

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, 2002

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 0-19756



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, California 94555

(Address of Principal Executive Offices including Zip Code)

(510) 574-1400

(Registrant's Telephone Number, Including Area Code)

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 reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

As of April 30, 2002, there were 88,759,931 shares of the Registrant's Common Stock outstanding.

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Protein Design Labs, Nuvion and SMART are registered U.S. trademarks and the PDL logo and and ZamyI are trademarks of Protein Design Labs, Inc. Zenapax is a registered U.S. trademark of Hoffmann-La Roche Inc. All other company names and trademarks included in this Quarterly Report are trademarks, registered trademarks or trade names of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	Three Months Ended March 31,	
	2002	2001
Revenues:		
Revenue under agreements with third parties	\$ 14,326	\$ 16,710
Interest and other income	7,139	9,460
Total revenues	21,465	26,170
Costs and expenses:		

Research and development	13,187	13,671
General and administrative	4,157	3,620
Interest expense	2,240	2,248
	-----	-----
Total costs and expenses	19,584	19,539
	-----	-----
Net income	\$ 1,881	\$ 6,631
	=====	=====
Net income per share:		
Basic	\$ 0.02	\$ 0.08
	=====	=====
Diluted	\$ 0.02	\$ 0.07
	=====	=====
Weighted average number of shares:		
Basic	88,645	87,230
	=====	=====
Diluted	91,750	92,564
	=====	=====

See accompanying notes

PROTEIN DESIGN LABS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value per share)

	March 31, 2002	December 31, 2001
	-----	-----
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 234,262	\$ 120,268
Marketable securities	403,825	530,047
Other current assets	5,417	4,144
	-----	-----
Total current assets	643,504	654,459
Property, plant and equipment, net	47,663	42,111
Convertible note receivable	30,000	30,000
Other assets	4,635	3,328
	-----	-----
Total assets	\$ 725,802	\$ 729,898
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,095	\$ 1,249
Accrued compensation	1,627	2,000
Accrued clinical trials	1,713	2,588
Accrued interest	1,008	3,071
Other accrued liabilities	2,218	3,123
Deferred revenue	100	100
Current portion of long-term debt	440	432
	-----	-----
Total current liabilities	9,201	12,563
Convertible subordinated notes	150,000	150,000
Other long-term debt	8,777	8,892
	-----	-----
Total liabilities	167,978	171,455
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; 88,691 and 88,499 shares issued and outstanding at March 31, 2002 and December 31, 2001, respectively	887	885

Additional paid-in capital	625,148	624,094
Accumulated deficit	(74,042)	(75,923)
Accumulated other comprehensive income	5,831	9,387
	-----	-----
Total stockholders' equity	557,824	558,443
	-----	-----
Total liabilities and stockholders' equity	\$ 725,802	\$ 729,898
	=====	=====

See accompanying notes

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

	Three Months Ended March 31,	
	----- 2002	2001 -----
Cash flows from operating activities:		
Net income	\$ 1,881	\$ 6,631
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,232	1,024
Amortization of convertible notes offering costs	180	180
Change in book value of certain debt securities	2,468	(1,668)
Changes in assets and liabilities:		
Other current assets	(1,273)	(4,773)
Other assets	(246)	50
Accounts payable	846	(349)
Accrued liabilities	(4,214)	(975)
Deferred revenue	--	(1,355)
	-----	-----
Total adjustments	(1,007)	(7,866)
	-----	-----
Net cash provided by (used in) operating activities	874	(1,235)
	-----	-----
Cash flows from investing activities:		
Purchases of marketable securities	(19,954)	(307,044)
Maturities of marketable securities	140,000	89,885
Purchase of property, plant and equipment	(7,874)	(1,327)
	-----	-----
Net cash used in investing activities	112,172	(218,486)
	-----	-----
Cash flows from financing activities:		
Proceeds from issuance of capital stock, net of issuance costs	1,055	1,406
Payments on other long-term debt	(107)	(99)
	-----	-----
Net cash provided by financing activities	948	1,307
	-----	-----
Net increase (decrease) in cash and cash equivalents	113,994	(218,414)
Cash and cash equivalents at beginning of period	120,268	421,541
	-----	-----
Cash and cash equivalents at end of period	\$ 234,262	\$ 203,127
	=====	=====
Non-cash activities:		
Exchange of assets for third party preferred stock	\$ 1,241	\$ --

See accompanying notes

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2002
(unaudited)

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. PDL currently has antibodies under development for autoimmune and inflammatory conditions, asthma and cancer. PDL holds fundamental patents for its antibody humanization technology.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The Consolidated Balance Sheet as of March 31, 2002, the Consolidated Statements of Operations for the three months ended March 31, 2002 and 2001 and the Consolidated Statements of Cash Flows for the three months ended March 31, 2002 and 2001 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 and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States 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 our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, for the year ended December 31, 2001. The Consolidated Balance Sheet as of December 31, 2001 is derived from our audited financial statements. Results for any interim period are not necessarily indicative of results for any other interim period or for the entire year.

Cash Equivalents, Marketable Securities and Concentration of Credit Risk

We consider all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. Marketable securities in the Consolidated Balance Sheets includes the interest receivable associated with all marketable securities. We place our cash and marketable debt securities with high-credit-quality financial institutions and in securities of the U.S. government, U.S. government agencies and U.S. corporations and, by policy, limit the amount of credit exposure in any one financial instrument. To date, we have not experienced credit losses on investments in these instruments.

The following is a summary of all available-for-sale securities. Estimated fair value is based upon quoted market prices for these or similar instruments.

	Available-for-Sale-Securities			
(In thousands)	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
March 31, 2002				
Securities of the U.S. Government and its agencies maturing:				
Less than 1 year	\$ 50,537	\$ 1,128	\$ --	\$ 51,665
between 1-3 years	200,687	1,825	(732)	201,780
U.S. corporate debt securities maturing:				
Less than 1 year	35,980	850	--	36,830
between 1-3 years	110,790	2,916	(156)	113,550
Total marketable debt securities	\$ 397,994	\$ 6,719	\$ (888)	\$ 403,825
	=====	=====	=====	=====

During the quarters ended March 31, 2002 and 2001, there were no realized gains or losses on the sale of available-for-sale securities, as all securities liquidated prior to date were held to maturity.

Revenue Recognition

Contract revenues from research and development arrangements are recognized based on the performance requirements of the contracts. Revenues from achievement of milestones are recognized when the funding party agrees that the scientific, regulatory 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.

Our collaborative, humanization and patent licensing agreements with third parties provide for the payment of royalties to us based on net sales of the licensed product under the agreement. The agreements generally provide for royalty payments to us following completion of each calendar quarter or semi-annual period and royalty revenue is recognized in the quarter in which royalty reports are received by us from the third party. As a result of this policy and the seasonality of certain royalty revenues, our revenues in any period may not be predictive of revenues in any subsequent period. Non-refundable signing and licensing fees under collaborative and humanization agreements are recognized over the period in which performance obligations are achieved. Non-refundable signing and licensing fees under patent rights and patent licensing agreements are recognized when there are no future performance obligations remaining with respect to such fees. Maintenance fees are recognized when received or when collection is assured.

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 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 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 numerators and denominators of the basic and diluted net income per share computations for the periods presented below:

(In thousands, except basic and diluted net income per share)	Three Months Ended March 31,	
	2002	2001
Numerator:		
Net income	\$ 1,881	\$ 6,631
Denominator:		
Basic net income per share - weighted-average shares	88,645	87,230
Dilutive potential common shares: Stock options	3,105	5,334
Denominator for diluted net income per share	91,750	92,564
Basic net income per share	\$ 0.02	\$ 0.08
Diluted net income per share	\$ 0.02	\$ 0.07

Comprehensive Income

For the three months ended March 31, 2002, total comprehensive loss was \$1.7 million as compared to total comprehensive income of \$10.8 million for the three months ended March 31, 2001. Total comprehensive income (loss) is comprised of net income and unrealized gains and losses on our available-for-sale securities.

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. For example, we have 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, we accrue an amount based on an estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial. In addition, funded research and development to third parties is expensed on a straight-line basis over the period of performance. Our estimates and assumptions could differ significantly from the amounts which may actually be incurred.

Sale of Small Molecule Group

In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately-held detection-based drug discovery company, in exchange for 523,952 shares of Signature convertible preferred stock. The small molecule group primarily had been responsible for our chemistry, high-throughput screening and small-molecule drug discovery research efforts. The stock received was recorded at the net book value of the assets sold, which approximated \$1.2 million. Accordingly, there was no gain or loss recorded on this transaction.

In conjunction with this sale, 12 of our former employees became employed by Signature. We may be obligated to pay up to a maximum of \$320,000 in cash retention bonuses to designated key employees still employed by Signature after one year.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued FAS 141, "Business Combinations"(FAS 141). FAS 141 supersedes APB 16, "Business Combinations," and FAS 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises." FAS 141 requires the purchase method of accounting for all business combinations initiated after June 30, 2001 and eliminates the pooling-of-interests method. FAS 141 also includes guidance on the initial recognition and measurement of goodwill and other intangible assets arising from business combinations completed after June 30, 2001.

In July 2001, the FASB issued FAS 142, "Goodwill and Other Intangible Assets" (FAS 142). FAS 142 supersedes APB 17, "Intangible Assets," and requires the discontinuance of goodwill amortization. In addition, FAS 142 includes provisions regarding the reclassification of certain existing recognized intangibles as goodwill, reassessment of the useful lives of existing recognized intangibles, reclassification of certain intangibles out of previously reported goodwill and the testing for impairment of existing goodwill and other intangibles. FAS 142 is required to be applied for fiscal years beginning after December 15, 2001, with certain early adoption permitted. The adoption of FAS 142 did not have a material effect on our financial condition or results of operations.

In August 2001, the FASB issued FAS 143, "Accounting for Asset Retirement Obligations" (FAS 143). FAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated retirement costs. The Company is in the process of assessing the effect of adopting FAS 143, which will be effective for the Company's fiscal year ending December 31, 2003.

In October 2001, the FASB issued FAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (FAS 144), which supersedes FAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of"(FAS 121). FAS 144 addresses financial accounting and reporting for the impairment of long-lived assets and for long-lived assets to be disposed of. However, FAS 144 retains the fundamental provisions of FAS 121 for: 1) recognition and measurement of the impairment of long-lived assets to be held and used; and 2) measurement of long-lived assets to be disposed of by sale. FAS 144 is effective for fiscal years beginning after December 15, 2001. The adoption of FAS 144 did not have a material effect on our financial condition or results of operations.

Stock Split

In August 2001, we announced that our Board of Directors approved a two-for-one stock split of the outstanding shares of our common stock. The stock split was effected in the form of a stock dividend. Each stockholder of record at the close of business on September 18, 2001 was entitled to receive one additional share of common stock for every share of common stock held on that date. The stock dividend resulting from the stock split was distributed by our transfer agent on October 9, 2001. The accompanying financial statements reflect the effect of this stock split.

Subsequent Events

On May 1, 2002, we announced that Laurence Jay Korn, Ph.D., a co-founder of PDL and its Chief Executive Officer since 1987, has relinquished his responsibilities as Chief Executive Officer. Dr. Korn will continue to serve as Chairman of the Board and will continue to be an active employee in the areas of investor relations and business development. In addition, we announced that Daniel J. Levitt, M.D., Ph.D., President, Research and Development, PDL, has resigned to pursue other interests.

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. Although we have recorded small profits for the past two years, in general, our expenses have exceeded revenues. As of March 31, 2002, we had an accumulated deficit of approximately \$74.0 million. Our expenses may increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. Over the next several years, we expect to 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 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 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, 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 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.

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 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.

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.

In January 2002, we sold the assets of our small molecule group to Signature BioScience, Inc. (Signature), a privately-held detection-based drug discovery company, in exchange for 523,952 shares of Signature convertible preferred stock. The small molecule group primarily has been responsible for our chemistry, high-throughput screening and small-molecule drug discovery research efforts. The stock received was recorded at the net book value of the assets sold, which approximated \$1.2 million. Accordingly, there was no gain or loss recorded on this transaction.

In conjunction with this sale, 12 of our former employees became employed by Signature. We may be obligated to pay up to a maximum of \$320,000 in cash retention bonuses to designated key employees still employed by Signature after one year.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

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:

- Contract revenues from research and development arrangements are recognized based on the performance requirements of the contracts.
- Revenues from achievement of milestones are recognized when the funding party agrees that the milestone (typically scientific, regulatory or clinical results) stipulated in the agreement has been met.
- Our collaborative, humanization and patent licensing agreements with third parties provide for the payment of royalties to us based on net sales of the licensed product under the agreement. The agreements generally provide for royalty payments to us following completion of each calendar quarter or semi-annual period. Royalty revenue is recognized in the quarter in which

royalty reports are received by us from the third party. As a result of this policy and the seasonality of certain royalty revenues, as noted above, our revenues in any period may not be predictive of revenues in any subsequent period.

- Non-refundable signing and licensing fees under collaborative and humanization agreements are recognized over the period in which performance obligations are achieved.
- Non-refundable signing and licensing fees under patent rights and patent licensing agreements are recognized when there are no future performance obligations remaining with respect to such fees.
- Maintenance fees are recognized when received or when collection is assured.
- Expenses for research and development funding to third parties are generally recognized ratably over the performance period.
- We have 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.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2002 and 2001

The Company's total revenues for the three months ended March 31, 2002 were \$21.5 million compared to \$26.2 million in the first quarter of 2001. Total revenues recognized under agreements with third parties were \$14.3 million in the first quarter of 2002 compared to \$16.7 million in the comparable period in 2001. Interest and other income was \$7.1 million in the first quarter of 2002 compared to \$9.5 million in the comparable period in 2001, reflecting the decreased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates.

Revenues under agreements with third parties of \$14.3 million for the three months ended March 31, 2002 consisted principally of royalties, a product license option fee and license maintenance fees. In the first quarter of 2001, revenues of \$16.7 million under agreements with third parties consisted principally of royalties, a signing and licensing fee, milestone payments, portions of upfront fees paid to PDL pursuant to humanization agreements and a license maintenance fee.

Total costs and expenses for the three months ended March 31, 2002 were \$19.6 million compared with \$19.5 million in the comparable period in 2001.

Research and development expenses for the three months ended March 31, 2002 were \$13.2 million compared with \$13.7 million in the year- earlier quarter. Research and development costs decreased primarily due to lower clinical development expenses and reduced expenses as a result of the sale of the small molecule group.

General and administrative expenses for the three months ended March 31, 2002 increased to \$4.2 million from \$3.6 million in the comparable period in 2001. This increase was primarily the result of expenses associated with managing and supporting the Company's expanding operations including staff and support for general and administrative functions.

Interest expense for the three months ended March 31, 2002 and 2001 was essentially unchanged at \$2.2 million.

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, 2002, we had cash, cash equivalents and marketable securities in the aggregate of \$638.1 million, compared to \$650.3 million at December 31, 2001.

Net cash provided by our operating activities for the three months ended March 31, 2002 was approximately \$0.9 million compared with net cash used in our operating activities of \$1.2 million in the 2001 period. The change was primarily due to a decrease in interest receivable, interest payable, accrued clinical trials expense and other accrued liabilities, partially offset by an increase in other current assets for the 2002 period.

Net cash provided by our investing activities for the three months ended March 31, 2002 was \$112.2 compared to net cash used in our investing activities of \$218.5 million in 2001. The change in 2002 was primarily the result of maturities of marketable securities during the period as compared to our reinvestment activities associated with the purchases of short- and long-term investments in 2001.

Net cash provided by our financing activities for the three months ended March 31, 2002 was \$0.9 million compared to \$1.3 million in 2001. The change in 2002 from 2001 was primarily the result of a decrease in the exercise of outstanding 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 of third party licensees, including Synagis, Herceptin, Zenapax and Mylotarg; our ability to enter into additional collaborative, humanization and patent licensing arrangements; 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; resources we devote to 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, Somerville, New Jersey, Plymouth, Minnesota and Paris, France, we occupy leased facilities under agreements that expire in 2004, 2005, 2009 and 2003, 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 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 for two or more years, 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. 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. For certain 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.

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter as of March 31, 2002 are as follows:

(In thousands) CONTRACTUAL OBLIGATIONS (1)	PAYMENTS DUE BY PERIOD				
	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years	Total
Operating leases	\$ 1,246	\$ 2,276	\$ 1,667	\$ 1,457	\$ 6,646
Long-term debt	1,139	2,278	2,278	8,637	14,332
Convertible debentures (2)	8,250	16,500	16,500	150,000	191,250
Research funding	4,000	--	--	--	4,000
Capital improvements	7,700	--	--	--	7,700
Total contractual cash obligations	\$ 22,335	\$ 21,054	\$ 20,445	\$ 160,094	\$ 223,928

1. This table does not include (a) any milestone payments 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 to third parties as the amounts of such payments and / or likelihood of such payments are not known, (c) amounts that may be committed to construct our new manufacturing plant and (d) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

2. Our convertible debenture may be converted to common stock prior to the maturity date and therefore may not require use of our capital resources.

We are currently improving our existing manufacturing plant in Plymouth, Minnesota in order to manufacture initial commercial supplies of certain products, including at least ZamyL. We currently estimate this capital project will cost approximately \$10 million. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and are in negotiations with a developer to build a new commercial manufacturing plant on this property. When we implement these plans we will incur substantial costs. If the project moves forward, we expect to expend approximately \$200 million over the next three years.

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. The Company does not currently hedge interest rate exposure. As of March 31, 2002, 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, 2001.

PART II. OTHER INFORMATION

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. 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.

Although we have recorded small profits for the past two years, in general, our expenses have exceeded revenues. As of March 31, 2002, we had an accumulated deficit of approximately \$74 million. Our expenses may 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 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. 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 corporate collaborations 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, and
- our ability to successfully defend and enforce our patents.

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

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 collaborative, humanization, and patent licensing agreements. 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 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.

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. We recently entered into an agreement with our Chairman of the Board under which his 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.

We may not be able to obtain regulatory approvals required to market ZamyL.

We completed a Phase III clinical trial for our humanized antibody ZamyL in patients with acute myeloid leukemia. The trial compared treatment with ZamyL plus a standardized chemotherapy regimen to treatment with chemotherapy alone in patients who had failed to achieve complete remission with initial therapy, or who had relapsed within one year of achieving complete remission. Our initial review of the preliminary data from this trial indicated that ZamyL demonstrated a statistically significant difference in the overall response rate for patients who received ZamyL plus chemotherapy compared with patients who received chemotherapy alone. However, our Phase III study of ZamyL failed to meet the primary endpoint of the trial, requiring a complete response to occur within 70 days of the initiation of therapy. While we believe that additional endpoints may demonstrate that ZamyL was beneficial in this trial, we cannot predict whether the FDA or European regulatory authorities will accept our analysis of the relevant endpoints for this trial.

Further, the results seen in the initial review of the preliminary data may differ from the results that will be obtained as additional data are obtained and as the data are further analyzed. Accordingly, we cannot assure you that the complete analysis will confirm the results of the initial review, and the results of the complete analysis could be materially different from those seen in the initial review. Thus, there can be no assurance that the complete data and analysis from the Phase III clinical trial of ZamyL will support the filing of a BLA or approval of the product by the FDA or other regulatory authorities.

Also, we are in the process of analyzing survival rates for the ZamyL plus chemotherapy patient group and the chemotherapy only group as well as for various subgroups. If no discernable differences are apparent, then regulatory authorities may not attribute sufficient benefit to receiving ZamyL and, therefore, may not approve ZamyL for marketing. Moreover, only a limited analysis of adverse events occurring in this trial has been completed to date. In this preliminary review, serious adverse events occurred with greater frequency in patients receiving ZamyL plus chemotherapy (66 of 94 patients, 70%) than in patients receiving chemotherapy alone (49 of 97 patients, 50%)($p=0.005$). However, investigators attributed the serious adverse events to ZamyL therapy in only 13 of these 66 patients. No significant differences for serious adverse events were seen between treatment groups for any body system. Further, the mortality during induction therapy, defined as the first 70 days after initiation of therapy, was similar for the ZamyL plus chemotherapy (15%) and chemotherapy alone (13%) groups. However, if regulatory authorities determine that ZamyL causes an unacceptable incidence or severity of side effects, we may not be able to obtain regulatory approval of the drug, or further development may be slowed by the need to find dosing regimens that do not cause such side effects.

In addition, we initiated the Phase III study without a meeting with the FDA or European regulatory authorities to discuss the protocol and its adequacy to support approval of ZamyL. Once we analyze all of the data for the Phase III trial, discuss such data

with regulatory authorities, and/or file for regulatory approval, we may discover that the FDA or European regulatory authorities may not agree that the study will be adequate to obtain regulatory approval.

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 U.S. 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. Also, three opposition statements were filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998. We have received a final decision from the Japanese patent examiner supporting one aspect of the position of the opponents, and we are currently preparing a response. If the examiner maintains her decision, we will have the opportunity to appeal to the Japanese Supreme Court. The patent will remain valid and enforceable during this appeal process.

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.

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. 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 SMART[®] 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 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, however, do not cover treatment of either Crohn's disease or psoriasis - - - the two indications currently being investigated in our SMART Anti-Gamma Interferon Antibody clinical trials. Additional examples include an issued U.S. patent to Schering Corporation that may cover our humanized anti-IL-4 antibody, and issued U.S. and European patents to Genetics Institute (now a wholly-owned subsidiary of Wyeth) that may cover our SMART Anti-IL-12 Antibody. 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 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 conducted only a limited number of clinical trials to date. Moreover, 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 has been amended in that trial to attempt to determine an effective dosing regimen.

Even when a drug candidate shows indications 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 addressed 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. As a result, 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 collaborative agreements with several pharmaceutical and other companies to develop, manufacture and market Zenapax and some of our potential products. In some cases, we are relying on our collaborative 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 collaborative agreements can generally be terminated by our partners on short notice. A collaborator 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 collaborator continues its contributions 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 collaborative 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 collaborative partner's own financial, competitive, marketing and strategic considerations. Such considerations include:

- the commitment of management of the collaborative partners to the continued development of the licensed products or technology
- the relationships among the individuals responsible for the implementation and maintenance of the collaborative efforts, and
- the relative advantages of alternative products or technology 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.

Our ability to enter into new collaborations and the willingness of our existing collaborators 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 collaborations and 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 collaborative 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 dependent on the efforts of third parties. If we are successful in obtaining regulatory approval to market Zamyly, we intend to market and sell Zamyly both directly and through arrangements with collaborative partners. If we were to enter into co-promotion or other marketing arrangements with collaborative partners, 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. We recently announced that Laurence Jay Korn, Ph.D., a co-founder of PDL and its Chief Executive Officer since 1987, has relinquished his responsibilities as Chief Executive Officer. Dr. Korn will continue to serve as Chairman of the Board and Douglas O. Ebersole has been appointed our Chief Executive Officer on an interim basis. In addition, we announced that Daniel J. Levitt, M.D., Ph.D., President, Research and Development, has resigned. We believe that existing management can operate the Company effectively while we conduct searches to fill key positions; however, if we are unsuccessful in filling these positions or retaining qualified personnel, or if the searches are prolonged, our business could be impaired. In addition, we face competition for personnel from other companies, academic institutions, government entities and other organizations.

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, GlaxoSmithKline is responsible for manufacturing the humanized anti-IL-4 antibody and Scil Biomedicals is responsible for manufacturing the SMART Anti-L-Selectin Antibody. 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. 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 currently plan to improve our existing manufacturing plant in order to manufacture initial commercial supplies of certain products, including at least Zamyly. Our ability to file for, and to obtain, regulatory approval for Zamyly, as well as the timing of such filing, 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 this product.

In addition, we plan to construct a new commercial manufacturing plant. When 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. In May 2001, Novartis 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.

In addition to the risks described above with respect to Zamy, 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 U.S. and other countries. In the U.S., pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and nonclinical 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.

In addition to the requirement for FDA approval of each pharmaceutical product, each pharmaceutical product manufacturing facility must be registered with, and approved by, the FDA. The manufacturing 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 U.S., 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 U.S., we and our collaborative partners are subject to foreign regulatory requirements and, if the particular product is manufactured in the U.S., 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 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 U.S., 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 U.S. 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 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.

Potential new accounting pronouncements may impact our future financial position and results of operations.

There may be potential new accounting pronouncements or regulatory rulings which may have an impact on our future financial position and results of operations. In particular, there are a number of rule changes and proposed legislative initiatives following the Enron bankruptcy which could result in changes in accounting rules, including legislative and other proposals to account for employee stock options as an expense. These and other potential changes could materially increase the expenses we report under generally accepted accounting principles, and adversely affect our operating results.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a. Exhibits

None

b. Reports on Form 8-K filed during the quarter ended March 31, 2002.

The Company filed a Current Report on Form 8-K on March 20, 2002 (SEC File No. 000-19756) announcing the results of a Phase II clinical trial of Zenapax in the treatment of psoriasis.

SIGNATURES

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

Dated: May 13, 2002

PROTEIN DESIGN LABS, INC.
(Registrant)

By: /s/ Douglas O. Ebersole

Douglas O. Ebersole
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Robert Kirkman

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

