

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, 1997

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)2375 Garcia Avenue
Mountain View, CA 94043
(Address of principal executive offices)
Telephone Number (415) 903-3700

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 September 30, 1997, there were 18,216,787 shares of the Registrant's Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROTEIN DESIGN LABS, INC.
STATEMENTS OF OPERATIONS
(unaudited)

| | Three months ending 1997 ----- | September 30, 1996 ----- | Nine months ending 1997 ----- | September 30, 1996 ----- |
|---|--------------------------------------|--------------------------------|-------------------------------------|--------------------------------|
| Revenues | | | | |
| Research and development revenue under agreements with third parties (includes related party revenue of \$0.0M for the three and nine month periods ending September 30, 1997, and \$3.0M and \$10.0M for the three and nine month periods ending September 30, 1996) | \$ 4,550,000 | \$ 4,000,000 | \$ 9,341,074 | \$ 11,500,000 |
| Interest and other income | 2,485,425 | 1,553,310 | 6,607,549 | 4,629,472 |
| Total revenues | 7,035,425 | 5,553,310 | 15,948,623 | 16,129,472 |
| Costs and expenses: | | | | |
| Research and development | 6,311,140 | 8,492,291 | 19,123,686 | 22,119,234 |
| General and administrative | 1,629,373 | 1,366,343 | 4,650,699 | 3,992,667 |
| Total costs and expenses | 7,940,513 | 9,858,634 | 23,774,385 | 26,111,901 |
| Net loss | \$ (905,088) ===== | \$ (4,305,324) ===== | \$ (7,825,762) ===== | \$ (9,982,429) ===== |
| Net loss per share | \$ (0.05) ===== | \$ (0.28) ===== | \$ (0.45) ===== | \$ (0.64) ===== |
| Weighted average common shares outstanding | 18,170,000 ===== | 15,632,000 ===== | 17,433,000 ===== | 15,578,000 ===== |

See accompanying notes

PROTEIN DESIGN LABS, INC.
BALANCE SHEETS

| | September 30, 1997 | December 31, 1996 |
|--|-----------------------|----------------------|
| | ----- | ----- |
| | (unaudited) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 36,966,044 | \$ 14,141,184 |
| Short-term investments | 47,892,473 | 64,050,165 |
| Other current assets | 1,706,117 | 1,249,772 |
| | ----- | ----- |
| Total current assets | 86,564,634 | 79,441,121 |
| Property and equipment, net | 8,924,228 | 8,589,555 |
| Long-term investments | 76,962,879 | 21,475,483 |
| Other assets | 1,057,861 | 825,246 |
| | ----- | ----- |
| | \$ 173,509,602 | \$ 110,331,405 |
| | ===== | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 491,024 | \$ 1,029,157 |
| Accrued compensation | 780,562 | 635,729 |
| Accrued clinical trials | 1,443,390 | 1,843,206 |
| Other accrued liabilities | 1,611,185 | 1,711,663 |
| | ----- | ----- |
| Total current liabilities | 4,326,161 | 5,219,755 |
| Stockholders' equity: | | |
| Preferred stock, par value \$0.01 per share, 10,000,000 shares authorized; no shares issued and outstanding | - - | - - |
| Common stock, par value \$0.01 per share, 40,000,000 shares authorized; 18,216,787 and 15,759,089 issued and outstanding at September 30, 1997 and December 31, 1996, respectively | 182,168 | 157,591 |
| Additional paid-in capital | 211,635,609 | 140,328,297 |
| Accumulated deficit | (43,332,917) | (35,507,154) |
| Unrealized loss on investments | 698,581 | 132,916 |
| | ----- | ----- |
| Total stockholders' equity | 169,183,441 | 105,111,650 |
| | ----- | ----- |
| | \$ 173,509,602 | \$ 110,331,405 |
| | ===== | ===== |

See accompanying notes

PROTEIN DESIGN LABS, INC.
 STATEMENTS OF CASH FLOWS
 Increase (decrease) in cash and cash equivalents
 (unaudited)

| | Nine months ending 1997 | September 30, 1996 |
|--|----------------------------|-----------------------|
| | ----- | ----- |
| Cash flows from operating activities: | | |
| Net loss | \$ (7,825,762) | \$ (9,982,429) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 2,392,293 | 2,398,830 |
| Other | (879,337) | 278,566 |
| Changes in assets and liabilities: | | |
| Other current assets | (476,345) | (1,248,976) |
| Accounts payable | (538,133) | (9,163) |
| Accrued liabilities | (355,460) | 1,455,937 |
| | ----- | ----- |
| Total adjustments | 143,018 | 2,875,194 |
| | ----- | ----- |
| Net cash used in operating activities | (7,682,744) | (7,107,235) |
| Cash flows from investing activities: | | |
| Purchases of short- and long-term investments | (230,724,034) | (24,458,022) |
| Maturities of short- and long-term investments | 192,758,144 | 32,900,000 |
| Capital expenditures | (2,645,780) | (2,301,923) |
| Increase in other assets | (212,615) | (135,000) |
| | ----- | ----- |
| Net cash provided by (used in) investing activities | (40,824,285) | 6,005,055 |
| Cash flows from financing activities: | | |
| Net proceeds from issuance of common stock | 71,331,889 | 3,150,934 |
| | ----- | ----- |
| Net cash provided by financing activities | 71,331,889 | 3,150,934 |
| Net increase in cash and cash equivalents | 22,824,860 | 2,048,754 |
| Cash and cash equivalents at beginning of period | 14,141,184 | 4,686,259 |
| | ----- | ----- |
| Cash and cash equivalents at end of period | \$ 36,966,044 | \$ 6,735,013 |
| | ===== | ===== |

See accompanying notes

PROTEIN DESIGN LABS, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS
SEPTEMBER 30, 1997

1. Summary of Significant Accounting Policies

Organization and Business

Since the Company's founding in 1986, a primary focus of its operations has been research and development. Achievement of successful research and development and commercialization of products derived from such efforts is subject to high levels of risk and significant resource commitments. The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next few years, as it continues to develop its proprietary products and devote significant resources to preclinical studies, clinical trials, and manufacturing. The Company's revenues to date have consisted, and for the near future are expected to consist, principally of research and development funding, signing and licensing fees, milestone payments and royalties from pharmaceutical companies under collaborative research and development agreements and patent licensing agreements. These revenues may vary considerably from quarter to quarter and from year to year. Revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. For example, revenues for the first nine months of 1997, which included several non-recurring payments in connection with new humanization and patent licensing agreements, may not be indicative of revenues in future periods.

While the Company historically has received significant revenue pursuant to certain of its research and development agreements, the Company has recognized substantially all of the research and development and milestone revenue due under these agreements. Although the Company anticipates entering into new relationships from time to time, the Company presently does not anticipate continuing to realize non-royalty revenue from its new and proposed collaborations at levels commensurate with the non-royalty revenue historically recognized under its older collaborations. Moreover, the Company anticipates that its operating expenses will continue to increase significantly as the Company increases its research and development, manufacturing, preclinical and clinical activities, and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or licensing arrangements, royalties on Zenapax(R) sales or sales of other licensed products under the Company's patents, if any, or other sources, the Company expects to incur substantial and increased operating losses in the foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in new research programs, new headquarters and additional laboratory and manufacturing facilities or capacity, as the Company defends or prosecutes its patents and patent applications and as the Company invests in continuing research or acquires additional technologies, product candidates or businesses.

Basis of Presentation and Responsibility for Interim Financial Statements

The balance sheet as of September 30, 1997 and the statements of operations and cash flows for the nine month periods ending September 30, 1997 and 1996 are unaudited but include all adjustments (consisting of normal recurring adjustments) which the Company considers necessary for a fair presentation of the financial position at such dates and the operating results and cash flows for those periods. Although the Company believes that the disclosures in these financial statements are adequate

to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission. The accompanying financial statements should be read in conjunction with the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission for the year ended December 31, 1996. Results for any interim period are not necessarily indicative of results for any other interim period or for the entire year.

Cash Equivalents, Investments and Concentration of Credit Risk

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of acquisition to be cash equivalents. The Company places its cash and short-term and long-term investments with high-credit-quality financial institutions and in securities of the United States ("U.S.") government and U.S. government agencies, and by policy, limits the amount of credit exposure in any one financial instrument. To date, the Company has not experienced credit losses on investments in these instruments.

Revenue Recognition Under Development Contracts

Nonrefundable signing or licensing fee payments that are not dependent on future performance under agreements with third parties are recognized as revenue when received. Payments for research and development performed by the Company under contractual arrangements are recognized as revenue ratably over the quarter in which the related work is performed. Revenue from achievement of milestone events is recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met.

Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Common equivalent shares from options are included in the computation (using the treasury stock method) when their effect is dilutive.

New Accounting Standards

In February 1997, the Financial Accounting Standards Board issued Statement No. 128, Earnings per Share, which is required to be adopted on December 31, 1997. At that time, the Company will be required to change the method currently used to compute earnings per share and to restate all prior periods. Under the old and new requirements, there would be no change with respect to primary earnings per share and fully diluted earnings per share for the quarters ending September 30, 1997 and September 30, 1996 since the Company had losses in those periods and the dilutive effects of stock options under these methods do not apply.

Management Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, the Company has a policy of recording expenses for clinical trials based upon pro rating estimated total costs of a clinical trial over the estimated length of the clinical trial and the number of patients anticipated to be enrolled in the trial.

Expenses related to each patient are recognized ratably beginning upon entry into the trial and over the course of the trial. In the event of early termination of a clinical trial, management accrues an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial. These estimates and assumptions could differ significantly from the amounts which may actually be realized.

The Company recently received a notice from Boehringer Mannheim GmbH ("Boehringer Mannheim") invoking the dispute resolution provisions under its collaborative research agreement to address the reimbursement of up to \$2.0 million for the Phase II study of OST 577 for the treatment of CHB being conducted by Boehringer Mannheim. The Company is unable to predict the outcome of this proceeding but in any event has estimated and recorded a liability with respect to this matter.

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

This Quarterly Report contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to those discussed in "Risk Factors" as well as those discussed elsewhere in this document and the Company's Annual Report on Form 10-K, as amended, for the year ending December 31, 1996.

OVERVIEW

Since the Company's founding in 1986, a primary focus of its operations has been research and development. Achievement of successful research and development and commercialization of products derived from such efforts is subject to high levels of risk and significant resource commitments. The Company has a history of operating losses and expects to incur substantial additional expenses over at least the next few years, as it continues to develop its proprietary products and devote significant resources to preclinical studies, clinical trials, and manufacturing. The Company's revenues to date have consisted, and for the near future are expected to consist, principally of research and development funding, licensing and signing fees, milestone payments and royalties from pharmaceutical companies under collaborative research and development and licensing agreements. These revenues may vary considerably from quarter to quarter and from year to year. Revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. For example, revenues for the first nine months of 1997, which included several non-recurring payments in connection with new humanization and patent licensing agreements, may not be indicative of revenues in future periods.

THREE MONTHS ENDING SEPTEMBER 30, 1997 AND 1996

The Company's total revenues for the three months ending September 30, 1997 were \$7.0 million compared with total revenues of \$5.6 million for the three months ending September 30, 1996. Research and development revenues from agreements with third parties were \$4.6 million in the third quarter in 1997. In the comparable period of 1996, the Company received research and development reimbursement funding and upfront licensing and signing fees totaling \$4.0 million. In the third quarter of 1997 no research and development reimbursement funding was received. Interest and other income for the third quarter of 1997 were \$2.5 million compared to \$1.6 million in the comparable period in 1996. This increase is primarily attributable to the increased interest earned on the Company's cash, cash equivalents and investment balances as a result of the Company's follow-on public offering which was completed during the first quarter of 1997.

The Company's research and development revenues under agreements with third parties consisted of research and development reimbursement funding, licensing and signing fees and milestone payments. Research and development revenues from unrelated parties of \$4.6 million for the three months ending September 30, 1997 consisted of licensing and signing fees and milestone payments earned under licensing agreements compared to a \$1.0 million licensing and signing fee received from an unrelated party in the same period in 1996. In the third quarter of 1996, research and development revenues from related parties consisted of \$3.0 million solely from Boehringer Mannheim GmbH ("Boehringer Mannheim") under a research and development funding commitment that expired as scheduled in October 1996.

Total costs and expenses for the three months ending September 30, 1997 decreased to \$7.9 million from \$9.9 million in the comparable period in 1996. The decrease in costs and expenses was primarily due to reduced clinical trial expenses associated with PROTOVIR(TM), a product candidate.

Research and development expenses for the three months ending September 30, 1997 decreased to \$6.3 million from \$8.5 million in the comparable period of 1996. Excluding clinical trial costs for PROTOVIR (which included a \$1.1 million one-time charge for expenses associated with the halting of one clinical trial), the Company's 1997 ongoing expenses increased as a result of the addition of staff, the continuation of other clinical trials, costs of conducting preclinical tests, expansion of pharmaceutical development capabilities, including support for both clinical development and manufacturing process development, and increased manufacturing operations.

General and administrative expenses for the three months ending September 30, 1997 increased to \$1.6 million from \$1.4 million in the comparable period in 1996. These increases were primarily the result of increased staffing and associated expenses necessary to manage and support the Company's expanding operations.

NINE MONTHS ENDING SEPTEMBER 30, 1997 AND 1996

The Company's total revenues for the nine months ending September 30, 1997 were \$15.9 million compared to \$16.1 million in the same period in 1996. Research and development revenues from licensing and signing fees and milestone payments were \$9.3 million for the nine months ending September 30, 1997. In the comparable period of 1996, the Company received research and development reimbursement funding, licensing and signing fees and milestone payments totaling \$11.5 million. Interest and other income for the nine months ending September 1997 were \$6.6 million compared to \$4.6 million in the comparable period in 1996. This increase is primarily attributable to the increased interest earned on the Company's cash and cash equivalents balances as a result of the Company's follow-on public offering which was completed during the first quarter of 1997.

The Company's research and development revenues under agreements with third parties consisted of research and development reimbursement funding, licensing and signing fees and milestone payments. Research and development revenues from unrelated parties of \$9.3 million for the nine months ending September 30, 1997 consisted of licensing and signing fees and milestone payments earned under licensing agreements. This compares to \$1.5 million of similar revenue received from unrelated parties in the same period in 1996. In the comparable period of 1996, research and development revenues from related parties consisted of \$10.0 million solely from Boehringer Mannheim under a research and development funding commitment that expired as scheduled in October 1996 and a milestone payment.

Total costs and expenses for the nine months ending September 30, 1997 decreased to \$23.8 million from \$26.1 million in the comparable period in 1996. The decrease in costs and expenses was primarily due to reduced clinical trial expenses associated with PROTOVIR, a product candidate, including a \$1.1 million one-time charge for expenses associated with the halting of one clinical trial.

Research and development expenses for the nine months ending September 30, 1997 decreased to \$19.1 million from \$22.1 million in the comparable period in 1996. Excluding clinical trial costs for PROTOVIR, the Company's 1997 ongoing expenses increased as a result of the addition of staff, the continuation of other clinical trials, costs of conducting preclinical tests, expansion of pharmaceutical

development capabilities, including support for both clinical development and manufacturing process development, and increased manufacturing operations.

General and administrative expenses for the nine months ending September 30, 1997 increased to \$4.7 million from \$4.0 million in the comparable period in 1996. These increases were primarily the result of increased staffing and associated expenses necessary to manage and support the Company's expanding operations.

LIQUIDITY AND CAPITAL RESOURCES

To date, the Company has financed its operations primarily through public and private placements of equity, research and development revenue (including fees from humanization and patent licensing agreements) and interest income on invested capital. At September 30 and June 30, 1997, the Company had cash, cash equivalents and investments in the aggregate of \$161.8 million, compared to \$99.7 million at December 31, 1996. This increase in cash resources in 1997 primarily reflects the completion of a public offering of 2.275 million shares of the Company's common stock in the first quarter of 1997. The net proceeds of this offering to the Company were approximately \$68.2 million.

The Company recently received a notice from Boehringer Mannheim invoking the dispute resolution provisions under its collaborative research agreement to address the reimbursement of up to \$2.0 million for the Phase II study of OST 577 for the treatment of CHB being conducted by Boehringer Mannheim. The Company is unable to predict the outcome of this proceeding but in any event has estimated and recorded a liability with respect to this matter. The collaborative research agreement with Boehringer Mannheim provides for reimbursement from PDL of costs and expenses of up to \$2.0 million for a Phase II study of OST 577 and up to \$8.8 million for a Phase III study of OST 577 in the event certain conditions are met with respect to those studies.

Net cash used in operating activities was approximately \$7.7 million for the nine months ending September 30, 1997 compared to approximately \$7.1 million in the comparable period in 1996. The Company's future capital requirements will depend on numerous factors, including, among others, the progress of the Company's product candidates in clinical trials; the ability of the Company's collaborative partners to obtain regulatory approval and successfully manufacture and market the Company's products; the continued or additional support by collaborative partners or other third parties of research and clinical trials; enhancement of existing and investment in new research and development programs; the time required to gain regulatory approvals; the resources the Company devotes to self-funded products, manufacturing methods and advanced technologies; third party manufacturing commitments; the ability of the Company to obtain and retain funding from third parties under collaborative agreements; the development of internal marketing and sales capabilities; the demand for the Company's potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by the Company; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect the Company's proprietary technology. In order to develop and commercialize its potential products the Company may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders. The Company believes that existing capital resources will be adequate to satisfy its capital needs through at least 2000.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company's Annual Meeting of Stockholders was held on August 21, 1997 at its manufacturing facility in Plymouth, Minnesota. Of the 18,134,038 shares outstanding as of the record date, 11,358,861 shares were present at the meeting or represented by proxies, representing approximately 63% of the total votes eligible to be cast.

At the meeting, the stockholders voted to elect two (2) Class II directors of the Company to serve for a three-year term and until their successors are duly elected and qualified. The name of each Class II director elected at the Annual Meeting and the votes cast with respect to each such individual are set forth below.

| | For --- | Withheld ----- |
|-----------------------|------------|-------------------|
| Stanley Falkow, Ph.D. | 9,644,590 | 1,714,271 |
| Cary L. Queen, Ph.D. | 9,644,590 | 1,714,271 |

In addition, the stockholders voted to ratify the appointment of Ernst & Young LLP as the independent auditors of the Company for the fiscal year ending December 31, 1997. This proposal received 10,393,866 affirmative votes and 683,692 negative votes. There were 281,303 abstentions.

ITEM 5. OTHER INFORMATION--RISK FACTORS

RISK FACTORS

This Quarterly Report contains, in addition to historical information, forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in forward-looking statements. Factors that may cause such a difference include those discussed in the material set forth under "Risk Factors" and elsewhere in this document and the Company's Annual Report on Form 10-K, as amended, for the year ending December 31, 1996.

HISTORY OF LOSSES; FUTURE PROFITABILITY UNCERTAIN. The Company has a history of operating losses and expects to incur substantial additional expenses with resulting quarterly losses over at least the next several years as it continues to develop its potential products, to invest in new research areas and to devote significant resources to preclinical studies, clinical trials and manufacturing. As of September 30, 1997, the Company had an accumulated deficit of approximately \$43.3 million. To date, the Company has not received regulatory approval to distribute any products. The time and resource commitment required to achieve market success for any individual product is extensive and uncertain and in some cases controlled by the Company's collaborators. No assurance can be given that the Company's, or any of its collaborative partners', product development efforts will be successful, that required regulatory approvals can be obtained, that potential products can be manufactured at an acceptable cost and with appropriate quality, or that any approved products can be successfully marketed.

The Company has not received any material revenues from product sales or royalties from licenses to the Company's technology, and potential products that may be marketed by the Company, if any, are not expected to be approved for marketing for at least the next several years. The Company's revenues to date have consisted, and for the near future are expected to consist, principally of research and development funding, licensing and signing fees, milestone payments and royalties from pharmaceutical and other biotechnology companies under collaborative research and development and patent licensing agreements. These revenues may vary considerably from quarter to quarter and from year to year, and revenues in any period may not be predictive of revenues in any subsequent period, and variations may be significant depending on the terms of the particular agreements. For example, revenues in each of the first three quarters of 1997, which included several non-recurring payments in connection with new humanization and patent licensing agreements, may not be indicative of revenues in future quarters. While the Company historically has received significant revenue pursuant to certain of its research and development agreements, the Company has recognized substantially all of the research and development and milestone revenues due under these collaborations. Although the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate continuing to realize non-royalty revenue from its new and proposed collaborations at levels commensurate with the revenue historically recognized under its older collaborations. Moreover, the Company anticipates that its operating expenses will continue to increase significantly as the Company increases its research and development, manufacturing, preclinical, clinical and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations or licensing arrangements, royalties on sales of Zenapax(R) or other products covered by licenses under the Company's patents, if any, or other sources, the Company expects to incur substantial and increased operating losses in the

foreseeable future as certain of its earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as the Company invests in new headquarters and additional laboratory and manufacturing facilities or capacity, as the Company defends or prosecutes its patents and patent applications, and as the Company invests in continuing and new research programs or acquires additional technologies, product candidates or businesses. The amount of net losses and the time required to reach sustained profitability are highly uncertain. To achieve sustained profitable operations, the Company, alone or with its collaborative partners, must successfully discover, develop, manufacture, obtain regulatory approvals for and market its potential products. No assurances can be given that the Company will be able to achieve or sustain profitability, and results are expected to fluctuate from quarter to quarter.

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

In advanced clinical development, numerous factors may be involved that may lead to different results in larger, later-stage trials from those obtained in earlier stage trials. For example, early stage trials usually involve a small number of patients and thus may not accurately predict the actual results regarding safety and efficacy that may be demonstrated with a large number of patients in a later-stage trial. Also, differences in the clinical trial design between an early-stage and late-stage trial may cause different results regarding the safety and efficacy of a product to be obtained. In addition, many early stage trials are unblinded and based on qualitative evaluations by clinicians involved in the performance of the trial, whereas later stage trials are generally required to be blinded in order to provide more objective data for assessing the safety and efficacy of the product. The Company may at times elect to aggressively enter potential products into Phase I/II trials to determine preliminary efficacy in specific indications. In addition, in certain cases the Company has commenced clinical trials without conducting preclinical animal testing where an appropriate animal model does not exist. Similarly, the Company or its partners at times will conduct potentially pivotal Phase II/III or Phase III trials based on limited Phase I or Phase I/II data. As a result of these and other factors, the Company anticipates that only some of its potential products will show safety and efficacy in clinical trials and that the number of products that fail to show safety and efficacy may be significant.

The Company has completed a Phase II trial evaluating PROTOVIR(TM) (MSL 109) for the prevention of CMV infections, death, or disease relapse in bone marrow transplant recipients. The clinical trial showed PROTOVIR to be well-tolerated and a preliminary analysis of data indicates that patients who did not have a CMV infection prior to transplant and received a graft from a CMV-positive donor showed a statistically significantly lower incidence of the primary endpoint (CMV infection, death, or disease relapse) in the PROTOVIR treatment group versus the control group at 98 days post-transplant. The Company is evaluating whether to pursue additional clinical trials involving PROTOVIR and there can be no assurance that further development will be pursued or be successful if pursued.

The Company and a number of other companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier-stage trials. For

example, in August 1996, the Company announced the halt of a Phase II/III clinical trial using PROTOVIR for treatment of CMV retinitis in acquired immune deficiency syndrome ("AIDS") patients conducted by the National Eye Institute ("NEI SOCA") due to lack of evidence of efficacy. Based on the findings and actions in the above study, enrollment in a Phase II clinical trial for treatment of CMV retinitis in AIDS patients conducted by the National Institute of Allergy and Infectious Disease was suspended, and the trial was subsequently terminated.

DEPENDENCE ON COLLABORATIVE PARTNERS. The Company has collaborative agreements with several pharmaceutical companies to develop, manufacture and market certain potential products, which include the most advanced products under development by the Company. The Company granted to its collaborative partners certain exclusive rights to commercialize the products covered by these collaborative agreements. In some cases, the Company is relying on its collaborative partners to conduct clinical trials, to compile and analyze the data received from such trials, to obtain regulatory approvals and, if approved, to manufacture and market these licensed products, including Zenapax and the Company's Human Anti-Hepatitis B Virus Antibody (OST 577). As a result, the Company often has little or no control over the development of these potential products and little or no opportunity to review clinical data prior to or following public announcement.

The Company's collaborative research agreements are generally terminable by its partners on short notice. Suspension or termination of certain of the Company's current collaborative research agreements could have a material adverse effect on the Company's operations and could significantly delay the development of the affected products. Continued funding and participation by collaborative partners will depend not only on the timely achievement of research and development objectives by the Company and the successful achievement of clinical trial goals, neither of which can be assured, but also on each collaborative partner's own financial, competitive, marketing and strategic considerations. Such considerations include, among other things, the commitment of management of the collaborative partners to the continued development of the licensed products, the relationships among the individuals responsible for the implementation and maintenance of the collaborative efforts, the relative advantages of alternative products being marketed or developed by the collaborators or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully. In this regard, the Company has, at times, experienced difficulty in its continuing relationship with Boehringer Mannheim GmbH ("Boehringer Mannheim") due to a number of factors, including disagreements regarding reimbursement for certain costs related to and the timing of the initiation and design of certain proposed clinical trials involving the development of certain products licensed to Boehringer Mannheim, particularly OST 577. The Company recently received a notice from Boehringer Mannheim invoking the dispute resolution provisions under its collaborative research agreement to address the reimbursement of up to \$2.0 million for the Phase II study of OST 577 for the treatment of chronic hepatitis B ("CHB") being conducted by Boehringer Mannheim. The Company is unable to predict the outcome of this proceeding but in any event has estimated and recorded a liability with respect to this matter.

The Company has been advised by Boehringer Mannheim that as of October 30, 1997, sixteen patients have been enrolled in Boehringer Mannheim's 200 patient Phase II study of OST 577 for the treatment of CHB. Of the sixteen, ten patients have been randomized for treatment with OST 577. In accordance with the clinical trial protocol, randomization in this trial has been suspended pending completion of a predefined interim safety analysis review with the FDA that is scheduled to take place after ten patients have been treated with OST 577 for a period ranging from initial treatment up to a maximum of four weeks. After the data from these initial ten patients is evaluated and reviewed with the FDA, the trial could be continued or it may be necessary or advisable to modify or terminate the trial. Moreover, this clinical trial is an open-label study and Boehringer Mannheim will have regular access to the results of the trial such that they may, at any point in the trial determine to modify, suspend or halt the trial. Such a modification, suspension or halting of Boehringer Mannheim's trial could significantly delay or impair the clinical development of OST 577. In addition, continued enrollment at the rate experienced to date in this trial or any other delays in the trial could result in a decision by Boehringer Mannheim to terminate the trial or to modify the design of the trial, and could result in a situation in which additional Phase II studies are necessary for various reasons, such as if the standard of care were to change. In any event, Phase II trials, if successful, must generally be followed by one or more Phase III clinical trials prior to applying for regulatory approval.

Further, Roche Holding Ltd, including its subsidiaries ("Roche") and the parent company of Boehringer Mannheim have agreed to an acquisition of Boehringer Mannheim by Roche, which may be concluded in the future. The Company has not been advised of any anticipated changes to the existing collaborative arrangement with the Company resulting from a completed acquisition. However, the Company expects that Roche, if such acquisition occurs, will review the various drug development programs of the Company and Boehringer Mannheim, including those for OST 577, PROTOVIR, the SMART(TM) Anti-L-Selectin Antibody and an antibody to an undisclosed cardiovascular target. If the acquisition is

completed, the Company cannot predict the outcome or timing of such review or whether or not it will occur and in particular, whether Roche will decide to continue, modify or terminate the clinical development program for OST 577 for CHB or the planned Phase II/III trial of OST 577 in patients receiving liver transplants for end-stage liver disease due to CHB and some or all of the other Boehringer Mannheim clinical development programs being conducted with the Company.

In addition, certain collaborative partners have developed and may be developing competitive products that may result in delay or a relatively smaller resource commitment to product launch and

support efforts than might otherwise be obtained if the potentially competitive product were not under development or being marketed. For example, Roche controls the development of Zenapax, the most advanced of the Company's products in development, and the Company is dependent upon the resources and activities of Roche to pursue commercialization of Zenapax in order for the Company to achieve milestones or royalties from the development of this product. There can be no assurance that Roche will proceed to bring this product to market in a rapid and timely manner, if at all, or if marketed, that other independently developed products of Roche (including CellCept(R)) or others will not compete with or prevent Zenapax from achieving meaningful sales. Also, Roche has stated that it plans to conduct or support other clinical trials of Zenapax in autoimmune indications. There can be no assurance that Roche will continue or pursue additional clinical trials in these indications or that, even if the additional clinical trials are completed, Zenapax will be shown to be safe and efficacious, or that the trials will result in approval to market Zenapax in these indications. Any adverse event or announcement related to Zenapax would have a material adverse effect on the business and financial condition of the Company.

Further, because the Company expects, in some cases, to rely on its contractual rights to access data collected by its collaborative partners in various phases of its clinical development efforts, the Company is dependent on the continued satisfaction by such parties of their contractual obligations to provide such access and cooperate with the Company in the preparation and submission of appropriate filings with the FDA and equivalent foreign government regulatory agencies. The Company currently relies on Boehringer Mannheim for the manufacturing and clinical development of OST 577. Boehringer Mannheim has marketing rights to this antibody in countries outside of North America. There can be no assurance that Boehringer Mannheim will provide timely access to the manufacturing and clinical data, that the U.S. Food and Drug Administration ("FDA") will permit the Company to rely on that data or that the trials conducted by Boehringer Mannheim will produce data appropriate for approval by the FDA. If the Company were unable to rely on the clinical data collected by Boehringer Mannheim or its other collaborative partners, the Company may be required to repeat clinical trials or perform supplemental clinical trials in order to achieve regulatory approval in North America. Compliance with these requirements could significantly delay commercialization efforts and require substantially greater investment by the Company, either of which would have a material adverse effect on the business and financial condition of the Company.

The Company's ability to enter into new collaborations and the willingness of the Company's existing collaborators to continue development of the Company's potential products is dependent upon, among other things, the Company's patent position with respect to such products. In this regard, in 1996 the Company was issued patents by the U.S. Patent and Trademark Office ("PTO") and European Patent Office ("EPO") with claims that the Company believes, based on its survey of the scientific literature, cover most humanized antibodies. Eighteen notices of opposition to the European patent have been filed with the EPO, and either or both patents may be further challenged through administrative or judicial proceedings. The Company has applied for similar patents in Japan and other countries. The Company has entered into several collaborations related to both the humanization and patent licensing of certain antibodies whereby it granted nonexclusive licenses to its patent rights relating to such antibodies, and the Company anticipates entering into additional collaborations and patent licensing agreements partially as a result of the Company's patent and patent applications with respect to humanized antibodies. As a result, the inability of the Company to successfully defend the opposition proceeding before the EPO or, if necessary, to defend patents granted by the PTO or EPO or to successfully prosecute the corresponding patent applications in Japan or other countries could adversely affect the ability of the Company to enter into additional collaborations or patent licensing agreements and could therefore have a material adverse effect on the Company's business or financial condition.

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

The rate of completion of the Company's or its collaborators' clinical trials is significantly dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including, among others, the size of the patient population, perceived risks and benefits of the drug under study, availability of competing therapies, access to reimbursement from insurance companies or government sources, design of the protocol, proximity of and access by patients to clinical sites, patient referral practices, eligibility criteria for the study in question and efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment in the trial. Delays in the planned rate of patient enrollment may result in increased costs and expenses in completion of the trial or may require the Company to undertake additional studies in order to obtain regulatory approval if the applicable standard of care changes in the therapeutic indication under study. For example, patient accrual in the Company's ongoing Phase II/III trial of the SMART M195 Antibody in myeloid leukemia has been negatively affected by changes in referral patterns, with such patients now more commonly being treated in local hospitals rather than being referred to tertiary care hospitals where the Company's trial is being conducted. There can be no assurance that any actions by the Company to accelerate accrual in this trial will be successful or, to the extent that they involve modifications in the design of the trial, will not cause that trial to be considered a Phase II clinical trial and thereby require one or more additional potentially pivotal trials to be conducted.

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

Patents in the U.S. are issued to the party that is first to invent the claimed invention. Since patent applications in the U.S. are maintained in secrecy until patents issue, PDL cannot be certain that it was the first inventor of the inventions covered by its pending patent applications or that it was the first to file patent applications for such inventions. The patent positions of biotechnology firms generally are highly uncertain and involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, and patents of biotechnology products are uncertain so that even issued patents may later be modified or revoked by the PTO or the courts in proceedings instituted by third parties. Moreover, the issuance of a patent in one country does not assure the issuance

of a patent with similar claims in another country and claim interpretation and infringement laws vary among countries, so the extent of any patent protection may vary in different territories.

PDL has several patents and exclusive licenses covering its humanized and human antibody technology, respectively. With respect to its human antibody technology and antibodies, PDL has exclusively licensed certain patents from Novartis Pharmaceuticals Corporation ("Novartis") (formerly known as Sandoz Pharmaceuticals Corporation). With respect to its SMART antibody technology and antibodies, in January and December 1996, PDL was issued fundamental patents by the EPO and PTO. In addition, in June 1996 PDL was issued a U.S. patent covering Zenapax and certain related antibodies against the IL-2 receptor. PDL is also currently prosecuting other patent applications with the PTO and in other countries, including members of the European Patent Convention, Canada, Japan and Australia. The patent applications are directed to various aspects of PDL's SMART and human antibodies, antibody technology and other programs, and include claims relating to compositions of matter, methods of preparation and use of a number of PDL's compounds. However, PDL does not know whether any pending applications will result in the issuance of patents or whether such patents will provide protection of commercial significance. Further, there can be no assurance that PDL's patents will prevent others from developing competitive products using related technology.

With respect to its issued antibody humanization patents, PDL believes the patent claims cover Zenapax and, based on its review of the scientific literature, most humanized antibodies. The EPO (but not PTO) procedures provide for a nine-month opposition period in which other parties may submit arguments as to why the patent was incorrectly granted and should be withdrawn or limited. The entire opposition process, including appeals, may take several years to complete, and during this lengthy process, the validity of the EPO patent will be at issue, which may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on this patent. Eighteen notices of opposition to PDL's European patent were filed during the opposition period, including oppositions by major pharmaceutical and biotechnology companies, which cited references and made arguments not considered by the EPO and PTO before grant of the respective patents. PDL intends to vigorously defend the European and, if necessary, the U.S. patent; however, there can be no assurance that the Company will prevail in the opposition proceedings or any litigation contesting the validity or scope of these patents. In addition, such proceedings or litigation, or any other proceedings or litigation to protect the Company's intellectual property rights or defend against infringement claims by others, could result in substantial costs and a diversion of management's time and attention, which could have a material adverse effect on the business and financial condition of the Company.

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to PDL's programs. Some of these applications or patents may be competitive with PDL's applications or contain claims that conflict with those made under PDL's patent applications or patents. Such conflict could prevent issuance of patents to PDL, provoke an interference with PDL's patents or result in a significant reduction in the scope or invalidation of PDL's patents, if issued. An interference is an administrative proceeding conducted by the PTO to determine the priority of invention and other matters relating to the decision to grant patents. Moreover, if patents are held by or issued to other parties that contain claims relating to PDL's products or processes, and such claims are ultimately determined to be valid, no assurance can be given that PDL would be able to obtain licenses to these patents at a reasonable cost, if at all, or to develop or obtain alternative technology.

The Company is aware that Celltech Limited ("Celltech") has been granted a patent by the EPO covering certain humanized antibodies, which PDL has opposed, and Celltech announced in September 1996 that it had received a notice of allowance of a corresponding U.S. patent (the "U.S. Adair Patent"). There can be no assurance that the claims in the European patent or, if issued, the U.S. patent would not be interpreted to cover any or all of PDL's SMART antibodies or be competitive with or conflict with claims in PDL's patents or patent applications. If the U.S. Adair Patent issues and if it or any corresponding international patent is determined to be valid and to cover any of PDL's SMART antibodies, there can be no assurance that PDL would be able to obtain a license on commercially reasonable terms, if at all. If the claims of the U.S. Adair Patent conflict with claims in PDL's patents or patent applications, there can be no assurance that an interference would not be declared by the PTO, which could take several years to resolve and could involve significant expense to the Company. Also, such conflict could prevent issuance of patents to PDL relating to humanization of antibodies or result in a significant reduction in the scope or invalidation of PDL's patents, if issued. Moreover, uncertainty as to the validity or scope of patents issued to PDL relating generally to humanization of antibodies may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents.

PDL has obtained a nonexclusive license under a patent held by Celltech (the "Boss Patent") relating to PDL's current process for producing SMART and human antibodies. An interference proceeding was declared in early 1991 by the PTO between the Boss Patent and a patent application filed by Genentech, Inc. ("Genentech") to which PDL does not have a license. PDL is not a party to this proceeding, and the timing and outcome of the proceeding or the scope of any patent that may be subsequently issued cannot be predicted. If the Genentech patent application were held to have priority over the Boss Patent, and if it were determined that PDL's processes and products were covered by a patent issuing from such patent application, PDL may be required to obtain a license under such patent or to significantly alter its processes or products. There can be no assurance that PDL would be able to successfully alter its processes or products to avoid infringing such patent or to obtain such a license on commercially reasonable terms, if at all, and the failure to do so could have a material adverse effect on PDL.

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

Also, Genentech has patents in the U.S. and Europe that relate to chimeric antibodies. Such European patent was revoked in May 1997 in connection with European opposition proceedings. Genentech may choose to appeal that ruling and, if so, revocation of the European patent would be stayed pending resolution of the appeal. If Genentech were to assert that the Company's SMART antibodies infringe these patents, PDL may have to choose whether to seek a license or to challenge in court the validity of such patents or Genentech's claim of infringement. There can be no assurance that PDL would be successful in either obtaining such a license on commercially reasonable terms, if at all, or that it would be successful in such a challenge of the Genentech patents, and the failure to do so would have a material adverse effect on the business and financial condition of the Company.

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

ABSENCE OF MANUFACTURING EXPERIENCE; DEPENDENCE ON MANUFACTURING BY BOEHRINGER MANNHEIM. Of the products developed by the Company which are currently in clinical development, Roche is responsible for manufacturing Zenapax and Boehringer Mannheim is responsible for manufacturing OST 577. If further development occurs, the Company intends to continue to manufacture the SMART M195 Antibody and PROTOVIR as well as some of its other products in preclinical development. PDL currently leases approximately 45,000 square feet housing its manufacturing facility in Plymouth, Minnesota. PDL intends to continue to manufacture potential products for use in preclinical and clinical trials using this manufacturing facility in accordance with standard procedures that comply with current Good Manufacturing Practices ("cGMP") and appropriate regulatory standards. The manufacture of sufficient quantities of antibody products in accordance with such standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays. For example, PDL has experienced some difficulties in the past in manufacturing certain potential products on a consistent basis. Production interruptions, if they occur, could significantly delay clinical development of potential products, reduce third party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization of such products and impair their competitive position, which would have a material adverse effect on the business and financial condition of the Company.

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

In addition, PDL and Boehringer Mannheim have agreed to negotiate additional agreements under which each company could manufacture and supply the other with certain of the antibodies covered by the agreement. There can be no assurance that the parties will enter into an agreement that will provide for the Company's potential product requirements to be met in a consistent, timely and cost effective manner. Specifically, with respect to OST 577, the Company currently does not manufacture this product and has no alternative manufacturing sources for this product. In the event that Boehringer Mannheim and the Company are unable to reach an acceptable agreement, or if material is not supplied in accordance with such an agreement, there can be no assurance that the Company could make alternative

manufacturing arrangements on a timely basis, if at all, and the inability to do so could have a material adverse effect on the business and financial condition of the Company.

UNCERTAINTIES RESULTING FROM MANUFACTURING CHANGES. Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. When certain changes are made in the manufacturing process, it is necessary to demonstrate to the FDA that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced, if results of prior preclinical studies and clinical trials performed using the previously produced drug material are to be relied upon in regulatory filings. Such changes could include, for example, changing the cell line used to produce the antibody, changing the fermentation or purification process or moving the production process to a new manufacturing plant. Depending upon the type and degree of differences between the newer and older drug material, various studies could be required to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material, possibly requiring additional animal studies or human clinical trials. Manufacturing changes have been made or are likely to be made for the production of PDL's products currently in clinical development. There can be no assurance that such changes will not result in delays in development or regulatory approvals or, if occurring after regulatory approval, in reduction or interruption of commercial sales. Such delays could have an adverse effect on the competitive position of those products and could have a material adverse effect on the business and financial condition of the Company.

Roche has equipped a manufacturing facility that is expected to be used to produce Zenapax. Successful Phase III trials of Zenapax in kidney transplantation were conducted using material produced for Roche by a third party contract manufacturer at a different facility using a different cell line and a different manufacturing process. Roche has produced Zenapax at its facility using the new cell line and process and has produced data indicating that the newly produced material is substantially similar to the material used in the Phase III clinical trials. However, there can be no assurance that changes in the manufacturing site or any other manufacturing changes by Roche will not cause delays in the development or commercialization of Zenapax. Such delays could have an adverse effect on the competitive position of Zenapax and could have a material adverse effect on the business and financial condition of the Company.

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

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

recruiting and retaining highly qualified personnel. The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. The Company's competitors may develop and introduce other technologies or approaches to accomplishing the intended purposes of the Company's products which may render the Company's technologies and products noncompetitive and obsolete.

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

Any potential product that the Company or its collaborative partners succeed in developing and for which regulatory approval is achieved must then compete for market acceptance and market share. For certain of the Company's potential products, an important factor will be the timing of market introduction of competitive products. Accordingly, the relative speed with which the Company and its collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies is expected to be an important determinant of market success. For example, with respect to the speed of development of OST 577, the Company is aware that other drugs such as lamivudine from Glaxo Wellcome plc are in advanced clinical development or have been submitted for approval in certain jurisdictions for the treatment of CHB by competitive companies that have significantly greater experience and resources in developing antiviral products than the Company and Boehringer Mannheim. The availability of lamivudine could have a material adverse impact on the clinical development and commercial potential of OST 577.

Other competitive factors include the capabilities of the Company's collaborative partners, product efficacy and safety, timing and scope of regulatory approval, product availability, marketing and sales capabilities, reimbursement coverage, the amount of clinical benefit of the Company's products relative to their cost, method of administration, price and patent protection. There can be no assurance that the Company's competitors will not develop more efficacious or more affordable products, or achieve earlier product development completion, patent protection, regulatory approval or product commercialization than the Company. The occurrence of any of these events by the Company's competitors could have a material adverse effect on the business and financial condition of the Company.

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

POTENTIAL VOLATILITY OF STOCK PRICE. The market for the Company's securities is volatile and investment in these securities involves substantial risk. The market prices for securities of biotechnology companies (including the Company) have been highly volatile, and the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. Factors such as results of clinical trials, delays in manufacturing or clinical trial plans, fluctuations in the Company's 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 the Company or its competitors, initiation, termination or modification of agreements with collaborative partners, failures or unexpected delays in manufacturing or in obtaining regulatory approvals or FDA advisory panel recommendations, developments or disputes as to patent or other proprietary rights, loss of key personnel, litigation, public concern as to the safety of drugs developed by the Company, regulatory developments in either the U.S. or foreign countries (such as opinions, recommendations or statements by the FDA or FDA advisory panels, health care reform measures or proposals), market acceptance of products developed and marketed by the Company's collaborators, and general market conditions could result in the Company's failure to meet the expectations of securities analysts or investors. In such event, or in the event that adverse conditions prevail or are perceived to prevail with respect to the Company's business, the price of PDL's common stock would likely drop significantly. In the past, following significant drops in the price of a company's common stock, securities class action litigation has often been instituted against such a company. Such litigation against the Company could result in substantial costs and a diversion of management's attention and resources, which would have a material adverse effect on the Company's business and financial condition.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Number

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11.1 Statement of Computation of Earnings Per Share

(b) No Reports on Form 8-K were filed during the quarter ending September 30, 1997

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, 1997

PROTEIN DESIGN LABS, INC.
(Registrant)

/s/ Laurence Jay Korn

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

/s/ Fred Kurland

Fred Kurland
Chief Financial Officer
(Chief Accounting Officer)

| | |
|------|--|
| 11.1 | Statement of Computation of Earnings Per Share |
| 27 | Financial Data Schedule |

PROTEIN DESIGN LABS, INC.
 STATEMENT OF COMPUTATION OF EARNING PER SHARE
 (In thousands except per share amounts)

| | Three months ending September 30, 1997 | 1996 | Nine months ending September 30, 1997 | 1996 |
|--|---|------------|--|------------|
| | ----- | ----- | ----- | ----- |
| Computation of common and common equivalent shares outstanding: | | | | |
| Weighted average common shares outstanding | 18,170 | 15,632 | 17,433 | 15,578 |
| Weighted average shares outstanding assuming conversion of preferred stock | -- | -- | -- | -- |
| | ----- | ----- | ----- | ----- |
| | 18,170 | 15,632 | 17,433 | 15,578 |
| | ----- | ----- | ----- | ----- |
| Stock related to SAB No. 55, 64, and 83 | -- | -- | -- | -- |
| | ----- | ----- | ----- | ----- |
| Total weighted average common and common equivalent shares outstanding | 18,170 | 15,632 | 17,433 | 15,578 |
| | ===== | ===== | ===== | ===== |
| Net loss | \$ (905) | \$ (4,305) | \$ (7,826) | \$ (9,982) |
| | ===== | ===== | ===== | ===== |
| Loss per share | \$ (0.05) | \$ (0.28) | \$ (0.45) | \$ (0.64) |
| | ===== | ===== | ===== | ===== |

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM STATEMENT OF OPERATIONS AND BALANCE SHEET AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH 10Q

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| | | |
|---------|-------------|---------|
| 9-MOS | | |
| | DEC-31-1997 | |
| | JAN-01-1997 | |
| | SEP-30-1997 | |
| | | 36,966 |
| | | 124,855 |
| | | 2,765 |
| | | 0 |
| | | 0 |
| | | 0 |
| | | 20,405 |
| | (11,481) | |
| | 173,510 | |
| 4,326 | | |
| | | 0 |
| 0 | | |
| | | 0 |
| | | 182 |
| | | 169,002 |
| 173,510 | | |
| | | 0 |
| | 15,949 | |
| | | 0 |
| | (23,775) | |
| | 0 | |
| | 0 | |
| | 0 | |
| | (7,826) | |
| | | 0 |
| (7,826) | | |
| | | 0 |
| | | 0 |
| | | 0 |
| | (7,826) | |
| | (.45) | |
| | (.45) | |