

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 September 30, 2002

OR

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

Commission File Number: 0-19756

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

Yes ☒

No ☐

As of October 31, 2002, there were 89,062,766 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.

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Signatures

Protein Design Labs, Nuvion and SMART are registered U.S. trademarks and the PDL logo and Zaml 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 (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
<i>(In thousands, except per share data)</i>	2002	2001	2002	2001
Revenues:				
Royalties	\$ 5,991	\$ 4,905	\$ 33,158	\$ 24,973
License and other	<u>551</u>	<u>3,150</u>	<u>2,502</u>	<u>12,497</u>
Total revenues	6,542	8,055	35,660	37,470
Costs and expenses:				
Research and development	14,306	12,463	42,268	38,342
General and administrative	<u>4,735</u>	<u>3,736</u>	<u>13,681</u>	<u>11,408</u>
Total costs and expenses	<u>19,041</u>	<u>16,199</u>	<u>55,949</u>	<u>49,750</u>
Operating loss	(12,499)	(8,144)	(20,289)	(12,280)
Interest income	6,542	8,616	20,135	27,020
Interest expense	<u>(2,034)</u>	<u>(2,248)</u>	<u>(6,516)</u>	<u>(6,745)</u>
Net income (loss)	<u>\$ (7,991)</u>	<u>\$ (1,776)</u>	<u>\$ (6,670)</u>	<u>\$ 7,995</u>
Net income (loss) per share:				
Basic	<u>\$ (0.09)</u>	<u>\$ (0.02)</u>	<u>\$ (0.08)</u>	<u>\$ 0.09</u>
Diluted	<u>\$ (0.09)</u>	<u>\$ (0.02)</u>	<u>\$ (0.08)</u>	<u>\$ 0.08</u>
Weighted average number of shares:				
Basic	<u>88,999</u>	<u>87,718</u>	<u>88,798</u>	<u>87,464</u>
Diluted	<u>88,999</u>	<u>87,718</u>	<u>88,798</u>	<u>94,239</u>

See accompanying notes

PROTEIN DESIGN LABS, INC.
CONSOLIDATED BALANCE SHEETS

<i>(In thousands, except per share data)</i>	September 30, 2002	December 31, 2001
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 239,439	\$ 120,268
Marketable securities	384,390	530,047
Other current assets	<u>3,662</u>	<u>4,144</u>
Total current assets	627,491	654,459
Property, plant and equipment, net	61,340	42,111
Convertible note receivable	30,000	30,000
Other assets	<u>4,394</u>	<u>3,328</u>
Total assets	<u>\$ 723,225</u>	<u>\$ 729,898</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 932	\$ 1,249
Accrued compensation	1,804	2,000
Accrued clinical trial costs	3,311	2,588
Accrued interest	1,008	3,071
Other accrued liabilities	3,250	3,123
Deferred revenue	549	100
Current portion of other long-term debt	<u>458</u>	<u>432</u>
Total current liabilities	11,312	12,563
Convertible subordinated notes	150,000	150,000
Other long-term debt	<u>8,544</u>	<u>8,892</u>
Total liabilities	169,856	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; 89,025 and 88,499 shares issued and outstanding at September 30, 2002 and December 31, 2001, respectively	890	885
Additional paid-in capital	627,390	624,094
Accumulated deficit	(82,593)	(75,923)
Accumulated other comprehensive income	<u>7,682</u>	<u>9,387</u>
Total stockholders' equity	553,369	558,443
Total liabilities and stockholders' equity	<u>\$ 723,225</u>	<u>\$ 729,898</u>

See accompanying notes

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

	Nine Months Ended September 30,	
	2002	2001
<i>(In thousands)</i>		
Cash flows from operating activities:		
Net income (loss)	\$ (6,670)	\$ 7,995
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	3,971	3,508
Amortization of convertible notes offering costs	540	541
Changes in assets and liabilities:		
Interest receivable	3,468	(2,950)
Other current assets	433	(4,339)
Other assets	(316)	74
Accounts payable	(317)	220
Accrued liabilities	(1,409)	(1,611)
Deferred revenue	449	(1,355)
Total adjustments	6,819	(5,912)
Net cash provided by operating activities	149	2,083
Cash flows from investing activities:		
Purchase of convertible note	--	(30,000)
Purchases of marketable securities	(79,954)	(437,011)
Maturities of marketable securities	220,000	177,885
Purchase of property, plant and equipment	(24,003)	(4,546)
Net cash provided by (used in) investing activities	116,043	(293,672)
Cash flows from financing activities:		
Proceeds from issuance of capital stock, net of issuance costs	3,301	6,762
Payments on other long-term debt	(322)	(296)
Net cash provided by financing activities	2,979	6,466
Net increase (decrease) in cash and cash equivalents	119,171	(285,123)
Cash and cash equivalents at beginning of period	120,268	421,541
Cash and cash equivalents at end of period	\$ 239,439	\$ 136,418
Non-cash activities:		
Exchange of assets for third party preferred stock	\$ 1,290	\$ --

See accompanying notes

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2002
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. (PDL) is a biotechnology company engaged in the development of humanized antibodies to prevent or treat various disease conditions. We currently have antibodies under development for autoimmune and inflammatory conditions, asthma and cancer. We hold fundamental patents for our antibody humanization technology.

Basis of Presentation and Responsibility for Quarterly Financial Statements

The Consolidated Balance Sheet as of September 30, 2002, the Consolidated Statements of Operations for the three and nine months ended September 30, 2002 and 2001 and the Consolidated Statements of Cash Flows for the nine months ended September 30, 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 normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission. The accompanying financial statements should be read in conjunction with our Annual Report on Form 10-K/A 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.

Reclassifications

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

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.

Revenue Recognition

We currently recognize three types of revenues resulting from the licensing and use of our technology, and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use in drug development and production. Revenues, and their respective treatment for financial reporting purposes, are as follows:

Upfront and License Maintenance Fees

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

- Under patent license agreements, the licensee typically obtains a non-exclusive license to our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements.
- Under patent rights agreements, licensees currently purchase a research patent license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. All of the research is performed by the licensee, and therefore, upon delivery of the patent rights agreements, the earnings process is complete and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses. Subsequent to execution of the agreement, the licensee has the right to purchase patent licenses to certain designated targets, for which the licensee pays separate consideration at a later date. Such consideration is recognized upon exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.
- Under our humanization agreements, at times referred to in our previous filings as research and development agreements, the licensee typically pays an upfront fee for us to humanize an antibody. These upfront fees are recognized on a percent completion basis, as the humanization work is performed, which is typically over three to six months.
- Under patent license agreements and humanization agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

Milestone Payments

Certain agreements include milestone payments which are recognized as revenue when earned as part of a multi-element arrangement. Each element of the contract represents a separate earnings process and as such we recognize milestone amounts when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones include delivery of a humanized antibody meeting a certain binding affinity and, at the customer's election, delivery of a cell line meeting certain criteria described in the original agreement. We recognize these milestones when we have no further performance obligations with respect to that milestone and the funding party confirms that the milestone stipulated in the agreement has been met.
- Patent license agreements and humanization agreements sometimes require our customers to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the customer's product. Because we have no obligations with respect to any of this activity, we record these milestone payments as revenue when received and we have confirmed that the milestone has been achieved.
- We may also receive certain milestone payments in connection with licensing technology to or from our partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when we or they achieve certain levels of development with respect to the licensed technology. These fees are recognized when we have no further performance obligations with respect to the applicable milestone and it is confirmed that the milestone stipulated in the agreement has been met.

Royalties

Under some of our agreements, we also receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from such licensees approximately one quarter in arrears; that is, generally at the end of the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we have adopted an accounting policy of recording the royalty revenue in the quarter it is reported to us (i.e. a one quarter lag).

Net Income (Loss) Per Share

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

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

<i>(In thousands, except per share data)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Numerator:				
Net income (loss)	\$ (7,991)	\$ (1,776)	\$ (6,670)	\$ 7,995
Denominator:				
Basic net income (loss) per share - weighted- average shares	88,999	87,718	88,798	87,464
Dilutive potential common shares - stock options	--	--	--	6,775
Denominator for diluted net income (loss) per share	<u>88,999</u>	<u>87,718</u>	<u>88,798</u>	<u>94,239</u>
Basic net income (loss) per share	<u>\$ (0.09)</u>	<u>\$ (0.02)</u>	<u>\$ (0.08)</u>	<u>\$ 0.09</u>
Diluted net income (loss) per share	<u>\$ (0.09)</u>	<u>\$ (0.02)</u>	<u>\$ (0.08)</u>	<u>\$ 0.08</u>

For the three months ended September 30, 2002 and 2001 and the nine months ended September 30, 2002, 1,643,000, 4,784,000 and 2,402,000 shares respectively, related to outstanding stock options were excluded from the diluted net loss per share computation because the inclusion of these shares would be anti-dilutive due to the net loss in each period.

Comprehensive Income (Loss)

For the three months ended September 30, 2002 total comprehensive loss was \$(8.4) million as compared to total comprehensive income of \$4.7 million for the three months ended September 30, 2001. For the nine months ended September 30, 2002, total comprehensive loss was \$(8.4) million as compared to total comprehensive income of \$18.7 million for the nine months ended September 30, 2001. Total comprehensive income (loss) is comprised of net income (loss) 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, our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement

of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the trial. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial. 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 plus transaction costs incurred, which approximated \$1.3 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. We believe that if such amounts are paid, they will be recorded as an increase in the carrying value of the preferred stock.

Recent Accounting Pronouncements

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 in January 2002 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.

In June 2002, the FASB issued FAS 146, "Accounting for Costs Associated with Exit or Disposal Activities" (FAS 146), which addresses accounting for restructuring, discontinued operation, plant closing, or other exit or disposal activities. FAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. FAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The adoption of FAS 146 is not expected to have a significant impact on our financial position 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.

Capitalization of Interest Cost

In the third quarter ended September 30, 2002, we capitalized a portion of our interest on borrowings in connection with the renovation of our existing manufacturing facilities and the development activities for our future manufacturing facilities. Capitalized interest is added to the cost of the underlying assets and is amortized over the useful lives of the assets. Interest of \$0.2 million was capitalized in the period ended September 30, 2002. No interest was capitalized in 2001.

2. Short and Long-Term Investments

We invest our excess cash balances primarily in short-term and long-term marketable debt securities. These securities are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The cost of securities sold is based on the specific identification method, when applicable.

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			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<i>(In thousands)</i>				
September 30, 2002				
Securities of the U.S.				
Government and its				
agencies maturing:				
Less than 1 year	\$ 50,548	\$ 533	\$ --	\$ 51,081
Between 1-3 years	180,514	2,838	--	183,352
U.S. corporate debt				
securities maturing:				
Less than 1 year	85,301	1,795	--	87,096
Between 1-3 years	<u>60,345</u>	<u>2,516</u>	<u>--</u>	<u>62,861</u>
Total marketable debt				
securities	<u>\$ 376,708</u>	<u>\$ 7,682</u>	<u>\$ --</u>	<u>\$ 384,390</u>

During the nine months ended September 30, 2002 and 2001, there were no realized gains or losses on the sale of available-for-sale securities, as all securities liquidated in those periods were held to maturity.

3. Subsequent Events

In November 2002, we announced that the Company successfully filled two key positions. Specifically, on November 5, we announced that our Board of Directors elected Mark McDade to serve as our new Chief Executive Officer and a director of the Company. In addition, on November 7, we announced that our Board of Directors elected Steven Benner to serve as our new Senior Vice President and Chief Medical Officer.

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

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

OVERVIEW

In general, we have a history of operating losses and may not achieve sustained profitability. Although we have recorded small profits for the past two years, in general, our expenses have exceeded revenues. As of September 30, 2002, we had an accumulated deficit of approximately \$82.6 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 rights or patent licensing or humanization agreements, significant royalties on sales of products licensed under

our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

Our revenues, expenses and operating results will likely fluctuate in future periods. Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of our licensees, potential reductions in royalties payable to us due to credits for prior payments to us, the timing of royalty reports, some of which are required quarterly and others semi-annually, our method of accounting for royalty revenues from our licensees in the period reported to us, and our ability to successfully defend and enforce our patents.

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

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

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 recognized by us in our first and second quarters than in other quarters. The seasonality of Synagis sales could contribute to fluctuation of our royalty 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 plus transaction costs incurred, which approximated \$1.3 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. We believe that if such amounts are paid, they will be recorded as an increase in the carrying value of the preferred stock.

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:

We currently recognize three types of revenues resulting from the licensing and use of our technology, and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use in drug development and production. Revenues, and their respective treatment for financial reporting purposes, are as follows:

Upfront and License Maintenance Fees

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

- Under patent license agreements, the licensee typically obtains a non-exclusive license to our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements.
- Under patent rights agreements, licensees currently purchase a research patent license, in exchange for an upfront fee, and a right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. All of the research is performed by the licensee, and therefore, upon delivery of the patent rights agreements, the earnings process is complete and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses. Subsequent to execution of the agreement, the licensee has the right to purchase patent licenses to certain designated targets, for which the licensee pays separate consideration at a later date. Such consideration is recognized upon exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.
- Under our humanization agreements, at times referred to in our previous filings as research and development agreements, the licensee typically pays an upfront fee for us to “humanize” an antibody. These upfront fees are recognized on a percent completion basis, as the humanization work is performed, which is typically over three to six months.
- Under patent license agreements and humanization agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

Milestone Payments

Certain agreements include milestone payments which are recognized as revenue when earned as part of a multi-element arrangement. Each element of the contract represents a separate earnings process and as such we recognize milestone amounts when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our

customer confirms that we have met the requirements under the terms of the agreement. Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones include delivery of a humanized antibody meeting a certain binding affinity and, at the customer's election, delivery of a cell line meeting certain criteria described in the original agreement. We recognize these milestones when we have no further performance obligations with respect to that milestone and the funding party confirms that the milestone stipulated in the agreement has been met.
- Patent license agreements and humanization agreements sometimes require our customers to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the customer's product. Because we have no obligations with respect to any of this activity, we record these milestone payments as revenue when received and we have confirmed that the milestone has been achieved.
- We may also receive certain milestone payments in connection with licensing technology to or from our partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when we or they achieve certain levels of development with respect to the licensed technology. These fees are recognized when we have no further performance obligations with respect to the applicable milestone and it is confirmed that the milestone stipulated in the agreement has been met.

Royalties

Under some of our agreements, we also receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from such licensees' approximately one quarter in arrears; that is, generally at the end of the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we have adopted an accounting policy of recording the royalty revenue in the quarter it is reported to us (i.e. a one quarter lag).

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the trial. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2002 and 2001

Revenues

The Company's total revenues for the three months ended September 30, 2002 were \$6.5 million compared to \$8.1 million in the third quarter of 2001. Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth were \$6.0 million in the third quarter of 2002 compared to \$4.9 million in the comparable period in 2001. This \$1.1 million increase in royalty revenue was primarily the result of increased net sales of the product Herceptin partially offset by a change in estimated Zenapax royalties reported by our licensee Roche, related to sales reported to us in earlier periods. Royalty payments from sales of Herceptin accounted for 70% of our revenues for the three months ended September 30, 2002 compared to 39% in the comparable period in 2001. License and other revenue was \$0.6 million in the third quarter of 2002 compared to \$3.2 million in the comparable period in 2001. License and other revenue recognized primarily consists of upfront patent licensing and patent rights fees, amortization of upfront fees associated with humanization agreements and license maintenance fees. The \$2.6 million decrease in license and other revenue was primarily due to the recognition of a milestone associated with a development agreement in the third quarter of 2001, partially offset by an increase in the recognition of license maintenance fees in the third quarter of 2002.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2002 increased to \$14.3 million compared with \$12.5 million in the year-earlier quarter. Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. Research and development costs increased \$1.8 million for the three-month period ended September 30, 2002 as compared to the 2001 period primarily due to higher clinical development expenses for our major research and development projects, which increased by \$0.7 million, and an increase in research and development personnel headcount and associated costs. We expect our research and development expenses will increase further as we advance our product candidates into later stages of development and add new product candidates.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2002 increased to \$4.7 million from \$3.7 million in the comparable period in 2001. General and administrative costs include costs of personnel, professional services, consulting and other expenses related to our administrative functions and an allocation of facility costs. General and administrative expenses increased \$1.0 million for the three months ended September 30, 2002 as compared to the 2001 period primarily due to increased personnel and recruiting costs and legal costs related to our intellectual property, licensing and other contractual matters. We expect that general and administrative expenses will continue to increase as we continue to build our organization.

Interest Income and Expense

Interest income for the three months ended September 30, 2002 decreased to \$6.5 million compared to \$8.6 million in the 2001 period reflecting the decreased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates.

Interest expense for the three months ended September 30, 2002 decreased to \$2.0 million as compared to \$2.2 million in the 2001 period as a result of capitalizing \$0.2 million of our interest cost. In September 2002, we capitalized a portion of our interest cost in connection with the renovation of our existing manufacturing facilities and the development activities for our future manufacturing facilities.

Nine Months Ended September 30, 2002 and 2001

Revenues

The Company's total revenues for the nine months ended September 30, 2002 were \$35.7 million compared to \$37.5 million in the 2001 period. Royalty revenues recognized under agreements with Roche, Genentech, MedImmune and Wyeth were \$33.2 million in the first nine months of 2002 compared to \$25.0 million in the comparable period in 2001. This \$8.2 million increase in royalty revenue was primarily the result of increased net sales of the products Synagis and Herceptin reported by two licensees. Royalty payments from two companies accounted for 50% and 35% of our revenues for the nine months ended September 30, 2002 compared to 36% and 23% in the 2001 period. License and other revenue was \$2.5 million for the nine months ended September 30, 2002 compared to \$12.5 million in the comparable period in 2001. License and other revenue recognized primarily consists of upfront patent licensing and patent rights fees, milestones, amortization of upfront fees associated with humanization agreements and license maintenance fees. The \$10.0 million decrease in license and other revenue was primarily due to the recognition of less revenue under patent licensing, patent rights, humanization agreements in the first nine months of 2002 as compared to the first nine months of 2001.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2002 increased to \$42.3 million compared with \$38.3 million in the year-earlier period. Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. Research and development costs increased \$4.0 million for the nine-month period ended September 30, 2002 as compared to the 2001 period primarily due to higher research and development funding provided to a third party, which increased by \$1.7 million, and an increase in research and development personnel headcount and associated costs. We expect our research and development expenses will increase further as we advance our product candidates' progress into later stages of development and add new product candidates.

Below is a summary of products and the related stages of development for each product in clinical development, including the research and development expenses recognized in connection with each product. The information in the column labeled "Estimated Completion of Phase" is only our estimate of the timing of completion of product development phases. The actual timing

of completion of those phases could differ materially from the estimates provided in the table. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the “Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we can not accurately predict the timing and level of such expenses,” “If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products,” “Our clinical trial strategy may increase the risk of clinical trial difficulties,” “If our collaborations are not successful, we may not be able to effectively develop and market some of our products,” “If we do not attract and retain key employees, our business could be impaired,” and “We may be unable to obtain or maintain regulatory approval for our products” sections of our Risk Factors below. For further information on our products refer to our Annual Report on Form 10-K/A filed with the Securities and Exchange Commission for the year ended December 31, 2001.

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Nine Months Ended September 30,	
					2002	2001
(In thousands)						
Humanized Anti-IL-4	Asthma	Phase IIa	GlaxoSmithKline	2003	\$ 2,251	\$ 2,106
SMART Anti-IL-12	Autoimmune Diseases	Phase I	--	2002	2,196	2,870
SMART Anti-Gamma Interferon			--		9,069	5,129
	Crohn's Disease	Phase II		2003		
Nuvion	Psoriasis	Phase I/II		2003		
			--		2,496	4,200
	Steroid Refractory Graft Vs. Host Disease	Phase II		2004		
	Primary Graft Vs. Host Disease	Phase I/II		2004		
	Ulcerative Colitis	Phase I		2003		
Remitogen			--		2,196	2,422
	Non-Hodgkin's B-Cell Lymphoma	Phase II		2002		
	Solid Tumors	Phase I		2003		
Zamyl	Acute Myeloid Leukemia	Phase III	--	Completed	3,927	4,213
Daclizumab	Asthma	Phase II	Roche	2003	5,946	6,394
Other (1)			--		<u>14,187</u>	<u>11,008</u>
Total Research and Development Costs					\$ 42,268	\$ 38,342

(1) No single potential product included in “other” constitutes more than 5% of the total research and development costs.

We cannot reliably estimate the overall completion dates or total costs to complete our major research and development programs. The clinical development portion of these programs spans as many as seven to ten years and any estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing biopharmaceutical products, including intense and changing government regulation, the uncertainty of future preclinical and clinical study results and success and uncertainties associated with process development and manufacturing. These risks and uncertainties make reliably estimating overall completion dates and total costs to complete development highly speculative. For additional discussion of factors affecting overall completion dates and total costs, see the “Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we cannot accurately predict the timing and level of such expenses” section of our Risk Factors below.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2002 increased to \$13.7 million from \$11.4 million in the comparable period in 2001. General and administrative costs include costs of personnel, professional services, consulting and other expenses related to our administrative functions and an allocation of facility costs. General and administrative expenses increased \$2.3 million for the nine months ended September 30, 2002 as compared to the 2001 period primarily due to increased personnel costs and legal costs related to our intellectual property, licensing and other contractual matters. We expect that general and administrative expenses will continue to increase as we continue to build our organization.

Interest Income and Expense

Interest income for the nine months ended September 30, 2002 decreased to \$20.1 million as compared to \$27.0 million in the 2001 period reflecting the decreased interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates.

Interest expense for the nine months ended September 30, 2002 decreased to \$6.5 million as compared to \$6.7 million in the 2001 period as a result of capitalizing \$0.2 million of our interest cost. In September 2002, we capitalized a portion of our interest cost in connection with the renovation of our existing manufacturing facilities and the development activities for our future manufacturing facilities.

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, 2002, we had cash, cash equivalents and marketable securities in the aggregate of \$623.8 million, compared to \$650.3 million at December 31, 2001.

Net cash provided by our operating activities for the nine months ended September 30, 2002 was approximately \$0.1 million compared with \$2.1 million in the 2001 period. The change was primarily due to a net loss for the nine months ended September 30, 2002, a decrease in interest receivable during the nine months ended September 30, 2002 versus an increase in interest receivable for the 2001 period and a decrease in other current assets during the nine months ended September 30, 2002 versus an increase in the prior-year period.

Net cash provided by our investing activities for the nine months ended September 30, 2002 was \$116.0 million compared to net cash used in our investing activities of \$293.7 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 nine months ended September 30, 2002 was \$3.0 million compared to \$6.5 million in the 2001 period. 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 by third party licensees, including Synagis, Herceptin, Zenapax and Mylotarg; our ability to enter

into additional collaborative, humanization, patent license and patent rights agreements; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; investment in existing and new research and development programs; time required to gain regulatory approvals; 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; Menlo Park, California; Somerville, New Jersey; Plymouth, Minnesota and Paris, France, we occupy leased facilities under agreements that expire in 2004, 2005, 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. Exelixis will perform certain genetic screens and other research activities intended to identify and validate targets for antibody therapeutics in oncology. We received an exclusive, worldwide license to develop antibodies against certain targets identified by Exelixis that are involved in cell growth, cell death and proliferation. Exelixis has the right to co-fund development of antibodies resulting from the collaboration. For antibody products we develop that Exelixis elects not to co-fund, we have agreed to make specified milestone payments and royalty payments on any product sales.

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter, as of September 30, 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	\$ 1,220	\$ 2,158	\$ 1,617	\$ 1,080	\$ 6,075
Long-term debt	1,139	2,278	2,278	8,250	13,945
Convertible debentures (2)	8,250	16,500	161,688	--	186,438
Research funding	2,000	--	--	--	2,000
Capital improvements	<u>12,300</u>	<u>--</u>	<u>--</u>	<u>--</u>	<u>12,300</u>
Total contractual cash obligations	<u>\$ 24,909</u>	<u>\$ 20,936</u>	<u>\$165,583</u>	<u>\$ 9,330</u>	<u>\$220,758</u>

- (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 in the future 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 debentures 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. We currently estimate this capital project will cost approximately \$10 million. In March 2002, we purchased approximately 29 acres in Brooklyn Park, Minnesota and we have begun to build a new commercial manufacturing plant on this property. As we implement these plans, we will incur substantial costs. 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. We do not currently hedge interest rate exposure. As of September 30, 2002, there has been no material change in our interest rate exposure from that described in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2001.

ITEM 4. CONTROLS AND PROCEDURES

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

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

PART II. OTHER INFORMATION

ITEM 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 September 30, 2002, we had an accumulated deficit of approximately \$82.6 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 partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We may be unable to achieve sustained profitability.

Our commitment of resources to the continued development of our products will require significant additional funds for development. Our operating expenses may also increase as:

- some of our earlier stage potential products move into later stage clinical development
- additional potential products are selected as clinical candidates for further development
- we invest in additional manufacturing capacity
- we defend or prosecute our patents and patent applications, and
- we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new agreements with third party business partners, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

Our revenues, expenses and operating results will likely fluctuate in future periods.

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be

predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon:

- the seasonality of sales of licensed products
- the existence of competing products
- the marketing efforts of our licensees
- potential reductions in royalties receivable due to credits for prior payments to us
- the timing of royalty reports, some of which are required quarterly and others semi-annually
- our ability to successfully defend and enforce our patents.

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

License and other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees, payments for manufacturing and clinical development services, and payments for the achievement of milestones under new and existing agreements with third party business partners. Revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

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

In addition, our expenses or other operating results may fluctuate due to the accounting treatment of securities we own or may purchase or securities we have issued or may issue. In May 2002, we entered into an agreement with our Chairman of the Board under which vesting of his stock options may accelerate in certain events, and such acceleration would trigger an accounting expense. In addition, we hold a \$30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the value of the Exelixis stock in our financial statements. Such a requirement could cause changes in the Exelixis stock price to contribute to fluctuation of our operating results from quarter to quarter.

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

Most of our current revenues are related to our humanization patents. At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European humanization patent. We have appealed this decision. Until our appeal is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if our appeal is unsuccessful, our ability to collect royalties on European sales of antibodies humanized by others would depend on the scope and validity of our second European patent, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, the Opposition Division's decision could encourage challenges of our related patents in other jurisdictions, including the 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 received a decision from the Japanese Opposition Board in March 2001, supporting one aspect of the position of the opponents, and we filed a response in September 2001. In April 2002, the examiner issued a further Office Action maintaining the earlier decision of the Opposition Board, to which we filed an additional response in May 2002. We now await a final decision from the examiner. If the examiner maintains her earlier decision, we will have the opportunity to appeal to the Tokyo High Court. The patent will remain valid and enforceable during this appeal process. If this appeal is unsuccessful, we will then have an opportunity to appeal to the Japanese Supreme Court.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings; however, we may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If our appeal with respect to our first European patent is unsuccessful or if the outcome of the other European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

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

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

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents.

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

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

We may require additional patent licenses in order to manufacture or sell our potential products.

Other companies, universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or may not be able to market our products at all.

Celltech has been granted a European patent covering humanized antibodies, which we have opposed. At an oral hearing in September 2000, the Opposition Division of the European Patent Office decided to revoke this patent. Celltech has appealed that decision. Also, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. In addition, Celltech has a third divisional application currently drafted with broad claims directed towards humanized antibodies. We cannot predict whether Celltech will be able to successfully appeal the decision of the Opposition Division with respect to their first European patent or whether Celltech's second European patent will be modified or revoked in any future opposition proceedings, or whether it will be able to obtain the grant of a patent from the pending divisional application with claims broad enough to generally cover humanized antibodies. Celltech has also been issued a corresponding U.S. patent that contains claims that may be considered broader in scope than their first European patent. We have entered into an agreement with Celltech providing each company with the right to obtain nonexclusive licenses for up to three antibody targets under the other company's humanization patents. Nevertheless, if our humanized antibodies were covered by Celltech's European or U.S. patents and if we were to need more than the three licenses under those patents currently available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

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

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

We are also aware of issued patents that could apply to one or more of our specific products. For example, a U.S. patent recently issued to Advanced Biotherapy, Inc. has claims to the use of anti-gamma interferon antibodies to treat certain autoimmune diseases. The currently issued 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, 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, and a recently issued U.S. patent to Genentech claiming humanized antibodies with certain framework region substitutions that may cover some of our antibodies in development. As a result, we might be required to obtain licenses from others. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or we may not be able to market our products at all.]

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

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products, and the majority of our expenses are to support these activities. The completion rate of clinical trials depends significantly upon the rate of patient enrollment, and our expense levels will vary depending upon the rate of enrollment. In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and is difficult to predict. The expenses associated with each phase of a trial depend upon the design of the trial. The design of each phase of trials depends in part upon results of prior phases, and additional trials may be necessary or appropriate at each phase. As a result the expense associated with future phases can not be predicted in advance. Further, we may decide to terminate trials in process or suspend trials. Failure to comply with extensive FDA regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to

unacceptable risks. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future.

If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products.

To obtain regulatory approval for the commercial sale of any of our potential products or to promote these products for expanded indications, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in indications for which approval is requested. We have 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 was amended in that trial to attempt to determine an effective dosing regimen. However, enrollment with this dosing regimen was progressing slowly. Therefore, in November 2002, we decided to terminate this study and we currently do not intend to conduct further clinical trials in this indication.

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

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

Continued funding and participation by partners will depend on the timely achievement of our research and development objectives, the retention of key personnel performing work under those agreements and on each partner's own financial, competitive, marketing and strategic considerations. Such considerations include:

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

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

Our lack of experience in sales, marketing and distribution may hamper market introduction and acceptance of our products.

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with partners. To market products directly, we must either establish a marketing group and direct sales force or obtain the assistance of another company. We may not be able to establish marketing, sales and distribution capabilities or succeed in gaining market acceptance for our products. If we were to enter into co-promotion or other marketing arrangements with pharmaceutical or biotechnology companies, our revenues would be subject to the payment provisions of these arrangements and dependent on the efforts of third parties. If we were to enter into co-promotion or other marketing arrangements with 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. In May 2002, we announced that Laurence Jay Korn, Ph.D., a co-founder of PDL and its Chief Executive Officer since 1987, relinquished his responsibilities as Chief Executive Officer. Dr. Korn continues to serve as Chairman of the Board and Douglas O. Ebersole is currently serving as our Chief Executive Officer on an interim basis. In addition, we announced in May 2002 that Daniel J. Levitt, M.D., Ph.D., President, Research and Development, resigned. We believe that existing management has operated the Company effectively while we conducted searches to fill key positions. In November 2002, we announced that the Company successfully filled two key positions. Specifically, on November 5, we announced that our Board of Directors elected Mark McDade to serve as our new Chief Executive Officer and a director of the Company. In addition, on November 7, we announced that our Board elected Steven Benner to serve as our new Senior Vice President and Chief Medical Officer. If we are unsuccessful in filling other positions or retaining qualified personnel, 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 are currently improving our existing manufacturing plant in order

to manufacture initial commercial supplies of certain products. Our ability to file for, and to obtain, regulatory approvals for such products, as well as the timing of such filings, will depend on our ability to successfully improve our existing manufacturing plant. We may be unable to do so, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis. Failure to do so could delay commercialization of our products.

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

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

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our SMART antibody technology. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

Any product that we or our collaborative partners succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, has received approval to market Simulect, a product competitive with Zenapax, in the U.S. and Europe. 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.

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 non-clinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires a number of years and the expenditure of substantial resources. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process and quality control procedures must conform to rigorous guidelines in order to receive FDA approval. Pharmaceutical product manufacturing establishments are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the 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 unfavorable FDA advisory panel recommendations
- delays in manufacturing or clinical trial plans
- fluctuations in our operating results
- disputes or disagreements with collaborative partners
- market reaction to announcements by other biotechnology or pharmaceutical companies
- announcements of technological innovations or new commercial therapeutic products by us or our competitors
- initiation, termination or modification of agreements with our collaborative partners
- loss of key personnel
- litigation or the threat of litigation
- public concern as to the safety of drugs developed by us
- sales of our common stock held by collaborative partners or insiders
- comments and expectations of results made by securities analysts, and
- general market conditions.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the common stock would likely drop significantly. A significant drop in the price of a company's common stock often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position and results of operations.

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

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

99.1 906 Certification for acting Chief Executive Officer

99.2 906 Certification for Principal Accounting Officer

(b) No Reports on Form 8-K were filed during the quarter ended September 30, 2002.

SIGNATURE

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

Dated: November 12, 2002

PROTEIN DESIGN LABS, INC.
(Registrant)

/s/ Douglas O. Ebersole
Douglas O. Ebersole
Chief Executive Officer (acting)
(Principal Executive Officer)

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

**CERTIFICATION BY DOUGLAS O. EBERSOLE PURSUANT TO
SECURITIES EXCHANGE ACT RULE 13a-14**

I, Douglas O. Ebersole, certify that:

1. I have reviewed the report being filed;
2. Based on my knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;
3. Based on my knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in the report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in paragraph (c) of this section) for the registrant and have:
 - a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the periodic reports are being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report ("Evaluation Date"); and
 - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
 - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

/s/ Douglas O Ebersole
Douglas O. Ebersole
Chief Executive Officer (acting)
(Principal Executive Officer)

**CERTIFICATION BY ROBERT L. KIRKMAN PURSUANT TO
SECURITIES EXCHANGE ACT RULE 13a-14**

I, Robert L. Kirkman, certify that:

1. I have reviewed the report being filed;
2. Based on my knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;
3. Based on my knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in the report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in paragraph (c) of this section) for the registrant and have:
 - a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the periodic reports are being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report ("Evaluation Date"); and
 - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
 - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

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