(Principal Executive Officer)



## CERTIFICATION

I, Robert L. Kirkman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protein Design Labs, Inc.;
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a. Designed such disclosure controls and procedures 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 the periodic reports are being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report ("Evaluation Date"); and
  - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ Robert L. Kirkman  
Robert L. Kirkman  
Vice President, Business  
Development and Corporate  
Communications  
(Principal Accounting Officer)