SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
[X] Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 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 | 94-3023969 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (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 [X] No [ ]

As of June 30, 1996, there were 15,612,671 shares of the Registrant's Common Stock outstanding.

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PROTEIN DESIGN LABS, INC.

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PART I. FINANCIAL INFORMATION

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 1996 | 1995 | 1996 | 1995 |
| Revenues: | | | | |
| Research and development revenue under collaborative agreements-related parties | $ 3,000,000 | $ 2,500,000 | $ 7,000,000 | $ 5,075,000 |
| Research and development revenue under collaborative agreements-other | 500,000 | - | 500,000 | - |
| Interest and other income | 1,527,741 | 1,560,810 | 3,076,162 | 3,103,131 |
| Total revenues | 5,027,741 | 4,060,810 | 10,576,162 | 8,178,131 |
| Costs and expenses: | | | | |
| Research and development | 7,155,596 | 5,301,793 | 13,626,943 | 9,770,600 |
| General and administrative | 1,349,721 | 1,196,735 | 2,626,324 | 2,323,856 |
| Total costs and expenses | 8,505,317 | 6,498,528 | 16,253,267 | 12,094,456 |
| Net loss | $(3,477,577) | $(2,437,718) | $(5,677,105) | $(3,916,325) |
| Net loss per share | $(0.22) | $(0.16) | $(0.37) | $(0.26) |
| Shares used in computation of net loss per share | 15,597,000 | 15,338,000 | 15,552,000 | 15,297,000 |

See accompanying notes

PROTEIN DESIGN LABS, INC.
BALANCE SHEETS

| | June 30, 1996 (unaudited) | December 31, 1995 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 5,345,127 | $ 4,686,259 |
| Short-term investments | 61,651,889 | 41,743,675 |
| Other current assets | 926,097 | 648,536 |
| Total current assets | 67,923,113 | 47,078,470 |
| Property and equipment, net | 7,841,000 | 7,850,485 |
| Long-term investments | 35,738,652 | 60,635,550 |
| Other assets | 927,891 | 847,891 |
| | $112,430,656 | $116,412,396 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 636,705 | $ 637,637 |
| Accrued compensation | 685,105 | 605,127 |
| Other accrued liabilities | 1,234,374 | 1,313,805 |
| Deferred revenue | 1,000,000 | 1,000,000 |
| Total current liabilities | 3,556,184 | 3,556,569 |
| Stockholders' equity: | | |
| Preferred stock, par value $0.1 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; 15,612,671 and 15,405,761 issued and outstanding at June 30, 1996 and December 31, 1995, respectively. | 156,127 | 154,058 |
| Additional paid-in capital | 138,089,791 | 135,616,420 |
| Accumulated deficit | (29,388,161) | (23,711,056) |
| Unrealized loss on investments | 16,715 | 796,405 |
| Total stockholders' equity | 108,874,472 | 112,855,827 |
| | $112,430,656 | $116,412,396 |

See accompanying notes

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

| | Six months ended June 30, 1996 | 1995 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net loss | $(5,677,105) | $(3,916,325) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,568,703 | 1,180,358 |
| Other | 28,509 | (1,280,954) |
| Changes in assets and liabilities: | | |
| Other current assets | (277,561) | (421,453) |
| Accounts payable | (932) | (157,122) |
| Accrued compensation | 79,978 | 128,816 |
| Other accrued liabilities | (79,430) | (369,569) |
| Deferred revenue | - | (75,000) |
| Total adjustments | 1,319,267 | (994,924) |
| Net cash used in operating activities | (4,357,838) | (4,911,249) |
| Cash flows from investing activities: | | |
| Purchases of short and long term investments | (20,965,288) | (51,339,086) |
| Maturities of short and long term investments | 25,000,000 | 26,000,000 |
| Sales of short and long term investments | - | 36,348,806 |
| Capital expenditures | (1,413,446) | (1,851,212) |
| Increase in other assets | (80,000) | (25,800) |
| Net cash provided by (used in) investing activities | 2,541,266 | 9,132,708 |
| Cash flows from financing activities: | | |
| Principal payments on capital lease obligations | - | (24,971) |
| Net proceeds from issuance of common stock | 2,475,440 | 1,156,210 |
| Net cash provided by financing activities | 2,475,440 | 1,131,239 |
| Net decrease in cash and cash equivalents | 658,868 | 5,352,698 |
| Cash and cash equivalents at beginning of period | 4,686,259 | 5,440,065 |
| Cash and cash equivalents at end of period | $ 5,345,127 | $10,792,763 |

See accompanying notes

PROTEIN DESIGN LABS, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS
JUNE 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 June 30, 1996 and the statements of operations and cash flows for the six month periods ended June 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 March 31, 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 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.

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, 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 for the year ended December 31, 1995 and the Company's Quarterly Report on Form 10-Q for the period ended March 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. To date, revenues have been generated primarily by amounts earned under license agreements and interest income. 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. The Company believes that increases in expenses in the coming years will exceed increases in non-royalty revenues under existing license agreements and that, as a result, in the absence of other sources of significant revenue, losses will increase from year to year.

Three months ended June 30, 1996 and 1995

The Company's total revenues for the three months ended June 30, 1996 were approximately $5.0 million, an increase from approximately $4.1 million for the comparable period in 1995. Research and development revenues increased by $1.0 million and interest income approximately equaled the year-earlier quarter.

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. The amount of revenue, if any, earned from each of these components is expected to vary from quarter to quarter and from year to year, and variations may be significant depending on the terms of the particular agreements. Related party research and development revenues for the three months ended June 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 efforts under the agreement by the Company. The Company expects that the current research and development

reimbursement funding arrangement with Boehringer Mannheim will expire as scheduled in October 1996. In addition, the Company earned research and development revenues of $0.5 million for the three months ended June 30, 1996 under the Company's development and licensing agreement with an unrelated third party compared to no revenues from unrelated third parties in the comparable period in 1995.

Interest and other income for the three months ended June 30, 1996 in the amount of $1.5 million approximately equaled that in the comparable period of 1995. Although cash and investments were lower, interest rates for the three month period ended June 30, 1996 were higher than the comparable period in 1995.

Total costs and expenses for the three months ended June 30, 1996 increased to approximately $8.5 million from approximately $6.5 million in the comparable period of 1995. The increase in costs and expenses was due primarily to increases in research and development efforts and related expenses.

Research and development expenses for the three months ended June 30, 1996 increased to approximately $7.2 million from approximately $5.3 million in the comparable period of 1995, primarily as a result of the Company's conducting additional development efforts independently and under its agreements with its collaborative partner Boehringer Mannheim. These expenses included the continuation of clinical trials, costs of conducting preclinical tests, expansion of pharmaceutical development capabilities including support for both clinical development and manufacturing process development, higher costs in the expanded operation of the manufacturing facility and the addition of staff. The Company anticipates that expenses for research and development will continue to increase as its initial products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development activities and as the Company expands its manufacturing capabilities in support of ongoing and planned clinical trials and potential commercial supplies.

General and administrative expenses for the three months ended June 30, 1996 increased to approximately $1.3 million from approximately $1.2 million in the comparable period of 1995. These increases are 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.

Six months ended June 30, 1996 and 1995

The Company's total revenues for the six months ended June 30, 1996 were approximately $10.6 million, an increase from approximately $8.2 million for the comparable period in 1995. Research and development revenues increased by approximately $2.4 million and interest income approximately equaled the year-earlier period.

Related party research and development revenues for the six months ended June 30, 1996 reflected amounts earned under the Company's agreement with Boehringer Mannheim, which increased by $2.0 million from the comparable period in 1995. This increase is attributable to increased efforts under the agreement by the Company as well as receipt of a milestone payment in January 1996. Increased funding from Boehringer Mannheim during the six months ended June 30, 1996 was partially offset by reduced funding from Hoffmann-La Roche Inc. and its parent Roche Holding Ltd. (collectively, "Roche"), which funding arrangement expired in January 1995. In addition, the Company earned research and development revenues of $0.5 million for the six months ended June 30, 1996 under the Company's development and licensing agreement with an unrelated third party compared to no revenues from unrelated third parties in the comparable period in 1995.

Interest and other income for the six months ended June 30, 1996 in the amount of $3.1 million approximately equaled that in the comparable period of 1995. Although cash and investments were lower, interest rates for the six month period ended June 30, 1996 were higher than the comparable period in 1995.

Total costs and expenses for the six months ended June 30, 1996 increased to approximately $16.3 million from approximately $12.1 million in the comparable period of 1995. The increase in costs and expenses was due primarily to increases in research and development efforts and related expenses.

Research and development expenses for the six months ended June 30, 1996 increased to approximately $13.6 million from approximately $9.8 million in the comparable period of 1995, primarily as a result of the Company's conducting additional development efforts independently and under its agreements with its collaborative partner Boehringer Mannheim. These expenses included the continuation of clinical trials, costs of conducting preclinical tests, expansion of pharmaceutical development capabilities including support for both clinical development and manufacturing process development, higher costs in the expanded operation of the manufacturing facility and the addition of staff. The Company anticipates that expenses for research and development will continue to increase as its initial products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development activities, as the Company expands its manufacturing capabilities in support of ongoing and planned clinical trials and potential commercial supplies.

General and administrative expenses for the six months ended June 30, 1996 increased to approximately $2.6 million from approximately $2.3 million in the comparable period of 1995. These increases are 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.

The Company believes that total costs and expenses will rise significantly over the coming quarters and years as the Company continues to invest in research, pharmaceutical development, manufacturing, preclinical, and clinical activities and as additional potential products enter human clinical trials or progress to more advanced stages of clinical development. The Company believes that revenues from research and development reimbursement funding from Boehringer Mannheim will be essentially unchanged in 1996, compared to 1995. The Company expects that the current research and development reimbursement funding arrangement with Boehringer Mannheim will expire as scheduled in October 1996. The Company further believes that research and development revenues under existing agreements with collaborative partners will terminate or decline over time, as fewer milestones remain unearned, as products covered by such agreements proceed through clinical trials, and before such products receive marketing approval from appropriate authorities, if ever, and begin to generate royalty payments. Overall, the Company believes that increases in expenses over the next several years will more than offset any increases in non-royalty revenues under existing agreements.

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 licensing agreements, capital lease financing and interest income on invested capital. At June 30, 1996, the Company had cash, cash equivalents and investments, both short and long term, in the aggregate of approximately $102.7 million as compared to approximately $107.1 million at December 31, 1995. 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 approximately $4.4 million for the six months ended June 30, 1996 compared to approximately $4.9 million in the comparable period of 1995. The Company expects to incur substantial additional costs in the future, including costs related to ongoing research and development activities, 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

The Company's Annual Meeting of Stockholders was held on June 27, 1996 at its principal offices in Mountain View, California. Of the 15,579,435 shares outstanding as of the record date, 10,923,164 shares were present at the meeting or represented by proxies, representing approximately 70% of the total votes eligible to be cast.

At the meeting, the stockholders voted to elect two (2) Class I 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 I director elected at the Annual Meeting and the votes cast with respect to each such individual are set forth below.

| | For | Withheld |
|---|---|---|
| George M. Gould, Esq. | 10,803,282 | 119,882 |
| Jon S. Saxe, Esq. | 10,803,317 | 119,847 |

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, 1996. This proposal received 10,909,067 affirmative votes and 9,047 negative votes. There were 5,050 abstentions.

ITEM 5. OTHER INFORMATION.

RISK FACTORS

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 this section as well as those discussed elsewhere in this document and the Company's Annual Report on Form 10-K for the year ended December 31, 1995 and Quarterly Report on Form 10-Q for the Quarter ended March 31, 1996.

History of Losses; Future Profitability Uncertain.

As of June 30, 1996, the Company had accumulated net losses of approximately $29.4 million. To date, the Company has not received regulatory approval to distribute any products nor generated any significant revenues from product sales. The Company's research efforts have focused on the development of humanized and human antibodies and other novel proteins to prevent or treat certain disease conditions, including viral infections, autoimmune diseases, cancer and cardiovascular conditions. PDL'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. No significant revenues have been generated 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 several years. The time and resource commitment required to achieve market success for any individual product is extensive and uncertain. No assurance can be given that the Company's or its collaborative partners' product development efforts will be successful, that required regulatory approvals can be obtained, that potential products can be manufactured at acceptable cost and with appropriate quality, or that any approved products can be successfully marketed. In the absence of revenues from new corporate collaborations or other sources, the Company expects to incur substantial operating losses in the foreseeable future as earlier stage products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development and as the Company invests in additional manufacturing capacity. Moreover, 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. 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 products. No assurances can be given that the Company will be able to achieve or sustain profitability.

Uncertainty of Clinical Trial Results.

Before obtaining regulatory approval for the commercial sale of any of its products under development, 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. While the Company has certain preclinical and clinical evidence supporting further research and development of its potential products, there can be no assurance that the Company will be permitted to undertake further clinical trials for any of its 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 products or will result in approval to market products. In any particular situation 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 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 and the Company announced the results of a Phase II/III clinical trial using the Company's SMART(TM) Anti-Tac Antibody, Zenapax, for the prevention of graft-versus-host disease. The analysis of this data by Roche led Roche to conclude that Zenapax was not effective in reducing the incidence of GvHD in the patient population studied. Roche is currently conducting two large, multinational Phase III trials of Zenapax for the reduction in the number of patients who experience kidney transplant rejection episodes within six months of transplantation. Enrollment has been completed and results are expected to be available in the third or fourth quarter of 1996. Although results of a Phase I trial in this indication were positive, the number of patients in that study was small and may not reflect the actual results that will be achieved when tested in a large number of patients. Moreover, no Phase II trial in this indication was conducted to obtain additional information about the use of Zenapax in patients prior to advancing to Phase III trials. Additionally, differences exist between the Phase I and Phase III trial designs, including, without limitation, the fact that most of the patients in the Phase I trial received kidney transplants from living related donors, whereas the Phase III trials only include patients who have received cadaverous transplants. Various factors, such as these, could lead to different results than those observed in the Phase I trial. Therefore, there can be no assurance that the results of the Phase III trials will be positive. If not, there would be a

material adverse effect on the Company's business and on the price of the Company's stock.

PDL is also conducting potentially pivotal trials of its PROTOVIR(TM) human anti-CMV antibody, both for treatment of CMV retinitis in AIDS patients and for the prevention of CMV infections in recipients of bone marrow transplants. Earlier stage trials were limited to small numbers of patients and had significant differences in design from the larger Phase II and Phase II/III trials currently being conducted. For example, both the Phase II and the Phase II/III trial for the treatment of CMV retinitis will allow additional types of background treatment (i.e., the other drugs used to treat CMV retinitis) in the placebo and treatment groups than were available and used in the Phase I/II trial. These trials will also utilize a more sensitive means of measuring progression (i.e., relapse) of CMV retinitis than was used in the Phase I/II trial. These or other differences in trial designs between the later stage and earlier stage clinical trials might lead to different results regarding the safety and efficacy of PROTOVIR in these later stage trials. There can be no assurance that the results of these trials will show PROTOVIR to be safe and efficacious and, if not, there would be a material adverse effect on the Company's business and on the price of the Company's stock.

Dependence on Collaborative Partners.

The Company has collaborative agreements with several pharmaceutical companies for the development, manufacturing and marketing of certain potential products, which include the most advanced products under development by the Company. The Company has granted to its collaborative partners certain exclusive rights to commercialize the products developed under these collaborative agreements. In some cases, the Company is relying on its collaborative partners to conduct clinical trials, to obtain regulatory approvals and, if approved, to manufacture and market these licensed products.

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 further 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 continue with additional or ongoing trials, that these trials will be successful or even if successful, that the results will be sufficient for regulatory approval, that Roche will proceed to bring this product to market in a rapid and timely manner, that Zenapax can be manufactured by Roche according to cGMP in a consistent and cost-effective manner or, once marketed, that other independently developed products of Roche or others will not compete with or prevent Zenapax from achieving meaningful sales.

In addition, 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. For example, the Company is currently relying on and may continue to rely on Boehringer Mannheim for the manufacturing and clinical development of OST 577, the Company's Human Anti-Hepatitis B Virus Antibody. Boehringer Mannheim has marketing rights to this antibody in most countries, but not in North America. There can be no assurance that Boehringer Mannheim will provide timely access to the manufacturing and clinical data, that the 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 is 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.

The Company's collaborative research agreements are generally terminable by its partners on short notice. Continued funding and participation by collaborative partners will depend not only on the timely achievement of research and development objectives by PDL 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 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 others, including their relative patent and proprietary technology positions, and the ability to manufacture successfully. For example, with respect to its continuing relationship with Boehringer Mannheim, the Company has experienced difficulty in the relationship due to a number of factors, including disagreements regarding the timing of the initiation of 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 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. Suspension or termination of any 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. While the Company is seeking additional collaborative arrangements to develop and commercialize its products in the future, there can be no assurance it will be able to do so on acceptable terms.

Limited Experience in, and Unpredictability of, Conducting Clinical Trials.

Although certain of the officers and employees of the Company have significant previous experience in the pharmaceutical industry, the Company itself 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 products in development. Certain of the Company's more advanced trials are being conducted with or by third party organizations, such as two trials of PROTOVIR, which are being conducted in collaboration with government-sponsored organizations. Certain of these relationships involve PDL surrendering significant control over some or all of the conduct of the clinical trial. There can be no assurance that surrendering or sharing control in certain of these trials will not result in delays due to factors such as changes in funding, reduction in the number of clinical sites participating in the trial or more limited patient accrual efforts than might otherwise be undertaken if PDL had sponsored the trial independently. If the Company or its collaborative partners are unable to commence or continue clinical trials as currently planned, complete the clinical trials on a timely basis or demonstrate the safety and efficacy of its potential products, the Company's business and financial condition would be materially and adversely affected. In addition, even if a potential product is successfully developed according to plans, there can be no assurance that the FDA or other regulatory authorities will approve the potential product on a timely basis or at all.

The rate of completion of the Company's clinical trials is significantly dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, perceived risks and benefits of the drug under study, availability of competing therapies, access to reimbursement from insurance companies, 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 in potentially requiring the Company to undertake additional studies in order to obtain regulatory approval in the event that the applicable standard of care changes in the therapeutic indication under study. Any such delays or additional studies could have a material adverse effect on the business and financial condition of the Company. For example, the recent FDA approvals of Vitrasert(TM), a ganciclovir implant developed by Chiron Corporation to treat CMV retinitis, and VISTIDE(TM), a drug developed by Gilead Sciences, Inc., for the systemic treatment of CMV retinitis in patients with AIDS, may adversely impact the accrual of patients or the interpretation of the clinical data resulting from the current clinical trials of PROTOVIR. Also, 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. While the Company is exploring various possible actions to accelerate accrual in these trials, there can be no assurance that any such actions, if taken, will be successful.

In addition, the Company is relying and intends to rely on CROs and other third parties under the management of the Company's clinical department for the conduct of clinical trials. There can be no assurance that PDL will be able to negotiate

arrangements with third parties for the conduct of PDL's clinical trials on acceptable terms in the future or that such arrangements will be successful.

Uncertainties Resulting From Manufacturing Changes.

Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is typically 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 studies 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 types 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 including 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.

Specifically, with respect to two of the antibodies in clinical development licensed from Sandoz, MSL 109 (PROTOVIR) and OST 577 (Human Anti-Hepatitis B Antibody), the cell lines developed by PDL for both antibodies and the production processes developed by PDL and Boehringer Mannheim for PROTOVIR and OST 577, respectively, are different from those utilized by Sandoz for the manufacture of the antibody supplies used in earlier clinical trials. With respect to the development of PROTOVIR, a decision to change the cell line and manufacturing procedure requires demonstration to the FDA that the new drug substance is acceptable. Although PDL has been permitted to enter new MSL 109 antibody material into ongoing U.S. clinical trials based on various laboratory tests, 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. If not, the Company may be required to conduct additional laboratory or clinical testing, which could result in significant delays or additional expenses and could have an adverse effect on the competitive position of PROTOVIR and a material adverse effect on the business and financial condition of the Company.

With respect to the development of OST 577, the Company has been advised that Boehringer Mannheim will be permitted to enter OST 577 manufactured by a new process into planned U.S. clinical trials. However, 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. If not, Boehringer Mannheim or the Company may be required to conduct additional laboratory or clinical testing, which could result in significant delays or additional expenses and could have an adverse effect on the competitive position of OST 577 and a material adverse effect on the business and financial condition of the Company.

In addition, the Company is aware that Roche has constructed a new manufacturing plant that could be used to produce Zenapax. If Roche decides to change the site of its production of Zenapax to that or another facility or to make other manufacturing changes, then there can be no assurance that such changes by Roche would 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.

Absence of Manufacturing Experience; Human Anti-HBV Antibody 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 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 delays, 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.

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. PDL is evaluating plans to improve and expand the capacity of its current manufacturing facility. Such plans, if instituted, may require a suspension of manufacturing operations during construction. Moreover, there can be no assurance that construction delays would not occur and, if so, 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 and thus could have a material adverse effect on the Company.

In addition, as part of the arrangement between PDL and Boehringer Mannheim, the parties have agreed to negotiate additional agreements in the future 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 internally and currently 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.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits.

| Number | | Page |
|---|---|---|
| 10.1 | Amendment No. 3 to the Joint Development, Marketing and License Agreement between the Company and Boehringer Mannheim GmbH dated and effective as of May 31, 1996 (with certain confidential information deleted and marked by brackets surrounding such information). | 24 |

(b) No Reports on Form 8-K were filed during the quarter ended June 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: August 13, 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)

AMENDMENT NO. 3 TO JOINT DEVELOPMENT, MARKETING AND LICENSE AGREEMENT

This AMENDMENT NO. 3 TO JOINT DEVELOPMENT, MARKETING AND LICENSE AGREEMENT (the "Amendment"), is made as of May 31, 1996 by and between Protein Design Labs, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 2375 Garcia Avenue, Mountain View, CA 94043 USA (hereinafter "PDL"), and Boehringer Mannheim GmbH, a German company having offices at Sandhofer Strasse 116 D-688298, Mannheim, Germany (hereinafter "BM") and amends that certain Joint Development, Marketing and License Agreement dated October 28, 1993, as amended December 5, 1994 and November 7, 1995 (the "Agreement"). Except as expressly provided herein, capitalized terms shall have the meaning set forth in the Agreement.

RECITALS

A. WHEREAS, PDL and BM are parties to the Agreement; and

B. WHEREAS, BM's rights to the [ ] Antibodies licensed under the Agreement have lapsed; and

C. WHEREAS, PDL and BM desire to amend certain provisions of the Agreement to provide for, among other matters, the reinstatement of certain rights and obligations of BM related solely to the [ ] antibody.

AGREEMENT

NOW THEREFORE, the parties agree as follows:

Except as expressly set forth herein, capitalized terms and references to Sections, Exhibits and Articles shall be deemed references to the Agreement.

1. AMENDMENTS OF AGREEMENT.

1.1 AMENDMENT OF DEFINITION OF [ ] ANTIBODY. Effective upon the execution of this Amendment, all BM rights to any human or humanized antibody that binds to the [ ] [

]

1.2 REINSTATEMENT OF RIGHTS AND OBLIGATIONS TO [ ] ANTIBODY. Effective upon execution of this Amendment, the [ ] Antibody will be reinstated

as a Pharmaceutical Product under the Agreement, provided that the Milestones set forth in Exhibit C related to "Each Human or Humanized Antibody to [ ]" shall be amended to refer solely to "Each Humanized Antibody to [ ]."

1.3 EXTENSION OF NON-AFFILIATE ASIAN RELATIONSHIPS TO INCLUDE [ ] ANTIBODY. Section 9.9 of the Agreement is amended and restated in its entirety as follows:

"9.9 NON-AFFILIATE ASIAN RELATIONSHIPS. Notwithstanding any other provision of this Agreement, for any Licensed Product directed against HBV or the [ ] receptor, if BM decides to sublicense rights to a non-Affiliate to develop, manufacture, market or sell such Licensed Product in any country in Asia or if BM decides to co-promote such a Licensed Product with any non-Affiliate or use a non-Affiliate as a distributor of such a Licensed Product, in any country in Asia, then PDL shall have the right, but not the obligation, to be present, at PDL's own expense, during face-to-face discussions and negotiations with such non-Affiliate (but shall not actively participate in such negotiations except to the extent requested by BM) and shall receive the royalty it would receive under this Agreement on Net Sales of such Licensed Product in such countries in Asia plus [ ] of any non-royalty consideration received by BM and its Affiliates from such arrangement with the non-Affiliate."

2. ADDITIONAL PDL DISCLOSURE RIGHTS FOR BM TECHNICAL INFORMATION FOR THE [ ] ANTIBODY. In addition to the disclosure rights of PDL pertaining to all data and BM Technical Information related to the [ ] Antibody in PDL's Territory (as provided in Section 2 of Amendment No. 2 to the Agreement), BM hereby consents to the further disclosure by PDL of all data and other BM Technical Information related to the [ ] Antibody to prospective potential Asian partners for a possible collaboration with BM involving the [ ] Antibody; provided that such disclosure is made pursuant to a confidentiality agreement.

3. STUDIES OF [ ] ANTIBODY. In the event that the currently planned [ ] study testing the [ ] Antibody in a [ ] is not negative, BM hereby agrees that it will promptly (and in any event within three months of the [ ] results), at its sole expense, initiate and complete a [ ] study of the [ ] Antibody in a [ ]; provided that BM and PDL do not conclude that [ ] should preclude further development of the [ ] Antibody.

4. NO OTHER CHANGES. On and after the date hereof, each reference in the Agreement to "this Agreement," "hereunder," "hereof," or words of like import referring to the Agreement, shall mean and be a reference to the Agreement as amended hereby. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed.

IN WITNESS WHEREOF, the parties have executed this Amendment through their duly authorized representatives as of the date first set forth above.

PDL:

Protein Design Labs, Inc.

By /s/ Douglas O. Ebersole
Vice President, Licensing
and General Counsel

BM:

Boehringer Mannheim GmbH

By /s/ Dr. Claus-Jorg Rutsch
Vice President Intl. Legal Affairs
Therapeutics

By /s/ Dr. Lothar Wieczorek
Vice President Project Development

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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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