

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, 1996

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, 1996, there were 15,653,678 shares of the Registrant's Common Stock outstanding.

This report contains 28 pages. The index to exhibits begins on page 27

INDEX

PART I. FINANCIAL INFORMATION

	Page No.
ITEM 1. FINANCIAL STATEMENTS	
Statements of Operations	
Three months ended September 30, 1996 and 1995	3
Nine months ended September 30, 1996 and 1995	
Balance Sheets	
September 30, 1996 and December 31, 1995	4
Statements of Cash Flows	
Nine months ended September 30, 1996 and 1995	5
Notes to Unaudited Financial Statements	6
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	8

PART II. OTHER INFORMATION

ITEM 5. OTHER INFORMATION - RISK FACTORS	13
ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K	25
Signatures	26

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	Three Months Ended September 30, 1996	Ended September 30, 1995	Nine Months Ended September 30, 1996	Ended September 30, 1995
	-----	-----	-----	-----
Revenues:				
Research and development revenue under collaborative agreements-related parties	\$ 3,000,000	\$ 2,500,000	\$ 10,000,000	\$ 7,575,000
Research and development revenue under collaborative agreements-other	1,000,000	-	1,500,000	-
Interest and other income	1,553,310	1,557,461	4,629,472	4,660,592
	-----	-----	-----	-----
Total revenues	5,553,310	4,057,461	16,129,472	12,235,592
Costs and expenses:				
Research and development	8,492,291	5,340,707	22,119,234	15,111,308
General and administrative	1,366,343	1,392,949	3,992,667	3,716,804
	-----	-----	-----	-----
Total costs and expenses	9,858,634	6,733,656	26,111,901	18,828,112
	-----	-----	-----	-----
Net loss	\$ (4,305,324)	\$ (2,676,195)	\$ (9,982,429)	\$ (6,592,520)
	=====	=====	=====	=====
Net loss per share	\$ (0.28)	\$ (0.17)	\$ (0.64)	\$ (0.43)
	=====	=====	=====	=====
Shares used in computation of net loss per share	15,632,000	15,380,000	15,578,000	15,325,000
	=====	=====	=====	=====

See accompanying notes

PROTEIN DESIGN LABS, INC.
BALANCE SHEETS

	September 30, 1996 ----- (unaudited)	December 31, 1995 -----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,735,013	\$ 4,686,259
Short-term investments	66,648,600	41,743,675
Other current assets	1,897,512	648,536
	-----	-----
Total current assets	75,281,126	47,078,470
Property and equipment, net	7,971,139	7,850,485
Long-term investments	26,074,354	60,635,550
Other assets	982,891	847,891
	-----	-----
	\$ 110,309,509	\$ 116,412,396
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 628,474	\$ 637,637
Accrued compensation	781,552	605,127
Accrued clinical trials	1,454,429	235,649
Other accrued liabilities	1,138,890	1,078,156
Deferred revenue	1,000,000	1,000,000
	-----	-----
Total current liabilities	5,003,345	3,556,569
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; 15,653,678 and 15,405,761 issued and outstanding at September 30, 1996 and December 31, 1995, respectively	156,537	154,058
Additional paid-in capital	138,764,875	135,616,420
Accumulated deficit	(33,693,485)	(23,711,056)
Unrealized gain on investments	78,237	796,405
	-----	-----
Total stockholders' equity	105,306,164	112,855,827
	-----	-----
	\$ 110,309,509	\$ 116,412,396
	=====	=====

See accompanying notes

STATEMENTS OF CASH FLOWS
Increase (decrease) in cash and cash equivalents
(unaudited)

	Nine months ended September 30, 1996	1995
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (9,982,429)	\$ (6,592,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,398,830	1,828,447
Other	278,566	(2,108,003)
Changes in assets and liabilities:		
Other current assets	(1,248,976)	(544,229)
Accounts payable	(9,163)	(274,896)
Accrued compensation	176,426	180,446
Other accrued liabilities	1,279,511	(79,410)
Deferred revenue	-	(75,000)
Total adjustments	2,875,194	(1,072,645)
Net cash used in operating activities	(7,107,235)	(7,665,165)
Cash flows from investing activities:		
Purchases of short and long term investments	(24,458,022)	(59,311,586)
Maturities of short and long term investments	32,900,000	29,000,000
Sales of short and long term investments	-	36,348,806
Capital expenditures	(2,301,923)	(2,850,961)
(Increase) decrease in other assets	(135,000)	25,200
Net cash provided by investing activities	6,005,055	3,211,459
Cash flows from financing activities:		
Principal payments on capital lease obligations	-	(24,971)
Net proceeds from issuance of common stock	3,150,934	1,398,934
Net cash provided by financing activities	3,150,934	1,373,963
Net increase (decrease) in cash and cash equivalents	2,048,754	(3,079,743)
Cash and cash equivalents at beginning of period	4,686,259	5,440,065
Cash and cash equivalents at end of period	\$ 6,735,013	\$ 2,360,322
	=====	=====

See accompanying notes

NOTES TO UNAUDITED FINANCIAL STATEMENTS
SEPTEMBER 30, 1996

1. ORGANIZATION AND BUSINESS.

Protein Design Labs, Inc. (the "Company") is a biotechnology company incorporated in the State of Delaware on July 24, 1986. The Company is engaged in the research and development of human therapeutic products based on the concept of protein engineering.

2. BASIS OF PRESENTATION AND RESPONSIBILITY FOR INTERIM FINANCIAL STATEMENTS.

The balance sheet as of September 30, 1996 and the statements of operations and cash flows for the nine month periods ended September 30, 1996 and 1995 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, 1995 and the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission for the quarter ended June 30, 1996.

Results for any interim period are not necessarily indicative of results for any other interim period or for the entire year.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES.

REVENUE RECOGNITION UNDER DEVELOPMENT CONTRACTS. Non-refundable signing fees that are not dependent on future performance under collaborative agreements 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 payment is received and 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. Deferred revenue arises principally due to timing of cash payments received under research and development contracts.

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 excluded in the computation because their net effect is anti-dilutive.

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. These estimates and assumptions could differ significantly from the amounts which may actually be realized.

4. ACCRUED CLINICAL TRIALS.

HALTED CLINICAL TRIAL. In August 1996, the National Eye Institute through its Center for Clinical Trials under the auspices of Studies of Ocular Complications of AIDS ("NEI SOCA"), acting on the recommendation of an independent data and safety monitoring board, halted its study of PROTOVIR(TM) (Human Anti-Cytomegalovirus Antibody), one of the Company's compounds, based on lack of evidence of efficacy. As a result of this action, the Company has accrued approximately \$1.1 million of estimated expenses in connection with the closing of this trial.

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

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 might cause such a difference include those discussed in the material set forth under "Risk Factors" and elsewhere in this document, the Company's Annual Report on Form 10-K for the year ended December 31, 1995 and the Company's Quarterly Report on Form 10-Q for the period ended June 30, 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. At September 30, 1996, the Company had an accumulated net loss of approximately \$33.7 million. 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 and milestone payments from pharmaceutical companies under collaborative research and development 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.

While the Company historically has received significant revenue pursuant to certain of its collaborations, the Company has recognized substantially all of the research and development and milestone revenue due under these collaborations. While the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate realizing 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, administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations, royalties on Zenapax sales 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 defends or prosecutes its patent and patent applications and as the Company invests in additional manufacturing facilities or capacity.

Three months ended September 30, 1996 and 1995

Total revenues for the three months ended September 30, 1996 increased to \$5.6 million, from \$4.1 million in the comparable period in 1995. Research and development revenues, consisting of reimbursement funding, up-front licensing and signing fees and milestone payments, increased by \$1.5 million, and interest income approximately equaled the year-earlier period.

The Company's research and development revenues under collaborative agreements primarily consist of up-front licensing and signing fees, research and development reimbursement funding and milestone payments. Increases in related party research and development revenues for the three months ended September 30, 1996 reflected amounts earned under the Company's joint development, marketing and licensing agreement with Boehringer Mannheim GmbH ("Boehringer Mannheim"), which increased by \$0.5 million from the comparable period in 1995. This increase is attributable to increased reimbursement funding under the agreement by the Company. The current research and development reimbursement funding arrangement with Boehringer Mannheim expired as scheduled in October 1996. In addition, the Company earned research and development revenues of \$1.0 million for the three months ended September 30, 1996 under the Company's development and licensing agreement with an unrelated third party compared to no revenues from such parties in the comparable period in 1995.

Interest and other income for the three months ended September 30, 1996 in the amount of \$1.6 million approximately equaled the amount in the comparable period of 1995. Although cash and investments were lower, interest rates on cash and investments for the three month period ended September 30, 1996 were higher than the comparable period in 1995.

Total costs and expenses for the three months ended September 30, 1996 increased to \$9.9 million from \$6.7 million in the comparable period in 1995. The increase in costs and expenses was due primarily to increases in research and development efforts and related expenses and the accrual of expenses associated with the halting of one clinical trial.

Research and development expenses for the three months ended September 30, 1996 increased to \$8.5 million from \$5.3 million in the comparable period in 1995, primarily as a result of the Company's conducting additional research and development efforts independently and under its agreements with its collaborative partner Boehringer Mannheim. These expenses included an accrual of expenses associated with the halting of one clinical trial; continuation of three other clinical trials; higher costs in the expanded operation of the manufacturing facility; expansion of pharmaceutical development capabilities, including support for both clinical development and manufacturing process development; costs of conducting preclinical tests; and the addition of staff.

General and administrative expenses for the three months ended September 30, 1996 in the amount of \$1.4 million equaled the amount in the comparable period in 1995. The Company believes that its general and administrative expenses will increase as the Company increases its staffing, enhances its administrative capabilities and expands its patent activities.

Nine months ended September 30, 1996 and 1995

Total revenues for the nine months ended September 30, 1996 increased to \$16.1 million, from \$12.2 million in the comparable period in 1995. Research and development revenues, consisting of reimbursement funding, up-front licensing and signing fees and milestone payments increased by approximately \$3.9 million, and interest income approximately equaled the year-earlier period.

The Company's research and development revenues under collaborative agreements primarily consist of up-front licensing and signing fees, research and development reimbursement funding and milestone payments. Increases in related party research and development revenues for the nine months ended September 30, 1996 principally reflected amounts earned under the Company's agreement with Boehringer Mannheim, which increased by \$2.4 million from the comparable period in 1995. This increase was attributable to increased research and development reimbursement funding under the agreement by the Company as well as receipt of a milestone payment in January 1996. Increased funding from Boehringer Mannheim during the nine months ended September 30, 1996 was partially offset by reduced funding from Hoffmann-La Roche Inc. and its parent Roche Holding Ltd. (collectively, "Roche"), which reimbursement arrangement expired in January 1995. The current research and development reimbursement funding arrangement with Boehringer Mannheim expired as scheduled in October 1996. In addition, the Company earned research and development revenues of \$1.5 million for the nine months ended September 30, 1996 under the Company's development and licensing agreements with unrelated third parties compared to no revenues from such parties in the comparable period in 1995.

Interest and other income for the nine months ended September 30, 1996 in the amount of \$4.6 million approximately equaled the amount in the comparable period of 1995. Although cash and investments were lower, interest rates on cash and investments for the nine month period ended September 30, 1996 were higher than the comparable period in 1995.

Total costs and expenses for the nine months ended September 30, 1996 increased to \$26.1 million from \$18.8 million in the comparable period in 1995. The increase in costs and expenses was due primarily to increases in research and development efforts and related expenses and an accrual of expenses associated with the halting of one clinical trial.

Research and development expenses for the nine months ended September 30, 1996 increased to \$22.1 million from \$15.1 million in the comparable period in 1995, primarily as a result of the Company's conducting additional research and development efforts independently and under its agreement with its collaborative partner Boehringer Mannheim. These expenses included the continuation of three clinical trials; higher costs in the expanded operation of the manufacturing facility; an accrual of expenses associated with the halting of one clinical trial; expansion of pharmaceutical development capabilities, including support for both clinical development and manufacturing process development; and the addition of staff.

General and administrative expenses for the nine months ended September 30, 1996 increased to \$4.0 million from \$3.7 million in the comparable period in 1995. These increases were primarily the result of increased staffing and associated expenses necessary to manage and support the Company's expanding operations. The Company believes that its general and administrative expenses will continue to increase as the Company increases its staffing, enhances its administrative capabilities and expands its patent activities.

Liquidity and Capital Resources

To date the Company has financed its operations primarily through public and private placements of equity, receipt of contract revenue and research and development funding under its collaborative agreements, capital lease financing and interest income on invested capital. At September 30, 1996, the Company had cash, cash equivalents and investments in the aggregate of \$99.5 million as compared to \$107.1 million at December 31, 1995. Pursuant to the agreement with Boehringer Mannheim, the Company may in the future be required to reimburse Boehringer Mannheim for up to \$2.0 million for Phase II studies and up to \$8.8 million for Phase III studies of the OST 577 Human Anti-Hepatitis B Antibody in the event certain conditions are met. The Company expects that its existing capital resources will enable the Company to maintain current and planned operations beyond 1997.

Net cash used in operating activities was \$7.1 million for the nine months ended September 30, 1996 compared to \$7.7 million in the comparable period in 1995. The Company expects to incur substantial additional costs in the future, including costs related to ongoing research and development activities, investment in or acquisition of third party research efforts, conducting preclinical and clinical trials, operation of its manufacturing facility and expansion of manufacturing capabilities, development of marketing and sales capabilities, increases in patent activities and continued expansion of general and administrative resources. These activities will require substantial additional financial resources before the Company can expect to realize significant revenue from product sales, if such revenues are ever achieved. There can be no assurance that additional funds will be available when required on terms acceptable to the Company, if at all.

Accounting Changes

In October 1995, the Financial Accounting Standards Board ("FASB") issued Financial Accounting Standards No. 123 "Accounting for Stock Based Compensation" ("FAS 123") which will be effective for the Company's 1996 fiscal year. FAS 123 allows companies which have stock-based compensation arrangements with employees to adopt a new fair-value basis of accounting for stock options and other equity instruments, or to continue to apply the existing accounting principles under APB Opinion 25, "Accounting for Stock Issued to Employees" but with additional financial statement disclosure. The Company expects to continue to account for stock-based compensation arrangements with employees under APB Opinion 25, and therefore does not expect FAS 123 to have a material impact on its financial position, results of operations and cash flows.

PART II. OTHER INFORMATION

ITEM 5. OTHER INFORMATION - RISK FACTORS

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 and to devote significant resources to preclinical studies, clinical trials, and manufacturing. As of September 30, 1996, the Company had accumulated net losses of approximately \$33.7 million. To date, the Company has not received regulatory approval to distribute any potential 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 generated 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 and milestone payments from pharmaceutical companies under collaborative research and development 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. While the Company historically has received significant revenue pursuant to certain of its collaborations, the Company has recognized substantially all of the research and development and milestone revenue due under these collaborations. While the Company anticipates entering into new collaborations from time to time, the Company presently does not anticipate realizing 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 and clinical activity, and administrative and patent activities. Accordingly, in the absence of substantial revenues from new corporate collaborations, royalties on Zenapax(R) sales 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 additional manufacturing facilities or capacity, as the Company defends or prosecutes its patents and patent applications, and as the Company invests in research or acquires additional technologies, product

candidates or businesses. 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, introduce 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. The results from preclinical studies and early clinical trials may not be predictive of results that will be obtained in later-stage clinical trials, and there can be no assurance that the Company's 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 reflect 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 at times has elected to aggressively enter many of its 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 II data. As a result, the Company anticipates that only some of its potential products will show efficacy in these clinical trials and that the number of products that fail to show efficacy may be significant.

The Company is conducting a Phase II trial evaluating PROTOVIR(TM) for the prevention of CMV infections in bone marrow transplant recipients based on very limited and inconclusive data from Phase I trials primarily designed to obtain safety data. Thus, there can be no assurance that the results of such trial will be favorable. In addition, an interim analysis of the data by an independent data and safety monitoring board is planned in this trial for the fourth quarter of 1996. No assurance

can be given that such analysis will not be unfavorable and result in an early termination of the trial.

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 June 1995, Roche Holding Ltd and its subsidiary Hoffmann-La Roche Inc. ("Roche") and the Company announced the results of a Phase II/III clinical trial using the Company's SMART Anti-Tac Antibody, Zenapax, for the prevention of graft-versus-host disease ("GvHD"). The analysis of this data led Roche to conclude that Zenapax was not effective in reducing the incidence of GvHD in the patient population studied. In addition, in August 1996, the Company announced the halt of a Phase II/III clinical trial using the Company's PROTOVIR human anti-cytomegalovirus ("CMV") antibody for treatment of CMV retinitis in AIDS patients conducted by the National Eye Institute Studies of the Ocular Complications of AIDS study group ("NEI SOCA") due to lack of evidence of efficacy. Based on the findings and actions in the above study, a second Phase II clinical trial for treatment of CMV retinitis in AIDS patients conducted by the National Institute of Allergy and Infectious Disease through its Aids Clinical Trials Group ("NIAID ACTG") has had enrollment suspended with a recommendation to continue using a higher dose. There can be no assurance that enrollment will be resumed. Also, there is not sufficient data to determine whether the proposed higher dose might be effective if enrollment in the Phase II trial were resumed at a higher dose, and there can therefore be no assurance that such trial will be successful.

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 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.

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 its recently introduced product CellCept(R)) or others will not compete with or prevent Zenapax from achieving meaningful sales. Roche also has conducted or 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 will result in approval to market Zenapax in these indications. Any adverse event or announcement related to Zenapax would have a material adverse affect on the Company's 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, the Company recently was issued a patent by the European Patent Office ("EPO") with claims that, based on its survey of the scientific literature, the Company believes cover Zenapax and most other humanized antibodies. This patent is already subject to at least one opposition and the Company believes it is likely to be further challenged by some or all of the third parties who may be affected by the patent. The Company has applied for similar patents in the U.S. and Japan. The Company recently entered into several new collaborations related to the humanization of certain antibodies whereby it granted nonexclusive licenses to its patent rights relating to such antibodies, and the Company anticipates entering into additional collaborations 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 patent granted by the EPO or to successfully prosecute corresponding patent applications in the U.S. or elsewhere could adversely affect the ability of the Company to enter into additional collaborations and could therefore have a material adverse effect on the Company's business or financial condition.

LIMITED EXPERIENCE WITH CLINICAL TRIALS; RISKS OF DELAY. The Company has conducted only a limited number 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 that, 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.

In addition, recent FDA approvals of other products for treatment of CMV retinitis in patients with AIDS as well as the failure of PROTOVIR in the NEI SOCA Phase II/III trial may adversely impact the accrual of patients in the NIAID ACTG Phase II clinical trial of PROTOVIR, if enrollment is resumed. Any such delays or additional studies with respect to these or other potential products could have a material adverse effect on the business and financial condition of the Company.

UNCERTAINTY OF PATENTS AND PROPRIETARY TECHNOLOGY. The Company's success depends in part 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 invention 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 U.S. Patent and Trademark Office ("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, so the extent of any patent protection may vary in different territories.

PDL has several patents in the U.S. and has exclusively licensed certain patents regarding the trioma technique and related antibodies from Sandoz. In June 1996, PDL was issued a U.S. patent covering Zenapax and certain related antibodies against the IL-2 receptor. In addition, PDL is currently prosecuting other patent applications with the PTO and in other countries, including members of the European Patent Convention, Canada, Japan and Australia. The patent applications are directed to various aspects of 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.

In January 1996, PDL was issued a patent by the European Patent Office ("EPO") with claims that cover Zenepax and that PDL believes, based on its review of the scientific literature, covers most humanized antibodies. The EPO 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 may take several years to complete. The Company believes that its patent may be subject to challenge by some or all of the third parties who may be affected by the patent. At least one notice of opposition has already been filed, and the Company believes it is likely to be further challenged by some or all of the third parties who may be affected by the patent, either through the opposition procedure provided by the EPO or litigation or both. During this lengthy process, the validity of the patent is 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. For example, if significant prior art were to emerge during the opposition process, then the value of the patent to PDL could be severely limited. The Company intends to vigorously defend this patent and expects that opposition proceedings and significant litigation, if any, in this matter could involve substantial costs and expenses. There can be no assurance that the Company will prevail in any opposition proceedings or other litigation contesting the issuance or scope of this patent. In addition, the costs and expenses of litigation may have a material adverse effect on the business and financial condition of the Company. Moreover, there can be no assurance that other jurisdictions, such as the U.S. or Japan, will issue patents to the Company with similar claims, if at all.

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 applications. 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 and has announced that it has received a notice of allowance of a corresponding U.S. patent relating to humanization of antibodies (the "U.S. Adair Patent") and that Celltech expects the patent to issue in early 1997. The EPO has granted a patent to Celltech in the Adair patent family, which PDL has opposed, but because U.S. patent applications are maintained in secrecy, PDL cannot review the scope of the claims in the U.S. Adair Patent. Accordingly, there can be no assurance that such claims would not cover any 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 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 at a reasonable cost, if at all. If the claims of the 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. 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, during any period of uncertainty as to the validity or scope of patents, if any, issued to PDL in the U.S. relating generally to humanization of antibodies, it may limit the Company's ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on this patent.

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 subsequently issuing 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 impact on PDL.

The Company is aware of another Celltech patent issued in Europe to which it does not have a license (although Roche does have a license covering Zenapax) and 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 impact on the business and financial condition of the Company.

Also, Genentech has a patent in the U.S. and Europe that relates to chimeric antibodies and which is being opposed in Europe. The European patent is currently in the opposition process. If Genentech were to assert that the Company's SMART antibodies infringe this patent, 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 patent, and the failure to do so would have a material adverse impact 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. The Company intends to manufacture the SMART M195 Antibody, PROTOVIR and 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. 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 generally 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 collaborative 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 thus could have a material adverse effect on the business and financial condition of the Company. Moreover, even if such alternative manufacturing arrangements are made, such arrangements would likely involve manufacturing changes from the process used by Boehringer Mannheim and could result in risks as described in "Uncertainties Resulting from Manufacturing Changes".

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 that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced if results of prior preclinical 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 an existing manufacturing facility that is expected to be used to produce Zenapax. Phase III trials of Zenapax in kidney transplantation were conducted using material produced for Roche by a third party manufacturer. Roche has stated that it has produced Zenapax at its own facility and has data indicating that this material is comparable to the material used in the Phase III clinical trials. However, there can be no assurance that Roche's manufacturing method and facility would be accepted by regulatory agencies as developed and Roche may be required to adopt some modifications or changes in the manufacturing method or facility that may 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.

In addition, with respect to two of the antibodies in clinical development licensed from Sandoz Pharmaceuticals Corporation ("Sandoz"), PROTOVIR and OST 577, the cell lines developed by PDL for both antibodies and the production processes developed by PDL for PROTOVIR and Boehringer Mannheim for OST 577 are different from those utilized by Sandoz for the manufacture of the antibody supplies used in earlier clinical trials. There can be no assurance that this new material, when used in humans, will have the same characteristics or produce results similar to the antibody material originally developed and used by Sandoz in earlier clinical trials. Accordingly, Boehringer Mannheim or the Company may be required to conduct additional laboratory or clinical testing, which could result in significant delays and/or additional expenses and could have a material adverse effect on the competitive position of these potential products and 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. 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. 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.

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), 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	Page
11.1 Statement of Computation of Earnings Per Share	28
(b) No Reports on Form 8-K were filed during the quarter ended September 30, 1996.	

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 11, 1996

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)

26

Exhibit Index

Exhibit 11.1 - Statement of Computation of Earning Per Share.
Exhibit 27.1 - Financial Data Schedule.

PROTEIN DESIGN LABS, INC.

Exhibit 11.1 STATEMENT OF COMPUTATION OF EARNINGS PER SHARE
(In thousands except per share amounts)

	Three Months Ended September 30, 1996	September 30, 1995	Nine Months Ended September 30, 1996	September 30, 1995
	-----	-----	-----	-----
Computation of common and common equivalent shares outstanding:				
Weighted average common shares outstanding	15,632	15,380	15,578	15,325
Weighted average shares outstanding assuming conversion of preferred stock	-	-	-	-
	-----	-----	-----	-----
	15,632	15,380	15,578	15,325
	-----	-----	-----	-----
Stock related to SAB No. 55, 64. and 83	-	-	-	-
	-----	-----	-----	-----
Total weighted average common and common equivalent shares outstanding	15,632	15,380	15,578	15,325
	=====	=====	=====	=====
Net loss	\$ (4,305)	\$ (2,676)	\$ (9,982)	\$ (6,593)
	=====	=====	=====	=====
Loss per share	\$ (0.28)	\$ (0.17)	\$ (0.64)	\$ (0.43)
	=====	=====	=====	=====

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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Protein Design Labs, Inc.
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9-MOS		
	DEC-31-1996	
	JAN-01-1996	
	SEP-30-1996	6,735
		92,723
		2,881
		0
		0
	102,339	16,362
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	110,310	
	5,003	0
	0	0
		0
		157
	105,150	
110,310		0
	16,130	0
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	0	
	0	
	0	
	(9,982)	
		0
	(9,982)	
		0
	0	
		0
	(9,982)	
	(.64)	
	(.64)	