UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2001

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	**94-3023969**
(State or Other Jurisdiction of Incorporation or Organization)	(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 [X] NO [ ]

As of October 31, 2001, there were 87,935,982 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.
QUARTERLY REPORT ON FORM 10-Q FOR THE PERIOD ENDED SEPTEMBER 30, 2001
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Protein Design Labs, our logo and SMART are registered U.S. trademarks and Nuvion, Remitogen and Zamyl 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 (loss) per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Revenues:				
Revenue under agreements with third parties	$ 8,055	$ 4,702	$ 37,433	$ 33,045
Interest and other income	8,616	4,892	27,057	12,413
Total revenues	16,671	9,594	64,490	45,458
Costs and expenses:				
Research and development	12,463	9,442	38,342	30,726
General and administrative	3,736	2,991	11,408	8,319
Interest expense	2,248	2,255	6,745	5,715
Total costs and expenses	18,447	14,688	56,495	44,760
Net income (loss)	$ (1,776)	$ (5,094)	$ 7,995	$ 698

Net income (loss) per share:				
Basic	$ (0.02)	$ (0.06)	$ 0.09	$ 0.01
Diluted	$ (0.02)	$ (0.06)	$ 0.08	$ 0.01
Weighted average number of shares:				
Basic	87,718	80,100	87,464	78,990
Diluted	87,718	80,100	94,239	86,738

See accompanying notes

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

	September 30, 2001 (unaudited)	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 136,418	$ 421,541
Marketable securities	512,012	239,632
Other current assets	6,319	1,980
Total current assets	654,749	663,153
Property, plant and equipment, net	39,057	37,673
Convertible note receivable	30,000	--
Other assets	3,539	4,154
	$ 727,345	$ 704,980
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,282	$ 1,062
Accrued compensation	1,509	1,729
Accrued clinical trials	2,120	1,103
Accrued interest	1,008	3,071
Other accrued liabilities	2,347	2,692
Deferred revenue	100	1,455
Current portion of long-term debt	424	400
Total current liabilities	8,790	11,512
Convertible subordinated notes	150,000	150,000
Other long-term debt	9,004	9,324
Total liabilities	167,794	170,836
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; 87,823 and 87,152 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively	878	872
Additional paid-in capital	618,010	611,254
Accumulated deficit	(70,575)	(78,570)
Accumulated other comprehensive income	11,238	588
Total stockholders' equity	559,551	534,144
	$ 727,345	$ 704,980

See accompanying notes

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

	Nine Months Ended September 30,	
	2001	2000
Cash flows from operating activities:		
Net income	$ 7,995	$ 698
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,508	2,598
Amortization of convertible notes offering costs	541	298
Other	(2,950)	(288)
Changes in assets and liabilities:		
Other current assets	(4,339)	(866)
Other assets	74	(4,433)
Accounts payable	220	(159)
Accrued liabilities	(1,611)	1,085
Deferred revenue	(1,355)	802
Total adjustments	(5,912)	(963)
Net cash provided by (used in) operating activities	2,083	(265)
Cash flows from investing activities:		
Purchase of convertible note	(30,000)	--
Purchases of marketable securities	(437,011)	(52,500)
Maturities of marketable securities	177,885	5,000
Purchases of property, plant and equipment	(4,546)	(2,520)
Net cash used in investing activities	(293,672)	(50,020)
Cash flows from financing activities:		
Proceeds from convertible notes	--	150,000
Proceeds from issuance of capital stock, net of issuance costs	6,762	356,604
Payments on other long-term debt	(296)	(273)
Net cash provided by financing activities	6,466	506,331
Net increase (decrease) in cash and cash equivalents	(285,123)	456,046
Cash and cash equivalents at beginning of period	421,541	17,138
Cash and cash equivalents at end of period	$ 136,418	$ 473,184

See accompanying notes

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2001
(unaudited)

Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. 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 in the United States, Europe and Japan for its antibody humanization technology.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The Consolidated Balance Sheet as of September 30, 2001, the Consolidated Statements of Operations for the three and nine months ended September 30, 2001 and 2000 and the Consolidated Statements of Cash Flows for the nine months ended September 30, 2001 and 2000 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, 2000. The Consolidated Balance Sheet as of December 31, 2000 is derived from 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. The "Marketable securities" line item in the Consolidated Balance Sheets includes the interest receivable associated with all marketable securities. The "Other" adjustments line item in the Consolidated Statements of Cash Flows represents the accretion of the book value of certain debt securities. We place our cash and marketable debt securities with high-credit-quality financial institutions and in securities of the U.S. government and 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
September 30, 2001				
Securities of the U.S. Government and its agencies maturing:				
within 1 year	$ 10,221	$ 61	$ --	$ 10,282
between 1-3 years	363,928	6,346	(13)	370,261
U.S. corporate debt securities maturing:				
between 1-3 years	126,625	4,844	--	131,469
Total marketable debt securities	$ 500,774	$ 11,251	$ (13)	$ 512,012

During the periods ended September 30, 2001 and 2000, there were no realized gains or losses on the sale of available-for-sale securities, as all securities liquidated prior to this 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 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 when royalty reports are received from the third party. 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 as revenue when there are no future performance obligations remaining with respect to such fees.

Net Income (Loss) Per Share

In accordance with Financial Accounting Standards Board Statement No. 128, "Earnings Per Share" (FAS 128), basic and diluted net income (loss) per share amounts have been computed using the weighted average number of shares of common stock outstanding during the periods presented. Calculation of diluted net income per share also includes the dilutive effect of outstanding stock options, 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. We incurred a net loss for the three month periods ended September 30, 2001 and 2000, and as such, we did not include the effect of outstanding stock options or convertible debt in the diluted net loss per share calculation as their effect is anti-dilutive.

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

(In thousands, except basic and diluted net income (loss) per share)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Numerator:				
Net income (loss)	$ (1,776)	$ (5,094)	$ 7,995	$ 698
Denominator:				
Basic net income (loss) per share - weighted-average shares	87,718	80,100	87,464	78,990
Dilutive potential common shares:				
Stock Options	--	--	6,775	7,748
Denominator for diluted net income (loss) per share	87,718	80,100	94,239	86,738
Basic net income (loss) per share	$ (0.02)	$ (0.06)	$ 0.09	$ 0.01
Diluted net income (loss) per share	$ (0.02)	$ (0.06)	$ 0.08	$ 0.01

Comprehensive Income

For the three months ended September 30, 2001 and 2000, total comprehensive income was $4.7 million and $4.5 million, respectively. For the nine months ended September 30, 2001 and 2000, total comprehensive income was $18.7 million and $1.1 million, respectively. Total comprehensive income is comprised of net income (loss) and unrealized gains and losses on the Company's available-for-sale securities.

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), which was adopted January 1, 2001. The adoption of FAS 133 did not have an effect on the results of operations or the financial position of the Company because the Company does not hold or use derivatives.

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, management accrues an amount based on its estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial. In addition, funded research is expensed on a straight-line basis over the period of the funding. Our estimates and assumptions could differ significantly from the amounts which may actually be incurred.

Research and Development Funding

In May 2001, we entered into a Collaboration Agreement with Exelixis, Inc. to provide $4.0 million in annual research funding for two or more years, and purchased a $30.0 million note, which is convertible after the first year of the collaboration into shares of

Exelixis common stock. For the three months ended September 30, 2001, we expensed $1.0 million in funding under this commitment.

Commitments

In June 2001, we leased additional general office space in Fremont, California under an agreement that will expire in August 2004. In May 2001, we leased additional general office and warehousing space in Plymouth, Minnesota under an agreement that will expire in February 2009, subject to our option to extend the lease for an additional five year term.

In September 2001, we extended the term of our existing lease on our manufacturing, laboratory and office space in Plymouth, Minnesota. Our lease will terminate in February 2009, subject to our option to extend the lease for an additional five year term.

At September 30, 2001, the additional future minimum non-cancelable payments under these operating lease agreements are approximately as follows (in thousands):

2001 (Remaining term)	$ 132
2002	533
2003	547
2004	861
2005	699
Thereafter	2,533
Total	5,305

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.

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, 2000.

OVERVIEW

In general, we have a history of operating losses and may not achieve sustained profitability. Our expenses have generally exceeded revenues. As of September 30, 2001, we had an accumulated deficit of approximately $70.1 million. Our losses 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 new research areas 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, 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 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 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.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2001 and 2000

The Company's total revenues for the three months ended September 30, 2001 were $16.7 million compared to $9.6 million in the third quarter of 2000. Total revenues recognized under agreements with third parties were $8.1 million in the third quarter of 2001 compared to $4.7 million in the comparable period in 2000. Interest and other income was $8.6 million in the third quarter of 2001 compared to $4.9 million in the comparable period in 2000, reflecting the increased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of our public offering of common stock in the second half of 2000, which raised approximately $343.6 million in net proceeds.

Revenues under agreements with third parties of $8.1 million for the three months ended September 30, 2001 consisted principally of royalties, a milestone payment and license maintenance fees. In the third quarter of 2000, revenues of $4.7 million under agreements with third parties consisted principally of royalties, portions of upfront fees paid to PDL pursuant to humanization agreements, research and development reimbursement funding, a milestone payment earned under a humanization agreement and a license maintenance fee.

Total costs and expenses for the three months ended September 30, 2001 were $18.4 million compared with $14.7 million in the comparable period in 2000.

Research and development expenses for the three months ended September 30, 2001 were $12.5 million compared with $9.4 million in the year- earlier quarter. Research and development costs increased primarily due to a payment to a third party related to research and development funding, the expansion of clinical development programs, including staff and support for both clinical development and manufacturing process development.

General and administrative expenses for the three months ended September 30, 2001 increased to $3.7 million from $3.0 million in the comparable period in 2000. These increases were primarily the result of expenses associated with managing and supporting the Company's expanding operations including pre-marketing expenses associated with our clinical development program.

Interest expense for the three months ended September 30, 2001 was essentially unchanged at $2.2 million compared to $2.3 million, in the year-earlier period.

Nine Months Ended September 30, 2001 and 2000

The Company's total revenues for the nine months ended September 30, 2001 were $64.5 million compared to $45.5 million in the comparable period in 2000. Total revenues recognized under agreements with third parties were $37.4 million in the nine months ended September 30, 2001 compared to $33.0 million in the comparable period in 2000. Interest and other income was $27.1 million in the nine month period of 2001 compared to $12.4 million in the comparable period in 2000, reflecting the increased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of our public offering of common stock in the second half of 2000, which raised approximately $343.6 million in net proceeds.

Revenues under agreements with third parties of $37.4 million for the nine months ended September 30, 2001 consisted principally of royalties, signing and licensing fees, milestone payments, portions of upfront fees paid to PDL pursuant to humanization agreements and license maintenance fees. In the comparable period in 2000, revenues of $33.0 million under agreements with third parties consisted principally of royalties, signing and licensing fees, portions of upfront fees paid to PDL pursuant to humanization agreements, research and development reimbursement funding, milestone payments earned under licensing agreements and license maintenance fees.

Total costs and expenses for the nine months ended September 30, 2001 were $56.5 million compared with $44.8 million in the comparable period in 2000.

Research and development expenses for the nine months ended September 30, 2001 were $38.3 million compared with $30.7 million in the year- earlier period. Research and development costs increased primarily due to the expansion of clinical development programs, including staff and support for both clinical development and manufacturing process development and payments to third parties related to manufacturing of certain potential products and research and development funding.

General and administrative expenses for the nine months ended September 30, 2001 increased to $11.4 million from $8.3 million in the comparable period in 2000. These increases were primarily the result of expenses associated with managing and supporting the Company's expanding operations, including pre-marketing expenses associated with our clinical development program.

Interest expense for the nine months ended September 30, 2001 was $6.7 million as compared to $5.7 million in the year-earlier period, primarily due to the interest expense associated with our convertible subordinated notes issued on February 15, 2000.

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 September 30, 2001, we had cash, cash equivalents and marketable securities in the aggregate of $648.4 million, compared to $661.2 million at December 31, 2000. The cash balance at September 30, 2001, reflects a reduction due to a $30 million loan to Exelixis, Inc. associated with our cancer target discovery collaboration announced in May 2001.

As set forth in the Consolidated Statements of Cash Flows, net cash provided by our operating activities for the nine months ended September 30, 2001 was approximately $2.1 million compared with net cash used in our operating activities of $0.3 million in the 2000 period. The change was primarily due to our net income for the 2001 period.

As set forth in the Consolidated Statements of Cash Flows, net cash used in our investing activities for the nine months ended September 30, 2001 was $293.7 compared to $50.0 million in 2000. The change in 2001 was primarily the result of our reinvestment activities associated with the purchases of marketable securities and a convertible note.

As set forth in the Consolidated Statements of Cash Flows, net cash provided by our financing activities for the nine months ended September 30, 2001 was $6.5 million compared to $506.3 million in 2000. The change in 2001 from 2000 was primarily the result of our sale of $150 million of convertible subordinated notes in February 2000 and our public offering of common stock in the second half of 2000, which raised approximately $343.6 million in net proceeds.

Our future capital requirements will depend on numerous factors, including, among others, 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.

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 September 30, 2001, 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, 2000.

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 in this document and in our Annual Report on Form 10-K

for the year ended December 31, 2000. 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.

Our expenses have generally exceeded revenues. As of September 30, 2001, we had an accumulated deficit of approximately $ 70.1 million. Our losses 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 new research areas 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.

In addition, our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include 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.

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 recently filed our response to the European Patent Office. Also, three opposition statements have been filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998. We received a notice from the Japanese Patent Office supporting one aspect of the position of the opponents to our Japanese humanization patent in the Japanese Patent Office opposition proceeding. We have filed a response to this notice and are awaiting a decision from the Japanese Patent Office Examiner.

We intend to vigorously defend our patents 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 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 an allowed divisional patent application in Europe 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 such European patent or whether its divisional patent application, once issued, will survive opposition proceedings. 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 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.

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.

Larger and later stage clinical trials may not produce the same results as early stage 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.

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 the 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 we may choose not to continue this trial or to further develop Nuvion for psoriasis. As a second example, Remitogen (SMART 1D10 Antibody) produced partial clinical responses in some B-cell lymphoma patients but at some dose levels there were significant side effects. Hence, we are conducting a Phase II trial of Remitogen to determine a useful dosing regimen.

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.

For example, we have entered Zamyl (SMART M195 Antibody) into a Phase III clinical trial in acute myelogenous leukemia with a clinical regimen that has not been tested previously with this antibody in combination with chemotherapy. Results from our prior Phase II and Phase II/III studies showed only a limited number of complete and partial remissions using the antibody without concomitant chemotherapy. In addition, based in part on the nature and severity of the disease, 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. This study may not be successful, or the FDA or European regulatory authorities may not agree that the study will be adequate to obtain regulatory approval, even if the study is successful.

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.

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 plc 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 current manufacturing plant in order to manufacture initial commercial supplies of certain products, including at least Zamyl in the event that the Phase III trial of that antibody is successful. Our ability to file for, and to obtain, marketing approval for Zamyl, as well as the timing of such filing, will depend on our ability to successfully improve our current 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. Recently, 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.

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, marketing 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 marketing 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.

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. Because we are located in a high technology area, we face competition for personnel from other companies, academic institutions, government entities and other organizations. We are currently conducting a search for several senior management personnel. If we are unsuccessful in filling these positions or retaining qualified personnel, our business could be impaired.

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.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a. Exhibits

None

b. Reports on Form 8-K filed during the quarter ended September 30, 2001.

None

SIGNATURES

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

Dated: November 9, 2001

PROTEIN DESIGN LABS, INC.
(Registrant)

By: /s/ Laurence Jay Korn

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

By: /s/ Robert Kirkman

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