

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, 1999

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	94-3023969
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	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 ☐

As of March 31, 1999, there were 18,618,825 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Statements of Operations  
Three months ended March 31, 1999 and 1998

Balance Sheets  
March 31, 1999 and December 31, 1998

Statements of Cash Flows  
Three months ended March 31, 1999 and 1998

Notes to Unaudited Financial Statements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT  
MARKET RISK

PART II. OTHER INFORMATION

ITEM 5. OTHER INFORMATION - RISK FACTORS

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

Signatures

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROTEIN DESIGN LABS, INC.

STATEMENTS OF OPERATIONS

(In thousands, except net loss per share data)

(unaudited)

	Three Months Ended March 31,	
	1999	1998
Revenues:		
Revenue under agreements with third parties	\$6,462	\$1,791
Interest and other income	2,373	2,444
Total revenues	8,835	4,235
Costs and expenses:		
Research and development	8,280	6,406
General and administrative	2,445	1,842
Total costs and expenses	10,725	8,248
Net loss	(\$1,890)	(\$4,013)
Net loss per share:		
Basic	(\$0.10)	(\$0.22)
Diluted	(\$0.10)	(\$0.22)
Weighted average number of shares:		
Basic	18,618	18,457
Diluted	18,618	18,457

See accompanying notes

PROTEIN DESIGN LABS, INC.

BALANCE SHEETS

(In thousands, except par value per share)

	March 31, 1999	December 31, 1998
	----- (unaudited)	-----
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$27,352	\$27,907
Short-term investments	14,948	59,233
Other current assets	5,436	4,608
	-----	-----
Total current assets	47,736	91,748
Property and equipment, net	22,931	23,016
Long-term investments	97,961	56,299
Other assets	1,083	787
	-----	-----
	\$169,711	\$171,850
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$1,474	\$1,310
Accrued compensation	989	925
Accrued clinical trials	1,225	1,293
Other accrued liabilities	1,466	3,591
Deferred revenue	4,025	2,235
	-----	-----
Total current liabilities	9,179	9,354
Commitments		
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, 40,000 shares authorized; 18,619 and 18,595 issued and outstanding at March 31, 1999 and December 31, 1998, respectively	186	186
Additional paid-in capital	231,497	231,035
Accumulated deficit	(70,774)	(68,884)
Unrealized gain on investments	(377)	159
	-----	-----
Total stockholders' equity	160,532	162,496
	-----	-----
	\$169,711	\$171,850
	=====	=====

See accompanying notes

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

(In thousands)

	Three Months Ended March 31,	
	1999	1998
Cash flows from operating activities:		
Net loss	(\$1,890)	(\$4,013)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	857	833
Other	185	376
Changes in assets and liabilities:		
Other current assets	(827)	(56)
Accounts payable	164	24
Accrued liabilities	(2,131)	(900)
Deferred revenue	1,791	1,963
Total adjustments	39	2,240
Net cash used in operating activities	(1,851)	(1,773)
Cash flows from investing activities:		
Purchases of short- and long-term investments	(59,500)	(41,979)
Maturities of short- and long-term investments	61,400	57,000
Capital expenditures	(770)	(665)
(Increase) decrease in other assets	(296)	16
Net cash provided by investing activities	834	14,372
Cash flows from financing activities:		
Proceeds from issuance of capital stock	462	2,732
Net cash provided by financing activities	462	2,732
Net increase (decrease) in cash and cash equivalents	(555)	15,331
Cash and cash equivalents at beginning of period	27,907	9,266
Cash and cash equivalents at end of period	\$27,352	\$24,597

See accompanying notes

PROTEIN DESIGN LABS, INC.  
NOTES TO FINANCIAL STATEMENTS  
March 31, 1999  
(unaudited)

Summary of Significant Accounting Policies

Organization and Business

Since the Company's founding in 1986, a primary focus of its operations has been research and development. Achievement of successful research and development and commercialization of products derived from such efforts is subject to high levels of risk and significant resource commitments. The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next few years as it continues to develop its proprietary products, devote significant resources to preclinical studies, clinical trials, and manufacturing and to defend its patents and other proprietary rights. The Company's revenues to date have consisted principally of research and development funding, licensing and signing fees, and milestone payments and royalties from pharmaceutical and biotechnology companies under collaborative research and development, humanization, patent licensing and clinical supply agreements. These revenues may vary considerably from quarter to quarter and from year to year, and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements.

The Company receives royalties on sales of Synagis[™], Herceptin[R] and Zenapax[R]. Royalty revenues from third party sales of these licensed humanized antibodies are subject to the specific terms of each agreement and, under the Company's policy, are recognized by the Company during the quarter such royalties are reported to PDL. This method of revenue recognition may increase fluctuations reported in any particular quarter since the agreements generally provide for royalty reports to the Company following completion of each calendar quarter or semi-annual period. Further, royalty revenues are unpredictable as they are dependent upon numerous factors including the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of the Company's licensees and the rights certain licensees have to partially offset certain previously paid milestones and third party royalties against royalties payable to the Company. In addition, expenses may fluctuate from quarter to quarter due to the timing of certain expenses, including milestone payments that may be payable by the Company under certain licensing arrangements.

Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate continuing to realize non-royalty revenue from its new and proposed collaborations at levels commensurate with the revenue historically recognized under its older collaborations. Moreover, the Company anticipates that it will incur significant operating expenses as the Company increases its research and development, manufacturing, preclinical, clinical, marketing and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under the Company's intellectual property rights, or other sources, the Company expects to incur substantial operating losses in the foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company undertakes marketing and market planning activities, as the Company invests in additional facilities or manufacturing capacity, as the Company defends or prosecutes its patents and patent applications and as the Company invests in research or acquires additional technologies, product candidates or businesses.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The balance sheet as of March 31, 1999 and the statements of operations and cash flows for the three month periods ended March 31, 1999 and 1998 are unaudited but include all adjustments (consisting of normal recurring adjustments) which the Company considers necessary for a fair presentation of the financial position at such dates and the operating

results and cash flows for those periods. Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with generally accepted accounting principles have 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 the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission for the year ended December 31, 1998. Results for any quarterly period are not necessarily indicative of results for any other quarterly period or for the entire year.

#### Cash Equivalents, Investments and Concentration of Credit Risk

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of acquisition to be cash equivalents. The "Other" adjustments line item in the Statements of Cash Flows represents the accretion of the book value of certain debt securities. The Company places its cash and short-term and long-term investments with high-credit-quality financial institutions and in securities of the U.S. government and U.S. government agencies and, by policy, limits the amount of credit exposure in any one financial instrument. To date, the Company has not experienced credit losses on investments in these instruments.

Cash and cash equivalents for the period ended March 31, 1999 increased primarily as a result of maturities of short-term and the redemption of certain long-term investments. The changes in short- and long-term investments were the result of reinvestment of these maturing and redeemed securities into investments with maturities longer than twelve months.

#### Revenue Recognition

Contract revenues from research and development arrangements are recorded as earned based on the performance requirements of the contracts. Revenues from achievement of milestone events are recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met. Deferred revenue arises principally due to timing of cash payments received under research and development contracts.

The Company's collaborative, humanization and patent licensing agreements with third parties provide for the payment of royalties to the Company based on net sales of the licensed product under the agreement. The agreements generally provide for royalty payments to the Company following completion of each calendar quarter or semi-annual period and royalty revenue is recognized when royalty reports are received from the third party. Non-refundable signing and licensing fees under these arrangements are recognized as revenue when there are no future performance obligations remaining with respect to such fees.

#### Net Income Per Share

In accordance with Financial Accounting Standards Board Statement No. 128, "Earnings Per Share" ("FAS 128"), basic net earnings (loss) per share have been computed using the weighted average number of shares of common stock outstanding during the periods presented and excluded the dilutive effect of stock options. If the Company had a net loss position for the applicable period, as is the case for the three month periods ended March 31, 1999 and 1998, FAS 128 specifies that the Company shall not include the effect of stock options outstanding for the applicable period as the effect would be antidilutive.

Following is a reconciliation of the numerators and denominators of the basic and diluted net loss per share computations for the periods presented below:

(In thousands, except basic and diluted net loss per share)

Three Months Ended March 31,	
-----	-----
1999	1998
-----	-----

Numerator:		
Net loss	\$ (1,890)	\$ (4,013)
	=====	=====
Denominator:		
Basic net loss per share -		
weighted-average shares	18,618	18,457
Dilutive potential common shares:		
Stock Options	--	--
	-----	-----
Denominator for diluted net		
loss per share	18,618	18,457
	=====	=====
Basic net loss per share	\$ (0.10)	\$ (0.22)
	=====	=====
Diluted net loss per share	\$ (0.10)	\$ (0.22)
	=====	=====

## Comprehensive Income

In accordance with Financial Accounting Standards Statement No. 130, "Reporting Comprehensive Income," ("FAS 130"), the Company is required to display comprehensive income and its components as part of the Company's complete set of financial statements. The measurement and presentation of net loss did not change. Comprehensive income is comprised of net loss and other comprehensive income. Other comprehensive income includes certain changes in equity of the Company that are excluded from net loss. Specifically, FAS 130 requires unrealized gains and losses on the Company's holdings of available-for-sale securities, which were reported separately in stockholders' equity, to be included in accumulated other comprehensive income. FAS 130 permits the disclosure of this information in notes to interim financial statements and the Company has elected this approach. For the three month periods ended March 31, 1999 and 1998, total comprehensive loss amounted to \$2.4 million and \$4.2 million, respectively.

## Derivative Instruments and Hedging Activities

In June 1998, the Financial Accounting Standards Board issued Statement No. 133 "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"). FAS 133 is not required to be adopted until 2000. However, the Company has reviewed FAS 133 and because it does not use derivatives, the adoption of FAS 133 is not expected to effect the results of operations or the financial position of the Company.

## Management Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, the Company has a policy of recording expenses for clinical trials based upon pro rating estimated total costs of a clinical trial over the estimated length of the clinical trial and the number of patients anticipated to be enrolled in the trial. Expenses related to each patient are recognized ratably beginning upon entry into the trial and over the course of the trial. In the event of early termination of a clinical trial, management accrues an amount based on its estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial. These estimates and assumptions could differ significantly from the amounts which may actually be realized.

In 1997, Boehringer Mannheim GmbH ("Boehringer Mannheim") invoked the dispute resolution provisions under its collaborative research agreement to address the reimbursement of up to \$2.0 million for the Phase II study of Ostavir[™] for the treatment of chronic hepatitis B ("CHB") then being conducted by Boehringer Mannheim as well as certain legal expenses related to Boehringer Mannheim's participation in the Company's public offering in the first quarter of 1997. In March 1998, Roche Holding Ltd acquired Boehringer Mannheim. The Company is unable to predict the outcome of this proceeding but in any event has estimated and recorded a liability with respect to this matter. The collaborative research agreement with Boehringer Mannheim provides for reimbursement from PDL of costs and expenses of up to \$2.0 million for a Phase II study of Ostavir in the event certain conditions are met with respect to that study.



## Other Accrued Liabilities

Other accrued liabilities decreased from December 31, 1998 infor the period ended March 31, 1999 primarily as a result of payments of approximately \$1.3 million for capital expenditures related to the Company's new Fremont, California facilities.

## Deferred Revenue

Deferred revenue increased from December 31, 1998 infor the period ended March 31, 1999 primarily as a result of research and development funding of \$2.4 million received in advance of the performance of the research.

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

This Quarterly Report contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to those discussed in "Risk Factors" as well as those discussed elsewhere in this document and the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission for the year ended December 31, 1998.

### OVERVIEW

Since the Company's founding in 1986, a primary focus of its operations has been research and development. Achievement of successful research and development and commercialization of products derived from such efforts is subject to high levels of risk and significant resource commitments. The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next few years as it continues to develop its proprietary products, devote significant resources to preclinical studies, clinical trials, and manufacturing and to defend its patents and other proprietary rights. The Company's revenues to date have consisted principally of research and development funding, licensing and signing fees, and milestone payments and royalties from pharmaceutical and biotechnology companies under collaborative research and development, humanization, patent licensing and clinical supply agreements. These revenues may vary considerably from quarter to quarter and from year to year, and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements.

The Company receives royalties on sales of Synagis[™], Herceptin[R] and Zenapax[R]. Royalty revenues from third party sales of these licensed humanized antibodies are subject to the specific terms of each agreement and, under the Company's policy, are recognized by the Company during the quarter such royalties are reported to PDL. This method of revenue recognition may increase fluctuations reported in any particular quarter since the agreements generally provide for royalty reports to the Company following completion of each calendar quarter or semi-annual period. Further, royalty revenues are unpredictable as they are dependent upon numerous factors including the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of the Company's licensees and the rights certain licensees have to partially offset certain previously paid milestones and third party royalties against royalties payable to the Company. In addition, expenses may fluctuate from quarter to quarter due to the timing of certain expenses, including milestone payments that may be payable by the Company under certain licensing arrangements.

Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate continuing to realize non-royalty revenue from its new and proposed collaborations at levels commensurate with the revenue historically recognized under its older collaborations. Moreover, the Company anticipates that it will incur significant operating expenses as the Company increases its research and development, manufacturing, preclinical, clinical, marketing and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under the Company's intellectual property rights, or other sources, the Company expects to incur substantial operating losses in the foreseeable future as certain of its earlier

stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in additional facilities or manufacturing capacity, as the Company defends or prosecutes its patents and patent applications and as the Company invests in research or acquires additional technologies, product candidates or businesses.

Contract revenues from research and development are recorded as earned based on the performance requirements of the contracts. Revenues from achievement of milestone events are recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met. Deferred revenue arises principally due to timing of cash payments received under research and development contracts.

## RESULTS OF OPERATIONS

### Three Months Ended March 31, 1999 and 1998

The Company's total revenues for the three months ended March 31, 1999 were \$8.8 million as compared to \$4.2 million in the first quarter of 1998. Total revenues recognized under agreements with third parties were \$6.5 million in the first quarter of 1999 compared to \$1.8 million in the comparable period in 1998. Interest and other income was approximately \$2.4 million in each of the first quarters of 1999 and 1998.

Revenues under agreements with third parties of \$6.5 million for the three months ended March 31, 1999 consisted principally of a \$3.0 million non-refundable, non-creditable signing and licensing fee from BioNet Pharma GmbH ("BioNet") for rights to the SMART[™] Anti-L-Selectin Antibody in Europe, the Middle East and Africa, royalties and research and development reimbursement funding. In the first quarter of 1998, revenues of \$1.8 million under agreements with third parties consisted principally of milestone payments earned under licensing agreements and research and development reimbursement funding.

Total costs and expenses for the three months ended March 31, 1999 increased to \$10.7 million from \$8.2 million in the comparable period in 1998. The increase in costs and expenses was primarily due to the addition of staff in the Company's pharmaceutical research and development programs, administrative functions and associated expenses to manage and support the Company's expanding operations.

Research and development expenses for the three month period ended March 31, 1999 increased to \$8.3 million from \$6.4 million in the comparable period in 1998. The increase in costs was primarily due to the addition of staff, the continuation of clinical trials, costs of conducting preclinical tests and expansion of research and pharmaceutical development capabilities, including support for both clinical development and manufacturing process development.

General and administrative expenses for the three months ended March 31, 1999 increased to \$2.4 million from \$1.8 million in the comparable period in 1998. These increases were primarily the result of increased staffing and associated expenses to manage and support the Company's expanding operations and payments of third party royalties due on sales of Zenapax.

## LIQUIDITY AND CAPITAL RESOURCES

To date, the Company has financed its operations primarily through public and private placements of equity securities, research and development revenues and interest income on invested capital. At March 31, 1999, the Company had cash, cash equivalents and investments in the aggregate of \$140.3 million, compared to \$143.4 million at December 31, 1998. Cash and cash equivalents and investments for the period do not include the \$3.0 million non-refundable, non-creditable signing and licensing fee from BioNet received in May 1999.

In 1997, Boehringer Mannheim GmbH ("Boehringer Mannheim") invoked the dispute resolution provisions under its collaborative research agreement with the Company to address the reimbursement of up to \$2.0 million for the Phase II study of Ostavir for the treatment of chronic hepatitis B ("CHB") then being conducted by Boehringer Mannheim as well as certain legal expenses related to Boehringer Mannheim's participation in the Company's public offering in the first quarter of 1997. In March 1998, Roche Holding Ltd acquired Boehringer Mannheim. The Company is unable to predict the outcome of this proceeding but in any event has estimated and recorded a liability with respect to this matter. The collaborative research agreement with Boehringer Mannheim provides for

reimbursement from PDL of costs and expenses of up to \$2.0 million for a Phase II study of Ostavir in the event certain conditions are met with respect to that study.

As set forth in the Statements of Cash Flows, net cash used in operating activities was \$1.9 million for the three months ended March 31, 1999 compared to \$1.8 million in the same period in 1998.

As set forth in the Statements of Cash Flows, net cash provided by investing activities for the three months ended March 31, 1999 was \$0.8 million. Net Cash provided by investing activities for the comparable period in 1998 was \$14.3 million resulting primarily from the maturities of short- and long-term investments.

As set forth in the Statements of Cash Flows, net cash provided by financing activities for each of the three months ended March 31, 1999 and 1998 was \$0.5 million and \$2.7 million, respectively, in each period resulting primarily from the exercise of outstanding stock options. Net cash provided by financing activities for the comparable period in 1998 was \$2.7 million. The 1998 amount resulted primarily from exercise of outstanding stock options.

The Company's future capital requirements will depend on numerous factors, including, among others, royalties from sales of products of third party licensees, including Synagis, Herceptin and Zenapax; the ability of the Company to enter into additional collaborative, humanization and patent licensing arrangements; the progress of the Company's product candidates in clinical trials; the ability of the Company's licensees to obtain regulatory approval and successfully manufacture and market products licensed under the Company's patents; the continued or additional support by collaborative partners or other third parties of research and development efforts and clinical trials; enhancement of existing and investment in new research and development programs; the time required to gain regulatory approvals; the resources the Company devotes to self-funded products, manufacturing facilities and methods and advanced technologies; the ability of the Company to obtain and retain funding from third parties under collaborative arrangements; the continued development of internal marketing and sales capabilities; the demand for the Company's potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by the Company; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect the Company's proprietary technology. In order to develop and commercialize its potential products the Company 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. The Company believes that existing capital resources will be adequate to satisfy its capital needs through at least 2001.

#### YEAR 2000 COMPLIANCE

As is true for most companies, the ability of the Company's systems and equipment as well as those of its key suppliers to address the Year 2000 ("Y2K") issue presents a potential risk for the Company. If systems software and/or equipment containing embedded software or controllers do not correctly recognize date information when the year changes to 2000, there could be an adverse impact on the Company's operations. The risk for the Company exists in two areas: systems used by the Company to run its business and systems used by the Company's suppliers. The Company is currently evaluating its exposure in these two areas. The Company has also reviewed, but views as a much less significant risk, claims related to potential warranty or other claims from its collaborative research customers.

Based on a preliminary assessment by an outside consultant retained by the Company in early 1998, the Company believes that its most important information systems are Y2K-compliant; however, the Company is in the process of conducting a comprehensive inventory and evaluation of its systems, equipment and facilities. In connection with its recent move to a new headquarters and research and development facility in Fremont, California, the Company has replaced or upgraded many of its systems and equipment that were known or believed to present potential Y2K problems. In addition, the Company specifically identified and contacted certain key vendors regarding Y2K compliance of its key information systems and has either received software upgrades or assurances that Y2K-compliant software will be made available in a manner designed for the Company to timely address the Y2K issue with respect to these systems.

The Company has retained this consultant to develop and implement a Y2K program, which retention includes the development of a more extensive inventory and assessment program for the Company with respect to Y2K risks. The consultant has expertise in assessing other organizations with similar vendors and computer systems. This program will include a comprehensive review of all major systems and equipment of the Company and will also include a contingency plan for any mission critical systems that may be identified as potential Y2K problems.

The Company has established a Y2K committee with responsibility for coordinating awareness and identifying potential Y2K risk areas within the Company. As part of its comprehensive review of potentially affected systems, equipment and facilities, the Company is also reviewing controllers used to perform key functions in its manufacturing facility in Plymouth, Minnesota. At this time, the Company has not reviewed all systems and processes for potential Y2K problems nor has the Company identified alternative remediation plans if upgrade or replacement is not feasible. The Company will consider the need for such remediation or replacement plans as it continues to assess the Y2K risk. For Y2K non-compliance issues identified to date, the cost of upgrade or remediation has not been and is not expected to be material to the Company's operating results. The Company has completed a work and project plan for Company awareness and is implementing a detailed assessment and inventory review process corresponding to the five-step General Accounting Office recommended process guidelines. For Y2K compliance, the total out-of-pocket costs expended to date and currently planned budget expenditures are less than \$100,000. If implementation of replacement systems is delayed, or if significant new non-compliance issues are identified, the Company's results of operations or financial condition could be materially adversely affected.

The Company has identified and inquired of most of its critical suppliers and has plans to initiate further inquiries of other suppliers in order to determine whether the operations and the products or services provided by these identified vendors are Y2K-compliant. Where practicable, the Company will attempt to mitigate its risks with respect to the failure of vendors to be Y2K-compliant. In the event that vendors are not compliant, the Company may adjust its purchasing decisions or seek alternative sources of supplies or services. However, many of the Company's vendors have been qualified for regulatory purposes such that qualifying new vendors could involve significant time and resource commitments by the Company. Failure of vendors to be Y2K-compliant remains a possibility and could limit the ability of the Company to manufacture material for clinical studies or timely conduct regulatory compliance programs that would result in a delay in the initiation or continuation of certain planned clinical studies. Significant delays or expenditures due to vendors' failures to become Y2K-compliant could have an adverse impact on the Company's results of operations or financial condition.

With respect to research conducted by the Company in support of its collaborative research customers, many of the systems and software used to support such efforts are new. Where appropriate, the Company has, as a condition to accepting such systems and software, required that the systems be Y2K-compliant.

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

The Company maintains 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. The Company does not use derivative financial instruments for speculative or trading purposes. The securities in the Company's investment portfolio are not leveraged and are classified as available for sale and therefore are subject to interest rate risk. The Company does not currently hedge interest rate exposure. As of March 31, 1999, there has been no material change in the Company's interest rate exposure from that described in the Company's Annual Report on Form 10-K for the year ended December 31, 1998.

## ITEM 5. OTHER INFORMATION - RISK FACTORS

### RISK FACTORS

This Quarterly Report contains, in addition to historical information, forward-looking statements which involve risks and uncertainties. The Company's 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 in this document and in the discussion captioned "Risk Factors" in the Company's Annual Report on Form 10-K for the year ending December 31, 1998.

**History Of Losses; Future Profitability Uncertain.** The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next several years as it continues to develop its potential products, to invest in new research areas and to devote significant resources to preclinical studies, clinical trials and manufacturing. As of March 31, 1999, the Company had an accumulated deficit of approximately \$70.8 million. The time and resource commitment required to achieve market success for any individual product is extensive and uncertain. No assurance can be given that the Company, its collaborative partners or licensees will successfully develop products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products.

The Company's revenues to date have consisted principally of research and development funding, licensing and signing fees, milestone payments and royalties from pharmaceutical and biotechnology companies under collaborative research and development, humanization, patent licensing and clinical supply agreements. These revenues may vary considerably from quarter to quarter and from year to year, and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. Further, royalty revenues are unpredictable as they are dependent upon numerous factors, including the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of the Company's licensees and rights certain licensees may have to partially offset certain previously paid milestones and third party royalties against royalties payable to the Company. In addition, expenses may fluctuate from quarter to quarter due to the timing of certain expenses, including milestone payments that may be payable under licensing arrangements.

Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate continuing to realize non-royalty revenue from its new and proposed collaborations at levels commensurate with the revenue historically recognized under its older collaborations. Moreover, the Company anticipates that it will incur significant operating expenses as the Company increases its research and development, manufacturing, preclinical, clinical, marketing and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under the Company's intellectual property rights, or other sources, the Company expects to incur substantial operating losses in the foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in additional facilities or manufacturing capacity, as the Company defends or prosecutes its patents and patent applications and as the Company invests in research or acquires additional technologies, product candidates or businesses. For example, revenues in the first quarter of 1999 included a \$3.0 million non-refundable, non-creditable licensing and signing fee from BioNet Pharma GmbH ("BioNet"). In the absence of similar substantial non-recurring revenues or significant royalty revenues in any future period, there can be no assurance that the Company will sustain or increase the

level of revenues in any future quarters from those reported in the first quarter of 1999.

Hoffmann-La Roche Inc. and its affiliates ("Roche") have received regulatory approval to distribute Zenapax in the U.S. and certain other countries. Zenapax, a product created by the Company, is licensed exclusively to Roche. The Company has also entered into nonexclusive patent license agreements covering Synagis[™], a product developed by MedImmune, Inc., and Herceptin[R], a product developed by Genentech, Inc. The Company recognizes royalty revenues when royalty reports are received from its collaborative partners, including Roche. With respect to royalties based on revenue from sales of Zenapax by Roche, royalties based on U.S. sales are reported to the Company on a quarterly basis and royalties based on sales outside of the U.S. are reported on a semi-annual basis. With respect to royalties on sales of Synagis and Herceptin, royalty reports are due in the quarter following the quarter in which sales occur or are reported by sublicensees, as the case may be. Each of these licensees has certain rights to partially offset certain payments previously made to the Company or paid to third parties. For example, Roche has a right to partially offset certain third party royalties, patent reimbursement expenses and previously paid milestones against royalties payable to the Company with respect to Zenapax. The Company records revenue when reports are received from its licensees. This method of accounting for royalty revenues from the Company's licensees, taken together with the unpredictable timing of payments of non-recurring licensing and signing fees, payments for manufacturing services and milestones under new and existing collaborative, humanization, patent licensing and clinical supply agreements, is likely to result in significant quarterly fluctuations in revenues in quarterly and annual periods. Thus, revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements.

The amount of net losses and the time required to reach sustained profitability are highly uncertain. To achieve sustained profitable operations, the Company, alone or with its collaborative partners, must successfully discover, develop, manufacture, obtain regulatory approvals for and market potential products. No assurances can be given that the Company will be able to achieve or sustain profitability, and results are expected to fluctuate from quarter to quarter and year to year.

**Dependence On Licensees With Respect to Marketed Products.** The Company is dependent upon the development and marketing efforts of its licensees with respect to products for which the Company may receive royalties. For example, in 1998, the Company began receiving royalties from sales of Zenapax, a product exclusively licensed to Roche. The Company's royalties on Zenapax depend upon the efforts of Roche and there can be no assurance that Roche's development, regulatory and marketing efforts will be successful, including without limitation, whether or how quickly Zenapax might receive regulatory approvals in various countries throughout the world and how rapidly it might be adopted by the medical community. Moreover, Simulect[R], a product competitive with Zenapax, is marketed in the U.S. and other countries and there can be no assurance that Roche will successfully market and sell Zenapax against this and other available competitive products. In addition, there can be no assurance that other independently developed products of Roche, including CellCept[R], or others will not compete with or prevent Zenapax from achieving meaningful sales. Roche's development and marketing efforts for CellCept may result in delays or a relatively smaller resource commitment to marketing and sales support efforts than might otherwise be obtained for Zenapax if this potentially competitive product were not under development or being marketed. In addition, Zenapax is being tested in certain early stage clinical trials in autoimmune indications. There can be no assurance that clinical development in autoimmune indications will continue or, that even if the further clinical development is pursued, that Zenapax will be shown to be safe and efficacious, or that the clinical trials will result in approval to market Zenapax in these indications. Any adverse event or announcement related to Zenapax would have a material adverse effect on the business and financial condition of the Company.

The Company has also entered into non-exclusive patent licensing arrangements for Synagis and Herceptin. The Company is dependent upon the further development, regulatory and marketing efforts of its licensees with respect to these products and there can be no assurance that the development, regulatory and marketing efforts of these licensees will be successful, including, without limitation, if and when regulatory approvals in various countries may be obtained and whether or how quickly these products might be adopted by the medical community.

Uncertainty Of Patents And Proprietary Technology; Opposition Proceedings. The Company's success is significantly dependent on its ability to obtain and maintain patent protection for its products and technologies and to preserve its trade secrets and operate without infringing on the proprietary rights of third parties. The Company files and prosecutes patent applications to protect its inventions. No assurance can be given that the Company's pending patent applications will result in the issuance of patents or that any patents will provide competitive advantages or will not be invalidated or circumvented by its competitors. Moreover, no assurance can be given that patents are not issued to, or patent applications have not been filed by, other companies which would have an adverse effect on the Company's ability to use, import, manufacture, market or sell its products or maintain its competitive position with respect to its products. Other companies obtaining patents claiming products or processes useful to the Company may bring infringement actions against the Company. As a result, the Company may be required to obtain licenses from others or not be able to use, import, manufacture, market or sell its products. Such licenses may not be available on commercially reasonable terms, if at all.

Patents in the U.S. are issued to the party that is first to invent the claimed invention. Since patent applications in the U.S. are maintained in secrecy until patents issue, the Company cannot be certain that it was the first inventor of the inventions covered by its pending patent applications or patents or that it was the first to file patent applications for such inventions. The patent positions of biotechnology firms generally are highly uncertain and involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, and patents of biotechnology products are uncertain, so that even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office ("PTO") or the 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 the extent of any patent protection may vary in different countries.

The Company has a number of patents and has exclusively licensed certain patents from third parties. In June 1996, the Company was issued a U.S. patent covering Zenapax and certain related antibodies against the IL-2 receptor. The Company has been issued patents by the PTO, the Japanese Patent Office ("JPO") and European Patent Office ("EPO") that relate to humanized antibodies and the methods of making those antibodies. With respect to its issued antibody humanization patents, the Company believes the patent claims cover Zenapax, Herceptin and Synagis and, based on its review of the scientific literature, most other humanized antibodies. In addition, the Company is currently prosecuting other patent applications with the PTO and in other countries, including members of the European Patent Convention, Canada, Japan and Australia. The patent applications are directed to various aspects of the Company's SMART and human antibodies, antibody technology and other programs, and include claims relating to compositions of matter, methods of preparation and use of a number of the Company's compounds. However, the Company does not know whether any pending applications will result in the issuance of patents or whether such patents will provide protection of commercial significance. Further, there can be no assurance that the Company's patents will prevent others from developing competitive products using related technology.

The Company's humanization patent issued by the EPO applies in the United Kingdom, Germany, France, Italy and eight other European countries. The EPO (but not PTO) procedures provided for an opposition period in which other parties submitted arguments as to why the patent was incorrectly granted and should be withdrawn or limited. Eighteen notices of opposition to the Company's European patent were filed during the opposition period, including oppositions by major pharmaceutical and biotechnology companies, which cited references and made arguments not considered by the EPO and PTO before grant of the respective patents. The Company submitted its response to the briefs filed by these parties and a preliminary view from the EPO was recently received on May 12, 1999. The preliminary view represents the initial non-binding statement from the EPO with respect to the issued European patent and does not represent the final determination concerning the patent. Complex preliminary views are common in EPO proceedings, and are intended to set an agenda for discussion at the oral hearing. The final determination from the EPO is expected to occur at an oral hearing currently scheduled to take place in March 2000. At or following the oral hearing, the Company expects that the European patent will either be maintained in full, maintained in an amended version or revoked. Any of the parties to the opposition may appeal a decision to a board of appeals within the EPO. Such an appeal can take 2 or more years to be resolved.

The preliminary view from the EPO raises significant questions regarding the validity of the European patent, which, if not satisfactorily responded to by the Company in the oral hearing, could result in revocation of certain claims or the entire European patent. If the key claims in the European patent are revoked following the oral hearing and the Company's other humanization patents do not provide sufficient coverage of certain products licensed under the Company's patents, then the Company's ability to collect royalties on European sales of existing licensed products and to license its patents relating to humanized antibodies may be materially adversely affected, which would have a material adverse effect on the business and financial condition of the Company. The Company is currently reviewing the preliminary view with counsel in preparation for the scheduled oral hearing. Although the entire opposition process, including appeals, may take several years to complete, and although the European patent remains issued and any revocation of the European patent is suspended during the appeals process, the validity of the European patent will be at issue, which may limit the Company's ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this patent. In addition, the Company may need to initiate formal legal actions, if permissible, in order to enforce its rights under its various humanization patents, including the European patent, and there can be no assurance that the Company will successfully enforce its rights under the European or similar U.S. and Japanese patents of the Company.

A 6-month opposition period has also begun with respect to the Company's humanization patent issued in Japan in late 1998. Similar to the process in Europe, third parties have the opportunity to file their opposition to the issuance of the JPO patent. The Company intends to vigorously defend the European patent and, if necessary, the Japanese patent and U.S. patents; however, there can be no assurance that the Company will prevail in the opposition proceedings or any litigation contesting the validity or scope of these patents. If the outcome of the European or Japanese opposition proceeding or any litigation involving the Company's antibody humanization patents were to be unfavorable, the Company's ability to collect royalties on existing licensed products and to license its patents relating to humanized antibodies may be materially adversely affected, which could have a material adverse effect on the business and financial condition of the Company. In addition, such proceedings or litigation, or any other proceedings or litigation to protect the Company's 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 have a material adverse effect on the business and financial condition of the Company.

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 the Company's programs. Some of these applications or patents may be competitive with the Company's applications or contain claims that conflict with those made under the Company's patent applications or patents. Such conflicts could prevent issuance of patents to the Company, provoke an interference with the Company's patents or result in a significant reduction in the scope or invalidation of the Company's patents, if issued. An interference is an administrative proceeding conducted by the PTO to determine the priority of invention and may determine questions of patentability. Moreover, if patents are held by or issued to other parties that contain claims relating to the Company's products or processes, and such claims are ultimately determined to be valid, no assurance can be given that the Company would be able to obtain licenses to these patents at a reasonable cost, if at all, or to develop or obtain alternative technology.

The Company is aware that Celltech Limited ("Celltech") has been granted a patent by the EPO covering certain humanized antibodies ("European Adair Patent"), which the Company has opposed, and that Celltech has also been issued a corresponding U.S. patent (the "U.S. Adair Patent") that contains claims that may be considered broader in scope than the European Adair Patent. The Company is currently reviewing the claims under the U.S. Adair Patent in an effort to determine its future course of action with respect to this patent. If it were determined that the Company's SMART antibodies were covered by the European or U.S. Adair Patents, the Company might be required to obtain a license under such patents or to significantly alter its processes or products, if necessary to make, use or sell its products in Europe and the U.S. There can be no assurance that the Company would be able to successfully alter its processes or products to avoid infringing such patents or to obtain such a license from Celltech on commercially reasonable terms, if at all, and the failure to do so could have a



material adverse effect on the business and financial condition of the Company.

In addition, if the claims of the U.S. Adair Patent or any related patent applications conflict with claims in the Company's U.S. patents or patent applications, there can be no assurance that an interference would not be declared by the PTO, which could take several years to resolve and could involve significant expense to the Company. Also, such conflict could prevent issuance of additional patents to the Company relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of the Company's patents, if issued. Moreover, uncertainty as to the validity or scope of patents issued to the Company relating generally to humanization of antibodies may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

The Company is aware that Lonza Biologics, Inc. has a patent issued in Europe to which the Company does not have a license (although Roche has advised the Company that it has a license covering Zenapax), which may cover a process the Company uses to produce its potential products. If it were determined that the Company's processes were covered by such patent, the Company might be required to obtain a license under such patent or to significantly alter its processes or products, if necessary to manufacture or import its products in Europe. There can be no assurance that the Company would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on the business and financial condition of the Company.

The Company is also aware of an issued U.S. patent assigned to Stanford University and Columbia University to which the Company does not have a license, which may cover a process the Company uses to produce its potential products. The Company has been advised that an exclusive license has been previously granted to a third party under this patent. If it were determined that the Company's processes were covered by such patent, the Company might be required to obtain a license under such patent or to significantly alter its processes or products, if necessary to manufacture or import its products in the U.S. There can be no assurance that the Company would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on the business and financial condition of the Company. Moreover, any alteration of processes or products to avoid infringing the patent could result in a significant delay in achieving regulatory approval with respect to the products affected by such alterations.

In addition to seeking the protection of patents and licenses, the Company also relies upon trade secrets, know-how and continuing technological innovation which it seeks to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. There can be no assurance that these agreements will not be breached, that the Company would have adequate remedies for any breach or that the Company's trade secrets will not otherwise become known, independently developed or patented by competitors.

**Uncertainty Of Clinical Trial Results.** Before obtaining regulatory approval for the commercial sale of any of its potential products, the Company must demonstrate through preclinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. There can be no assurance that the Company will be permitted to undertake or continue clinical trials for any of its potential products or, if permitted, that such products will be demonstrated to be safe and efficacious. Moreover, the results from preclinical studies and early-stage clinical trials may not be predictive of results that will be obtained in late-stage clinical trials. Thus, there can be no assurance that the Company's present or future clinical trials will demonstrate the safety and efficacy of any potential products or will result in approval to market products.

In advanced clinical development, numerous factors may be involved that may lead to different results in larger, late-stage clinical trials from those obtained in early-stage trials. For example, early-stage clinical trials usually involve a small number of patients, often at a single center, and thus may not accurately predict the actual results regarding safety and efficacy that may be demonstrated with a large number of patients in a late-stage multi-center clinical trial. Also, differences in the clinical trial design between early-stage and late-stage clinical trials may cause different results regarding the safety

and efficacy of a product to be obtained. In addition, many early-stage trials are unblinded and based on qualitative evaluations by clinicians involved in the performance of the trial, whereas late-stage trials are generally required to be blinded in order to provide more objective data for assessing the safety and efficacy of the product. Moreover, preliminary results from clinical trials may not be representative of results that may be obtained as the trial proceeds to completion.

The Company may at times elect to aggressively enter potential products into Phase I/II trials to determine preliminary safety and efficacy in specific indications. In addition, in certain cases the Company has commenced clinical trials without conducting preclinical animal testing where an appropriate animal model does not exist. Similarly, the Company or its partners at times will conduct potentially pivotal Phase II/III or Phase III trials based on limited Phase I or Phase I/II data. As a result of these and other factors, the Company anticipates that only some of its potential products will show safety and efficacy in clinical trials and that the number of products that fail to show safety and efficacy may be significant.

**Limited Experience With Clinical Trials; Risk Of Delay.** The Company has conducted only a limited number of clinical trials to date. There can be no assurance that the Company will be able to successfully commence and complete all of its planned clinical trials without significant additional resources and expertise. In addition, there can be no assurance that the Company will meet its contemplated development schedule for any of its potential products. The inability of the Company or its collaborative partners to commence or continue clinical trials as currently planned, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of its potential products, would have a material adverse effect on the business and financial condition of the Company.

The rate of completion of the Company's or its collaborators' clinical trials is significantly dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including, among others, the size of the patient population, perceived risks and benefits of the drug under study, availability of competing therapies, access to reimbursement from insurance companies or government sources, design of the protocol, proximity of and access by patients to clinical sites, patient referral practices, eligibility criteria for the study in question and efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment in the trial. Delays in the planned rate of patient enrollment may result in increased costs and expenses in completion of the trial or may require the Company to undertake additional studies in order to obtain regulatory approval if the applicable standard of care changes in the therapeutic indication under study. These considerations may lead the Company to consider the termination of ongoing clinical trials or halting further development of a product for a particular indication.

**Dependence On Collaborative Partners.** The Company has collaborative agreements with several pharmaceutical or other companies to develop, manufacture and market certain potential products. The Company granted its collaborative partners certain exclusive rights to commercialize the products covered by these collaborative agreements. In some cases, the Company is relying on its collaborative partners to conduct clinical trials, to compile and analyze the data received from such trials, to obtain regulatory approvals and, if approved, to manufacture and market these licensed products. As a result, the Company often has little or no control over the development and marketing of these potential products and little or no opportunity to review clinical data prior to or following public announcement.

The Company's collaborative research agreements are generally terminable by its partners on short notice. Suspension or termination of certain of the Company's current collaborative research agreements could have a material adverse effect on the Company's operations and could significantly delay the development of the affected products. For example, Boehringer Mannheim GmbH ("Boehringer Mannheim") and the Company from time to time had differences with respect to the clinical development of certain products licensed by the Company to Boehringer Mannheim under a collaborative agreement. In December 1997, as a result of Boehringer Mannheim's internal review of products licensed from the Company, product rights to the Human Anti-Hepatitis B Antibody ("Ostavir") were returned to the Company. In March 1998, Roche acquired Corange Limited ("Corange"), the parent company of Boehringer Mannheim. Roche's review of the products acquired from Boehringer Mannheim resulted in a decision to return the SMART Anti-L-Selectin Antibody and an antibody directed against an undisclosed cardiovascular target to the Company effective as of December 31, 1998. Although the Company has

licensed certain rights to the SMART Anti-L-Selectin Antibody to BioNet in order to continue its development, the development of this compound has been delayed as a result of the review and return of the product by Roche. Moreover, the development of the other compound returned by Roche has been delayed significantly and there can be no assurance that the Company will continue or initiate further development efforts with this compound. In addition, Roche acquired 1,682,877 shares of the Company's common stock held by Corange which are no longer subject to contractual limitations on disposition other than certain restrictions on transfers of significant blocks of stock. Further, Boehringer Mannheim has invoked the dispute resolution provisions under its collaborative research agreement to address the reimbursement of up to \$2.0 million for the Phase II study of Ostavir for the treatment of chronic hepatitis B ("CHB") conducted by Boehringer Mannheim. The Company is unable to predict the outcome of this proceeding but in any event has estimated and recorded a liability with respect to this matter.

Continued funding and participation by collaborative partners will depend on the timely achievement of research and development objectives by the Company, the retention of key personnel performing work under those agreements and the successful achievement of research or clinical trial goals, none of which can be assured, as well as on each collaborative partner's own financial, competitive, marketing and strategic considerations. Such considerations include, among other things, the commitment of management of the collaborative partners to the continued development of the licensed products, the relationships among the individuals responsible for the implementation and maintenance of the collaborative efforts, the relative advantages of alternative products being marketed or developed by the collaborators or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

The Company's ability to enter into new collaborations and the willingness of the Company's existing collaborators to continue development of the Company's potential products depends upon, among other things, the Company's patent position with respect to such products. In this regard, the Company has been issued patents by PTO, EPO and JPO with claims that the Company believes, based on its survey of the scientific literature, cover most humanized antibodies. The Company has also been allowed patents with similar claims in other countries and has applied for similar patents in certain other countries. See "Risk Factors -- Uncertainty of Patents and Proprietary Technology; Opposition Proceedings." The EPO and JPO patents are currently in the opposition proceeding stages in those patent offices. In addition, all of the Company's antibody humanization patents may be further challenged through administrative or judicial proceedings. The Company has entered into several collaborations related to both the humanization and patent licensing of certain antibodies whereby it granted licenses to its patent rights relating to such antibodies, and the Company anticipates entering into additional collaborations and patent licensing agreements partially as a result of the Company's patent and patent applications with respect to humanized antibodies. As a result, the inability of the Company to successfully defend the opposition proceedings before the EPO or JPO or, if necessary, to defend patents granted by the PTO, EPO or JPO or to successfully prosecute the corresponding patent applications in other countries could adversely affect the ability of the Company to collect royalties on existing licensed products, and enter into additional collaborations, humanization or patent licensing agreements and could therefore have a material adverse effect on the Company's business or financial condition.

**Absence Of Manufacturing Experience.** Of the products developed by the Company which are currently in clinical development, Roche is responsible for manufacturing Zenapax and the Company is responsible for manufacturing the Company's other products for its own development. The Company currently leases approximately 47,000 square feet housing its manufacturing facilities in Plymouth, Minnesota. The Company intends to continue to manufacture potential products for use in preclinical and clinical trials using this manufacturing facility in accordance with standard procedures that comply with current Good Manufacturing Practices ("cGMP") and appropriate regulatory standards. The manufacture of sufficient quantities of antibody products in accordance with such standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays. For example, the Company has experienced some difficulties in the past in manufacturing certain potential products on a consistent basis. Production interruptions, if they occur, could significantly delay clinical development of potential products, reduce third party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization of such products and impair their

competitive position, which would have a material adverse effect on the business and financial condition of the Company.

The Company has no experience in manufacturing commercial quantities of its potential products and currently does not have sufficient capacity to manufacture all of its potential products on a commercial scale. In order to obtain regulatory approvals and to create capacity to produce its products for commercial sale at an acceptable cost, the Company will need to improve and expand its existing manufacturing capabilities, including demonstration to the FDA and corresponding foreign authorities of its ability to manufacture its products using controlled, reproducible processes. Accordingly, the Company is evaluating plans to improve and expand the capacity of its current manufacturing facility. Such plans, if fully implemented, would result in substantial costs to the Company and may require a suspension of manufacturing operations during construction. There can be no assurance that construction delays would not occur, and any such delays could impair the Company's ability to produce adequate supplies of its potential products for clinical use or commercial sale on a timely basis. Further, there can be no assurance that the Company will successfully improve and expand its manufacturing capability sufficiently to obtain necessary regulatory approvals and to produce adequate commercial supplies of its potential products on a timely basis. Failure to do so could delay commercialization of such products and impair their competitive position, which could have a material adverse effect on the business or financial condition of the Company.

**Uncertainties Resulting From Manufacturing Changes.** Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. When certain changes are made in the manufacturing process, it is necessary 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, if results of prior preclinical studies and clinical trials performed using the previously produced drug material are to be relied upon in regulatory filings. Such changes could include, for example, changing the cell line used to produce the antibody, changing the fermentation or purification process or moving the production process to a new manufacturing plant. Depending upon the type and degree of differences between the newer and older drug material, various studies could be required to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material, possibly requiring additional animal studies or human clinical trials. Manufacturing changes have been made or are likely to be made for the production of the Company's products currently in clinical development, in particular the SMART M195 and SMART Anti-CD3 Antibodies. There can be no assurance that such changes will not result in delays in development or regulatory approvals or, if occurring after regulatory approval, in reduction or interruption of commercial sales. In addition, manufacturing changes to its manufacturing facility may require the Company to shut down production for a period of time. There can be no assurance that the Company will be able to reinstitute production in a timely manner, if at all, following such shutdown. Delays as a result of manufacturing changes or shutdown of the manufacturing facility could have an adverse effect on the competitive position of those products and could have a material adverse effect on the business and financial condition of the Company.

**Dependence On Suppliers.** The Company is dependent on outside vendors for the supply of raw materials used to produce its product candidates. The Company currently qualifies only one or a few vendors for its source of certain raw materials. Therefore, once a supplier's materials have been selected for use in the Company's manufacturing process, the supplier in effect becomes a sole or limited source of such raw materials to the Company due to the extensive regulatory compliance procedures governing changes in manufacturing processes. Although the Company believes it could qualify alternative suppliers, there can be no assurance that the Company would not experience a disruption in manufacturing if it experienced a disruption in supply from any of these sources. Any significant interruption in the supply of any of the raw materials currently obtained from such sources, or the time and expense necessary to transition a replacement supplier's product into the Company's manufacturing process, could disrupt the Company's operations and have a material adverse effect on the business and financial condition of the Company. A problem or suspected problem with the quality of raw materials supplied could result in a suspension of clinical trials, notification of patients treated with products or product candidates produced using such materials, potential product liability claims, a recall of products or product candidates produced using such materials, and an interruption of supplies, any of which could have a material adverse effect on the business or financial

condition of the Company.

Competition; Rapid Technological Change. The Company's potential products are intended to address a wide variety of disease conditions, including autoimmune diseases, inflammatory conditions, cancers and viral infections. Competition with respect to these disease conditions is intense and is expected to increase. This competition involves, among other things, successful research and development efforts, obtaining appropriate regulatory approvals, establishing and defending intellectual property rights, successful product manufacturing, marketing, distribution, market and physician acceptance, patient compliance, price and potentially securing eligibility for reimbursement or payment for the use of the Company's products. The Company believes its most significant competitors may be fully integrated pharmaceutical companies with substantial expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and securing eligibility for reimbursement or payment, and substantially greater financial and other resources than the Company. Smaller companies also may prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies. Furthermore, academic institutions, governmental agencies and other public and private research organizations conduct research, seek patent protection, and establish collaborative arrangements for product development, clinical development and marketing. These companies and institutions also compete with the Company in recruiting and retaining highly qualified personnel. The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. The Company's competitors may develop and introduce other technologies or approaches to accomplishing the intended purposes of the Company's products which may render the Company's technologies and products noncompetitive and obsolete.

In addition to currently marketed competitive drugs, the Company is aware of potential products in research or development by its competitors that address all of the diseases being targeted by the Company. These and other products may compete directly with the potential products being developed by the Company. In this regard, the Company is aware that potential competitors are developing antibodies or other compounds for treating autoimmune diseases, inflammatory conditions, cancers and viral infections. In particular, a number of other companies have developed and will continue to develop human and humanized antibodies. In addition, protein design is being actively pursued at a number of academic and commercial organizations, and several companies have developed or may develop technologies that can compete with the Company's SMART and human antibody technologies. There can be no assurance that competitors will not succeed in more rapidly developing and marketing technologies and products that are more effective than the products being developed by the Company or that would render the Company's products or technology obsolete or noncompetitive. Further, there can be no assurance that the Company's collaborative partners will not independently develop products competitive with those licensed to such partners by the Company, thereby reducing the likelihood that the Company will receive revenues under its agreements with such partners.

Any potential product that the Company or its collaborative partners succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. For certain of the Company's potential products, an important factor will be the timing of market introduction of competitive products. Accordingly, the relative speed with which the Company and its 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 is expected to be an important determinant of market success. For example, Novartis has received approval to market Simulect, a product competitive with Zenapax, in the U.S. and Europe. In addition to an earlier launch in Europe, Novartis has a significant marketing and sales force directed to the transplantation market and there can be no assurance that Roche will successfully market and sell Zenapax against this and other available products.

Other competitive factors include the capabilities of the Company's collaborative partners, product efficacy and safety, timing and scope of regulatory approval, product availability, marketing and sales capabilities, reimbursement coverage, the amount of clinical benefit of the Company's products relative to their cost, method of administration, price and patent protection. There can be no assurance that the Company's competitors will not develop more efficacious or more affordable products, or achieve earlier product development completion, patent protection, regulatory approval or product commercialization than

the Company. The occurrence of any of these events by the Company's competitors could have a material adverse effect on the business and financial condition of the Company.

**Dependence on Key Personnel.** The Company's success is dependent to a significant degree on its key management personnel. To be successful, the Company will have to retain its qualified clinical, manufacturing, scientific and management personnel. The Company faces competition for personnel from other companies, academic institutions, government entities and other organizations. There can be no assurance that the Company will be successful in hiring or retaining qualified personnel, and its failure to do so could have a material adverse effect on the business and financial condition of the Company.

**Potential Volatility Of Stock Price.** The market for the Company's securities is volatile and investment in these securities involves substantial risk. The market prices for securities of biotechnology companies (including the Company) have been highly volatile, and 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. Factors such as disappointing sales of approved products, approval or introduction of competing products and technologies, results of clinical trials, delays in manufacturing or clinical trial plans, fluctuations in the Company's operating results, disputes or disagreements with collaborative partners, unfavorable news or information resulting in the reduction in value of significant intellectual property assets, market reaction to announcements by other biotechnology or pharmaceutical companies, announcements of technological innovations or new commercial therapeutic products by the Company or its competitors, initiation, termination or modification of agreements with collaborative partners, failures or unexpected delays in manufacturing or in obtaining regulatory approvals or FDA advisory panel recommendations, developments or disputes as to patent or other proprietary rights, loss of key personnel, litigation, public concern as to the safety of drugs developed by the Company, regulatory developments in either the U.S. or foreign countries (such as opinions, recommendations or statements by the FDA or FDA advisory panels, health care reform measures or proposals), market acceptance of products developed and marketed by the Company's collaborators, sales of the Company's common stock held by collaborative partners or insiders and general market conditions could result in the Company's failure to meet the expectations of securities analysts or investors. In such event, or in the event that adverse conditions prevail or are perceived to prevail with respect to the Company's business, the price of the Company's common stock would likely drop significantly. In the past, following significant drops in the price of a company's common stock, securities class action litigation has often been instituted against such a company. Such litigation against the Company could result in substantial costs and a diversion of management's attention and resources, which would have a material adverse effect on the Company's business and financial condition.

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

(a) Exhibits - None

(b) No Reports on Form 8-K were filed during the quarter ended March 31, 1999.

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, 1999

PROTEIN DESIGN LABS, INC.  
(Registrant)

Laurence Jay Korn  
Chief Executive Officer,  
Chairperson of the  
Board of Directors  
(Principal Executive Officer)

Jon Saxe  
Senior Adviser to the Chief  
Executive Officer  
(Chief Accounting Officer)

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION  
FROM THE ACCOMPANYING FINANCIAL STATEMENTS AND IS QU  
ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENT

1,000

	3-MOS	
	DEC-31-1999	
	Jan-01-1999	
	MAR-31-1999	
		27,352
	112,909	
	5,436	
		0
		0
	47,736	
		22,931
		0
	169,711	
9,179		
		0
0		
		0
		186
	160,346	
169,711		
		8,835
	8,835	
		0
		0
	10,725	
		0
		0
	(1,890)	
		0
(1,890)		
		0
		0
		0
	(1,890)	
	(\$0.10)	
	(\$0.10)	