

UNITED STATES  
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 June 30, 2000**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-19756

**PROTEIN DESIGN LABS, INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation or Organization)

**94-3023969**

(I.R.S. Employer Identification Number)

**34801 Campus Drive**

**Fremont, California, 94555**

(Address of Principal Executive Offices including Zip Code)

**(510) 574-1400**

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

As of June 30, 2000, there were 19,924,562 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.  
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**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except net income (loss) per share data)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	1999	2000	1999
Revenues:				
Revenue under agreements with third parties	\$15,893	\$6,039	\$28,343	\$12,501
Interest and other income	4,472	2,249	7,521	4,623
Total revenues	20,365	8,288	35,864	17,124
Costs and expenses:				
Research and development	10,216	8,513	21,284	16,793
General and administrative	2,870	2,450	5,329	4,895
Interest expense	2,257	--	3,460	--
Total costs and expenses	15,343	10,963	30,073	21,688
Net income (loss)	\$5,022	(\$2,675)	\$5,791	(\$4,564)
Net income (loss) per share:				
Basic	\$0.25	(\$0.14)	\$0.30	(\$0.25)
Diluted	\$0.23	(\$0.14)	\$0.27	(\$0.25)
Weighted average number of shares:				
Basic	19,757	18,625	19,609	18,622
Diluted	21,631	18,625	21,593	18,622

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See accompanying notes

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

	June 30, 2000	December 31, 1999
	----- (unaudited)	-----
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$194,973	\$17,138
Marketable securities	114,908	120,098
Other current assets	2,272	6,719
	-----	-----
Total current assets	312,153	143,955
Property and equipment, net	37,995	38,047
Other assets	4,510	549
	-----	-----
	\$354,658	\$182,551
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$573	\$877
Accrued compensation	1,229	1,090
Accrued clinical trials	1,239	712
Accrued interest	3,071	--
Other accrued liabilities	1,632	2,762
Deferred revenue	1,333	2,275
Current portion of long-term debt	384	368
	-----	-----
Total current liabilities	9,461	8,084
Convertible notes	150,000	--
Long-term debt	9,527	9,724
	-----	-----
Total liabilities	168,988	17,808
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 10,000 shares authorized; no shares issued and outstanding	--	--
Common stock, par value \$0.01 per share, 40,000 shares authorized; 19,925 and 19,281 issued and outstanding at June 30, 2000 and December 31, 1999, respectively	199	193
Additional paid-in capital	261,118	245,812
Accumulated deficit	(73,426)	(79,217)
Accumulated other comprehensive income (loss)	(2,221)	(2,045)
	-----	-----
Total stockholders' equity	185,670	164,743
	-----	-----
	\$354,658	\$182,551
	=====	=====

See accompanying notes

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**PROTEIN DESIGN LABS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS**  
(unaudited)  
(In thousands)

	Six Months Ended June 30,	
	2000	1999
Cash flows from operating activities:		
Net income (loss)	\$5,791	(\$4,564)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,665	1,766
Amortization of convertible debt offering costs	269	--
Other	179	(316)
Changes in assets and liabilities:		
Other current assets	4,447	1,424
Accounts payable	(304)	5
Accrued liabilities	2,607	(1,589)
Deferred revenue	(942)	1,625
Total adjustments	7,921	2,915
Net cash provided by (used in) operating activities	13,712	(1,649)
Cash flows from investing activities:		
Purchases of marketable securities	--	(81,336)
Maturities of marketable securities	5,000	69,900
Property, plant and equipment	(1,777)	(1,598)
Proceeds from sale of equipment	--	325
Increase in other assets	(4,231)	(183)
Net cash provided by (used in) investing activities	(1,008)	(12,892)
Cash flows from financing activities:		
Proceeds from convertible debt	150,000	--
Proceeds from issuance of capital stock	15,312	825
Payments on other long-term debt	(181)	--
Net cash provided by financing activities	165,131	825
Net increase (decrease) in cash and cash equivalents	177,835	(13,716)
Cash and cash equivalents at beginning of period	17,138	27,907
Cash and cash equivalents at end of period	\$194,973	\$14,191
	=====	=====

See accompanying notes

**PROTEIN DESIGN LABS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2000**  
(unaudited)

**Summary of Significant Accounting Policies**

***Organization and Business***

Since our founding in 1986, a primary focus of our operations has been research and development. Achievement of successful research and development and commercialization of products derived from our efforts is subject to high levels of risk and significant resource commitments. Our expenses have generally exceeded revenues. As of June 30, 2000, we had an accumulated deficit of approximately \$73.4 million. We believe that our losses may increase because of the extensive resource commitments

required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in new research areas and improve and expand our manufacturing capabilities. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We cannot assure you that we will be able to achieve or sustain profitability.

Our commitment of resources to the continued development of our existing products will require significant additional funds for development. These operating expenses may also increase as some of our earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as we invest in additional manufacturing capacity, as we defend or prosecute our patents and patent applications, and as we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of our licensees, potential reductions in royalties payable to us due to credits for prior payments to us, the timing of royalty reports, some of which are required quarterly and others semi-annually, our method of accounting for royalty revenues from our licensees and our ability to successfully defend and enforce our patents. Other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees and payments for manufacturing services and achievement of milestones under new and existing collaborative, humanization, and patent licensing agreements. Revenue historically recognized under our prior agreements may not be an indicator of revenue from any future collaborations.

In addition, our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include payments owed by us under licensing arrangements and due to our policy of recording expenses under certain collaborative agreements during the quarter in which such expenses are reported to us.

### ***Basis of Presentation and Responsibility for Quarterly Financial Statements***

The consolidated balance sheet as of June 30, 2000, and the consolidated statements of operations for the three and six month periods and cash flows for the six month periods ended June 30, 2000 and 1999 are unaudited, but include all adjustments (consisting only of normal recurring adjustments) which we consider necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in our financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S. 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 our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, for the year ended December 31, 1999. The balance sheet as of December 31, 1999 is derived from audited financial statements. Results for any interim period are not necessarily indicative of results for any other interim period or for the entire year.

### ***Cash Equivalents, Marketable Securities and Concentration of Credit Risk***

We consider all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. The "Other" adjustments line item in the Statements of Cash Flows represents the accretion of the book value of certain debt securities. We place our cash and marketable securities with high-credit-quality financial institutions and in securities of the U.S. government and U.S. government agencies and, by policy, limit the amount of credit exposure in any one financial instrument. To date, we have not experienced credit losses on investments in these instruments.

### ***Revenue Recognition***

Contract revenues from research and development arrangements are recorded as earned based on the performance requirements of the contracts. Revenues from achievement of milestone events are recognized when the funding party agrees that the scientific or clinical or regulatory results stipulated in the agreement have been met. Deferred revenue arises principally due to timing of cash payments received under research and development contracts.

Our collaborative, humanization and patent licensing agreements with third parties provide for the payment of royalties to us based on net sales of the licensed product under the agreement. The agreements generally provide for royalty payments to us following completion of each calendar quarter or semi-annual period and royalty revenue is recognized when royalty reports are received from the third party. Non-refundable signing and licensing fees under collaborative and humanization agreements are recognized over the period in which performance obligations are achieved. Non-refundable signing and licensing fees under patent licensing agreements are recognized as revenue when there are no future performance obligations remaining with respect to such fees.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). We are evaluating the effects, if any, that the adoption of SAB 101 in the fourth quarter of 2000, effective January 2000, may have on the results of our operations or our financial position. We have been advised that the Securities and Exchange Commission intends to provide additional guidance during the third quarter of 2000 with respect to the implementation of SAB 101. It is currently unknown whether such guidance and implementation of SAB 101 will require us to revise our revenue recognition practices or to restate revenues for the first and second quarters of 2000.

### ***Net Income (Loss) Per Share***

In accordance with Financial Accounting Standards Board Statement No. 128, "Earnings Per Share" ("FAS 128"), basic and diluted net income (loss) per share amounts have been computed using the weighted average number of shares of common stock outstanding during the periods presented. Calculation of diluted net income per share includes the dilutive effect of outstanding stock options, but does not include the dilutive effect of outstanding convertible debt because the convertible debt's conversion price was greater than the average market price of the common stock during the three and six month periods ended June 30, 2000. We incurred a net loss for the three and six month periods ended June 30, 1999, and as such, we did not include the effect of outstanding stock options in the diluted net loss per share calculation as their effect is anti-dilutive.

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

(In thousands, except basic and diluted net income (loss) per share)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	1999	2000	1999
Numerator:				
Net income (loss)	\$5,022	(\$2,675)	\$5,791	(\$4,564)
Denominator:				
Basic net income (loss) per share - weighted-average shares	19,757	18,625	19,609	18,622
Dilutive potential common shares: Stock Options	1,874	--	1,984	--
Denominator for diluted net income (loss) per share	21,631	18,625	21,593	18,622
Basic net income (loss) per share	\$0.25	(\$0.14)	\$0.30	(\$0.25)
Diluted net income (loss) per share	\$0.23	(\$0.14)	\$0.27	(\$0.25)

### ***Comprehensive Income (Loss)***

During the three months ended June 30, 2000 and 1999, total comprehensive income (loss) was \$5.3 million and \$(4.4) million, respectively. The Company's other comprehensive income (loss) for the three months ended June 30, 2000 and 1999 was \$0.3 million and \$(1.7) million, respectively. For the six months ended June 30, 2000 and 1999, total comprehensive income (loss) was \$5.6 million and \$(6.0) million, respectively. Other comprehensive income (loss) for the six months ended June 30, 2000 and 1999 was \$(0.2) million and \$(1.4) million, respectively. Other comprehensive income (loss) is comprised of unrealized gains and losses on the Company's available-for-sale securities.

### ***Accounting for Certain Transactions Involving Stock Compensation***

In April 2000, the Financial Accounting Standards Board Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB Opinion No. 25" (FIN 44) was issued. FIN 44 clarifies the application of APB No. 25 for certain issues. Among other issues, FIN 44 clarifies the definition of employee for purposes of applying APB No. 25, the criteria for determining whether a plan qualifies as a non-compensatory plan, the accounting consequences of various modifications to the term of a previously fixed stock option or award, and the accounting for an exchange of stock compensation awards in a business combination. FIN 44 is effective July 1, 2000, but certain conclusions in this interpretation cover specific events that occur after either December 15, 1998 or January 12, 2000. The Company believes that upon implementation, FIN 44 will not have a significant effect on its results of operations.

### ***Derivative Instruments and Hedging Activities***

In June 1998, the Financial Accounting Standards Board issued Statement No. 133 "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"). FAS 133 is not required to be adopted until 2001. However, the Company has reviewed FAS 133 and because it does not use derivatives, the adoption of FAS 133 is not expected to effect the results of operations or the financial position of the Company.

## **Management Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, we have a policy of recording expenses for clinical trials based upon pro rating estimated total costs of a clinical trial over the estimated length of the clinical trial and the number of patients anticipated to be enrolled in the trial. Expenses related to each patient are recognized ratably beginning upon entry into the trial and over the course of the trial. In the event of early termination of a clinical trial, management accrues an amount based on its estimate of the remaining non-cancellable obligations associated with the winding down of the clinical trial. Our estimates and assumptions could differ significantly from the amounts which may actually be realized.

## **Convertible Notes**

In February 2000, we issued 5.50% Convertible Subordinated Notes due February 15, 2007 with a principal amount of \$150 million (the Convertible Notes). The Convertible Notes are convertible into our common stock at a conversion price of \$151.00 per share, subject to adjustment as a result of certain events and at the holders' option. Interest on the Convertible Notes is payable semiannually in arrears on February 15 and August 15 of each year. The Convertible Notes are unsecured and are subordinated to all our existing and future Senior Indebtedness (as defined in the indenture relating to the Convertible Notes). The Convertible Notes may be redeemed at our option, in whole or in part, beginning on February 15, 2003 at the redemption prices set forth in the Convertible Notes indenture. In June 2000, a shelf registration statement was declared effective covering resales of the Convertible Notes and the common stock issuable upon conversion of the Convertible Notes. Issuance costs associated with the Convertible Notes are included in other assets and are amortized to interest expense over the term of the debt.

## **Stock Split**

In July 2000, we announced that our Board of Directors approved a two-for- one stock split of the outstanding shares of our common stock.

The stock split will be effected in the form of a stock dividend. Each stockholder of record at the close of business on August 1, 2000 will be entitled to receive one additional share of common stock for every share of common stock held on that date. The stock dividend resulting from the stock split is expected to be distributed by our transfer agent on August 22, 2000. The accompanying financial statements do not reflect the effect of this stock split.

As of June 30, 2000, we had approximately 20 million shares outstanding. Upon completion of the split, the number will increase to approximately 40 million.

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

*This Quarterly Report contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to those discussed in "Risk Factors" as well as those discussed elsewhere in this document and the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission for the year ended December 31, 1999.*

## **OVERVIEW**

Since our founding in 1986, a primary focus of our operations has been research and development. Achievement of successful research and development and commercialization of products derived from our efforts is subject to high levels of risk and significant resource commitments. Our expenses have generally exceeded revenues. As of June 30, 2000, we had an accumulated deficit of approximately \$73.4 million. We believe that our losses may increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in new research areas and improve and expand our manufacturing capabilities. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We cannot assure you that we will be able to achieve or sustain profitability.

Our commitment of resources to the continued development of our existing products will require significant additional funds for development. These operating expenses may also increase as some of our earlier stage potential products move into later stage clinical development, as additional potential products are selected as clinical candidates for further development, as we invest in additional manufacturing capacity, as we defend or prosecute our patents and patent applications, and as we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon the seasonality of sales of licensed products, the existence of competing products, the marketing efforts of our licensees, potential reductions in royalties payable to us due to credits for prior payments to us, the timing of royalty reports, some of which are required quarterly and others semi-annually, our method of accounting for royalty revenues from our licensees and our ability to successfully defend and enforce our patents. Other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees and payments for manufacturing services and achievement of milestones under new and existing collaborative, humanization, and patent licensing agreements. Revenue historically recognized under our prior agreements may not be an indicator of revenue from any future collaborations.

PDL has recognized revenue during the quarter ended June 30, 2000, in accordance with its historical practice. In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). We are evaluating the effects, if any, that the adoption of SAB 101 in the fourth quarter of 2000, effective January 1, 2000, may have on the results of our operations or our financial position. We have been advised that the Securities and Exchange Commission intends to provide additional guidance during the third quarter of 2000 with respect to the implementation of SAB 101. It is currently unknown whether such guidance and the implementation of SAB 101 will require us to revise our revenue recognition practices or to restate revenues for the first and second quarters of 2000.

In addition, our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include payments owed by us under licensing arrangements and due to our policy of recording expenses under collaborative agreements during the quarter in which such expenses are reported to us.

## **RESULTS OF OPERATIONS**

### **Three Months Ended June 30, 2000 and 1999**

The Company's total revenues for the three months ended June 30, 2000 were \$20.4 million compared to \$8.3 million in the second quarter of 1999. Total revenues recognized under agreements with third parties were \$15.9 million in the second quarter of 2000 compared to \$6.0 million in the comparable period in 1999. Interest and other income was \$4.5 million in the second quarter of 2000 compared to \$2.2 million in the comparable period in 1999, reflecting the increased interest earned on our cash, cash equivalents and marketable securities balances as a result of our sale of \$150 million in convertible subordinated notes in February 2000.

Revenues under agreements with third parties of \$15.9 million for the three months ended June 30, 2000 consisted principally of royalties, signing and licensing fees, payments earned under humanization agreements, research and development reimbursement funding and license maintenance fees. In the second quarter of 1999, revenues of \$6.0 million under agreements with third parties consisted principally of royalties, research and development reimbursement funding, payments earned under humanization agreements and a license maintenance fee.

Total costs and expenses for the three months ended June 30, 2000 were \$15.3 million compared with \$11.0 million in the comparable period in 1999.

Research and development expenses for the three month period ended June 30, 2000 were \$10.2 million compared with \$8.5 million in the year- earlier quarter. Research and development costs increased primarily due to the addition of staff, the expansion of clinical development programs, research and pharmaceutical development capabilities, including support for both clinical development and manufacturing process development and payments related to manufacturing of the humanized anti-IL-4 antibody.

General and administrative expenses for the three months ended June 30, 2000 increased to \$2.9 million from \$2.5 million in the comparable period in 1999. These increases were primarily the result of expenses associated with managing and supporting the Company's expanding operations.

Interest expense for the three month period ended June 30, 2000 increased to \$2.3 million from zero in the year earlier period primarily due to the interest expense associated with our convertible subordinated notes issued on February 15, 2000. '

### **Six Months Ended June 30, 2000 and 1999**

The Company's total revenues for the six months ended June 30, 2000 were \$35.9 million compared to \$17.1 million in the comparable period of 1999. Total revenues recognized under agreements with third parties were \$28.3 million in the six months ended June 30, 2000 compared to \$12.5 million in the comparable period in 1999. Interest and other income was \$7.5 million in the six month period of 2000 compared to \$4.6 million in the comparable period in 1999, reflecting the increased interest earned on our cash, cash equivalents and marketable securities balances as a result of our sale of \$150 million in convertible subordinated notes in February 2000.

Revenues under agreements with third parties of \$28.3 million for the six months ended June 30, 2000 consisted principally of royalties, signing and licensing fees, payments earned under humanization agreements, research and development reimbursement funding, license maintenance fees and a milestone payment earned under a licensing agreement. In the six month period of 1999, revenues of \$12.5 million under agreements with third parties consisted principally of royalties, signing and licensing fees, research and development reimbursement funding, payments earned under humanization agreements and a license maintenance fee.



Total costs and expenses for the six months ended June 30, 2000 were \$30.1 million compared with \$21.7 million in the comparable period in 1999.

Research and development expenses for the six month period ended June 30, 2000 were \$21.3 million compared with \$16.8 million in the year-earlier period. Research and development costs increased primarily due to the addition of staff, the expansion of clinical development programs, research and pharmaceutical development capabilities, including support for both clinical development and manufacturing process development and payments related to manufacturing of the humanized anti-IL-4 antibody.

General and administrative expenses for the six months ended June 30, 2000 increased to \$5.3 million from \$4.9 million in the comparable period in 1999. These increases were primarily the result of expenses associated with managing and supporting the Company's expanding operations.

Interest expense for the six month period ended June 30, 2000 increased to \$3.5 million from zero in the year earlier period primarily due to the interest expense associated with our convertible subordinated notes issued on February 15, 2000.

### **LIQUIDITY AND CAPITAL RESOURCES**

To date we have financed our operations primarily through public and private placements of equity securities, research and development revenues, interest income on invested capital and the sale of \$150 million in convertible subordinated notes in February 2000. At June 30, 2000, we had cash, cash equivalents and marketable securities in the aggregate of \$309.9 million, compared to \$137.2 million at December 31, 1999.

As set forth in the Consolidated Statements of Cash Flows, net cash provided by operating activities was \$13.7 million for the six months ended June 30, 2000 compared to net cash used in operating activities of \$1.6 million in the same period in 1999. This change was primarily the result of our net income for the six month period of 2000 as compared to a net loss in the comparable period of 1999.

As set forth in the Consolidated Statements of Cash Flows, net cash provided by financing activities for the six months ended June 30, 2000 was \$165.1 million, resulting primarily from the proceeds of the sale of \$150 million in convertible subordinated notes in February 2000 and the exercise of outstanding stock options.

Our future capital requirements will depend on numerous factors, including, among others, royalties from sales of products of third party licensees, including Synagis?, Herceptin?, Zenapax? and Mylotarg?; our ability to enter into additional collaborative, humanization and patent licensing arrangements; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; enhancement of existing and investment in new research and development programs; time required to gain regulatory approvals; resources we devote to self-funded products, manufacturing facilities and methods and advanced technologies; our ability to obtain and retain funding from third parties under collaborative arrangements; our continued development of internal marketing and sales capabilities; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. In order to develop and commercialize our potential products we may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders. We believe that existing capital resources will be adequate to satisfy our capital needs through at least 2002.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company maintains a non-trading investment portfolio of investment grade, highly liquid, debt securities which limits the amount of credit exposure to any one issue, issuer, or type of instrument. The Company does not use derivative financial instruments for speculative or trading purposes. The securities in the Company's investment portfolio are not leveraged and are classified as available for sale and therefore are subject to interest rate risk. The Company does not currently hedge interest rate exposure. As of June 30, 2000, there has been no material change in the Company's interest rate exposure from that described in the Company's Annual Report on Form 10-K for the year ended December 31, 1999.

## **PART II. OTHER INFORMATION**

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

The Company's 2000 Annual Meeting of Stockholders was held on June 15, 2000 at the Company's principal offices in Fremont, California. Of the 19,584,166 shares of common stock outstanding as of the record date, 16,051,839 shares were present at the meeting or represented by proxies, representing approximately 81% of the total votes eligible to be cast.

At the meeting, the stockholders voted to re-elect the Class II member of the Corporation's Board of Directors as follows:

Nominee	For	Withheld
-----	----	-----
Cary Queen	15,976,718	74,471

The stockholders also voted to approve an amendment to the Certificate of Incorporation to increase the number of authorized shares of Common Stock from 40,000,000 to 90,000,000 as follows:

For	Against	Abstentions
-----	-----	-----
13,657,029	2,383,846	10,314

In addition, the stockholders voted to approve an amendment to the Company's 1993 Employee Stock Purchase Plan to increase the number of shares of Common Stock reserved for issuance thereunder by 300,000 shares as follows:

For	Against	Abstentions
-----	-----	-----
15,785,613	252,550	13,026

Lastly, the stockholders voted to ratify the appointment of Ernst & Young LLP as the Corporation's independent auditors for the fiscal year ending December 31, 2000 as follows:

For	Against	Abstentions
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16,029,215	10,499	11,475

## ITEM 5. OTHER INFORMATION - RISK FACTORS

*This Quarterly Report contains, in addition to historical information, forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in forward-looking statements. Factors that may cause such a difference include those discussed in the material set forth in this document and in the discussion captioned "Risk Factors" in the Company's Annual Report on Form 10-K for the year ending December 31, 1999.*

### **We have a history of operating losses and may not achieve profitability.**

Our expenses have generally exceeded revenues. As of June 30, 2000, we had an accumulated deficit of approximately \$73.4 million. We believe that our losses may increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in new research areas and improve and expand our manufacturing capabilities. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We cannot assure you that we will be able to achieve or sustain profitability.

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

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

In the absence of substantial revenues from new corporate collaborations or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses.

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

Our revenues have varied in the past and will likely continue to fluctuate considerably from quarter to quarter and from year to year. As a result, our revenues in any period may not be predictive of revenues in any subsequent period. Our royalty revenues may be unpredictable and may fluctuate since they depend upon:

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

- our method of accounting for royalty revenues from our licensees, and
- our ability to successfully defend and enforce our patents.

Other revenue may also be unpredictable and may fluctuate due to the timing of payments of non-recurring licensing and signing fees and payments for manufacturing services and achievement of milestones under new and existing collaborative, humanization, and patent licensing agreements. Revenue historically recognized under our prior agreements may not be an indicator of non-royalty revenue from any future collaborations.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). We are evaluating the effects, if any, that the adoption of SAB 101 in the fourth quarter of 2000, effective January 1, 2000, may have on the results of our operations or our financial position. We have been advised that the Securities and Exchange Commission intends to provide additional guidance during the third quarter of 2000 with respect to the implementation of SAB 101. It is currently unknown whether such guidance and implementation of SAB 101 will require us to revise our revenue recognition practices or to restate revenues for the first and second quarters of 2000.

In addition, our expenses may be unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include payments owed by us under licensing arrangements and due to our policy of recording expenses under certain collaborative agreements during the quarter in which such expenses are reported to us.

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

PDL's two humanization patents issued by the European Patent Office (EPO) apply in the United Kingdom, Germany, France, Italy and eight other European countries. The EPO procedures provide for an opposition period in which other parties may submit arguments as to why a patent was incorrectly granted and should be withdrawn or limited. Eighteen notices of opposition to our first European patent were filed during the opposition period for the patent, including oppositions by major pharmaceutical and biotechnology companies. At an oral hearing in March 2000, the Opposition Division (OD) of the EPO decided to revoke the broad claims in our first European patent based on formal matters of European patent law, specifically that there had been an impermissible addition of subject matter after the filing of the original European patent application, but did not provide the rationale behind its decision. The decision upheld claims that protect Zenapax. The OD did not otherwise announce a decision on the issue of whether the claims in our patent are inventive in light of the prior art or other issues of patentability. We plan to appeal the OD's decision to the Technical Board of Appeals at the EPO. The Technical Board of Appeals will consider all issues anew. The appeal suspends the decision of the OD during the appeals process, which is likely to take several years.

Until our appeal regarding our first European patent is resolved, we may be limited in our ability to collect royalties or to negotiate future licensing or collaborative research and development arrangements based on this and our other humanization patents. Moreover, if our appeal is unsuccessful, our ability to collect royalties on European sales of antibodies humanized by others would depend on the scope and validity of our second European patent, whether the antibodies are manufactured in a country outside of Europe where they are covered by one of our patents, and in that case the terms of our license agreements with respect to that situation. Also, the OD's decision could encourage challenges of our related patents in other jurisdictions, including the U.S. The OD's decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, which might result in us initiating formal legal actions to enforce our rights under our various humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the appeals process with respect to our first European patent, if we were to commence an infringement action to enforce that patent, such an action would likely be stayed until the appeal is decided by the EPO. We have no assurance that we will successfully enforce our rights under our European or related U.S. and Japanese patents. The nine month opposition period for our second European antibody humanization patent ended in May 2000, and we have been advised that eight notices of opposition have been filed with respect to this patent. We have also been advised that three opposition statements have been filed with the Japanese Patent Office with respect to our humanization patent issued in Japan in late 1998.

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

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

Our success depends significantly on our ability to obtain and maintain patent protection for our products and technologies, to preserve our trade secrets and to operate without infringing on the proprietary rights of third parties. While we file and prosecute patent applications to protect our inventions, our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology.

A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications

or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents.

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

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

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

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

Celltech Chiroscience plc has been granted a patent by the EPO covering humanized antibodies (European Adair Patent), which we have opposed. Celltech has also been issued a corresponding U.S. patent (U.S. Adair Patent) that contains claims that may be considered broader in scope than the European Adair Patent. We have entered into an agreement with Celltech providing each company with the right to obtain nonexclusive licenses for up to three antibody targets under the other company's humanization patents. Nevertheless, if our SMART antibodies were covered by the European or U.S. Adair Patent and if we were to need more than the three licenses under those patents currently available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

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

Lonza Biologics, Inc. has a patent issued in Europe to which we do not have a license (although we have been advised by Roche that it has a license covering Zenapax) that may cover a process that we use to produce our potential products. If our processes were covered by this patent, we might be required to obtain a license under this patent or to significantly alter our processes or products in Europe. We might not be able to successfully alter our processes or products to avoid conflict with this patent or to obtain a license on commercially reasonable terms.

We do not have a license to an issued U.S. patent assigned to Stanford University and Columbia University, which may cover a process we use to produce our potential products. We have been advised that an exclusive license has been previously granted to a third party under this patent. If our processes were covered by this patent, we might be required to obtain a license or to significantly alter our processes or products in the U.S. We might not be able to successfully alter our processes or products to avoid conflict with this patent or to obtain a license on acceptable terms. Moreover, if we do not obtain the required licenses, any alteration of processes or products to avoid conflict with a competitive patent could result in a significant delay in our achieving regulatory approval for the products affected by these alterations.

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

To obtain regulatory approval for the commercial sale of any of our potential products or to promote these products for expanded indications, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in indications for which approval is requested. We have conducted only a limited number of clinical trials to date. We may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise. Our potential inability to commence or continue clinical trials, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of our potential products, further adds to the uncertainty of regulatory approval for our potential products.

Larger and later stage clinical trials may not produce the same results as early stage trials. Many companies in the pharmaceutical and biotechnology industries, including PDL, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials.

Research, preclinical testing and clinical trials may take many years to complete and the time required can vary depending on the indication being addressed and the nature of the product. We may at times elect to use aggressive clinical strategies in order to advance potential products through clinical development as rapidly as possible. For example, we may commence clinical trials without conducting preclinical animal testing, where an appropriate animal testing model does not exist, or we may conduct later stage trials based on limited early stage data. As a result, we anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

For example, we have entered the SMART M195 Antibody into a Phase III clinical trial in acute myelogenous leukemia with a clinical regimen that has not been tested previously with this antibody. Results from our prior Phase II and Phase II/III studies showed only a limited number of complete and partial remissions. In addition, we initiated a Phase III study without a meeting with the FDA or European regulatory authorities to discuss the protocol and its adequacy to support approval of the SMART M195 Antibody. We believe that our Phase III program is reasonable in view of the nature and severity of the disease. We cannot assure you that the study will be successful or that the FDA or European regulatory authorities will agree that the study will be adequate to obtain regulatory approval, even if the study is successful. In addition, the protocol for our Phase III trial includes an interim review by an independent data safety monitoring board. It is possible that the trial could be terminated upon such a review if the interim data do not show a sufficient probability of the trial being successful or if specified safety criteria are not met.

As a second example, the FDA recently placed a clinical hold on clinical trials of our SMART Anti-CD3 Antibody for kidney transplant indications. Although clinical trials of this antibody are no longer on hold, it was necessary to modify our clinical plans based on FDA concerns. Accordingly, we expect that the clinical development of this antibody for transplant indications will be lengthier, and there can be no assurance that we will be able, or will choose, to proceed with development of this antibody for transplant indications.

### **We may be unable to enroll sufficient patients to complete our clinical trials.**

The rate of completion of our clinical trials, and those of our collaborators, is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population
- perceived risks and benefits of the drug under study
- availability of competing therapies
- availability of clinical trial sites
- design of the protocol
- proximity of and access by patients to clinical sites
- patient referral practices of physicians
- eligibility criteria for the study in question, and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may have to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

### **We may be unable to obtain or maintain regulatory approval for our products.**

The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the U.S. and other countries. In the U.S., pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and nonclinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires a number of years and the expenditure of substantial resources. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

In addition to the requirement for FDA approval of each pharmaceutical product, each pharmaceutical product manufacturing facility must be registered with, and approved by, the FDA. The manufacturing and quality control procedures must conform to rigorous guidelines in order to receive FDA approval. Pharmaceutical product manufacturing establishments are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the U.S., foreign manufacturing establishments must comply with these FDA approved guidelines. These foreign manufacturing establishments are subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, pharmaceutical product manufacturing facilities may also be regulated by state, local and other authorities.

For the marketing of pharmaceutical products outside the U.S., we and our collaborative partners are subject to foreign regulatory requirements and, if the particular product is manufactured in the U.S., FDA and other U.S. export provisions. Requirements relating to the manufacturing, conduct of clinical trials, product licensing, promotion, pricing and reimbursement vary widely in different countries. Difficulties or unanticipated costs or price controls may be encountered by us or our licensees or marketing partners in our respective efforts to secure necessary governmental approvals. This could delay or prevent us or our licensees or our marketing partners from marketing potential pharmaceutical products.

Both before and after approval is obtained, a pharmaceutical product, its manufacturer and the holder of the Biologics License Application (BLA) for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny a BLA if applicable regulatory criteria are not satisfied. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which the pharmaceutical product may be marketed. Further, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA, the manufacturer continues to be subject to facility inspection and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals and/or the imposition of criminal penalties against the manufacturer and/or BLA holder.

**Our revenues from licensed technologies depend on the efforts and successes of our licensees.**

In those instances where we have licensed rights to our technologies, the product development and marketing efforts and successes of our licensees will determine the amount and timing of royalties we may receive, if any. We have no assurance that any licensee will successfully complete the product development, regulatory and marketing efforts required to sell products. The success of products sold by licensees, such as Roche, will be affected by competitive products, including potential competing therapies that are marketed by the licensee or others.

**If our collaborations are not successful, we may not be able to effectively develop and market some of our products.**

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

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

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

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

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

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

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with collaborative partners. To market products directly, we must either establish a marketing group and direct sales force or obtain the assistance of another company. We may not be able to establish marketing, sales and distribution capabilities or succeed in gaining market acceptance for our products. If we were to enter into co-promotion or other marketing arrangements with pharmaceutical or biotechnology companies, our revenues would be subject to the payment provisions of these arrangements and dependent on the efforts of third parties.

## **Manufacturing difficulties could delay commercialization of our products.**

Of the products that we currently have in clinical development, Roche is responsible for manufacturing Zenapax, SmithKline Beecham is responsible for manufacturing the humanized anti-IL-4 antibody and Scil is responsible for manufacturing the SMART Anti-L-Selectin Antibody. We are responsible for manufacturing our other products for our own development. We intend to continue to manufacture potential products for use in preclinical and clinical trials using our manufacturing facility in accordance with standard procedures that comply with appropriate regulatory standards. The manufacture of sufficient quantities of antibody products that comply with these standards is an expensive, time-consuming and complex process and is subject to a number of risks that could result in delays. For example, we and our collaborative partners have experienced some manufacturing difficulties. Product supply interruptions could significantly delay clinical development of our potential products, reduce third party or clinical researcher interest and support of proposed clinical trials, and possibly delay commercialization and sales of these products. Manufacturing difficulties can even interrupt the supply of marketed products, thereby reducing revenues and risking loss of market share. For example, Roche has received a warning letter from the FDA regarding deficiencies in the manufacture of various products. Although the letter primarily related to products other than Zenapax, Roche has also experienced difficulties in the manufacture of Zenapax. If these manufacturing difficulties are not corrected in a timely manner, or if future manufacturing difficulties arise, Zenapax supplies could be interrupted, which could cause a delay or termination of our clinical trials of Zenapax in autoimmune disease and could force Roche to withdraw Zenapax from the market temporarily or permanently, resulting in loss of revenue to us. These occurrences could materially impair our competitive position.

We do not have experience in manufacturing commercial quantities of our potential products, nor do we currently have sufficient capacity to manufacture all of our potential products on a commercial scale. In order to obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to improve and expand our existing manufacturing capabilities. We are reviewing plans to expand our manufacturing capacity, including possible acquisition and conversion of an existing building into a manufacturing plant or construction of an entirely new manufacturing plant. If we implement these plans we will incur substantial costs. Any construction delays could impair our ability to produce adequate supplies of our potential products for clinical use or commercial sale on a timely basis. Further, we may be unable to improve and expand our manufacturing capability sufficiently to obtain necessary regulatory approvals and to produce adequate commercial supplies of our potential products on a timely basis. Failure to do so could delay commercialization of these products and could impair our competitive position.

We are also investigating the use of contract manufacturing to produce commercial supplies of at least the SMART M195 Antibody in the event that the Phase III trial of that antibody is successful. We may be unable to secure such manufacturing capacity and to successfully produce commercial supplies on a timely basis. Failure to do so could delay commercialization of this product and could impair our competitive position.

## **Manufacturing changes may result in delays in obtaining regulatory approval or marketing for our products.**

Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. If we make changes in the manufacturing process, we may be required to demonstrate to the FDA and corresponding foreign authorities that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. This is particularly important if we want to rely on results of prior preclinical studies and clinical trials performed using the previously produced drug material. Depending upon the type and degree of differences between the newer and older drug material, we may be required to conduct additional animal studies or human clinical trials to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material. We have made manufacturing changes and are likely to make additional manufacturing changes for the production of our products currently in clinical development, such as the SMART M195 and SMART Anti-CD3 Antibodies. These manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

## **Our business may be harmed if we cannot obtain sufficient quantities of raw materials.**

We depend on outside vendors for the supply of raw materials used to produce our product candidates. Once a supplier's materials have been selected for use in our manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

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

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

Any product that we or our collaborative partners succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop

products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, has received approval to market Simulectr, a product competitive with Zenapax, in the U.S. and Europe. Since Novartis launched Simulect in the European Union earlier than Roche, Zenapax may have a smaller market share than Simulect and other available products.

Other competitive factors include:

- the capabilities of our collaborative partners
- product efficacy and safety
- timing and scope of regulatory approval
- product availability, marketing and sales capabilities
- reimbursement coverage
- the amount of clinical benefit of our products relative to their cost
- method of and frequency of administration of our products
- price of our products, and
- patent protection of our products.

**If we do not attract and retain key employees, our business could be impaired.**

To be successful, we will have to retain our qualified clinical, manufacturing, scientific and management personnel. Because we are located in a high technology area, we face competition for personnel from other companies, academic institutions, government entities and other organizations. We are currently conducting a search for a chief financial officer, as well as other senior management personnel. If we are unsuccessful in filling these positions or retaining qualified personnel, our business could be impaired.

**We may be subject to product liability claims, and our insurance coverage may not be adequate to cover these claims.**

We face an inherent business risk of exposure to product liability claims in the event that the use of products during research and development efforts or after commercialization results in adverse effects. This risk will exist even with respect to any products that receive regulatory approval for commercial sale. While we have obtained liability insurance for our products, it may not be sufficient to satisfy any liability that may arise. Also, adequate insurance coverage may not be available in the future at acceptable cost, if at all.

**We may require additional funds that may be difficult to obtain in order to continue our business activities as planned.**

Our operations to date have consumed substantial amounts of cash. We will be required to spend substantial funds in conducting clinical trials, to expand our marketing capabilities and efforts, to expand existing research and development programs, to develop and expand our development and manufacturing capabilities and to defend or prosecute our patents and patent applications.

In order to develop and commercialize our products, we may need to raise substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. Additional financing may not be available on acceptable terms, if at all, and may only be available on terms dilutive to existing stockholders or that would increase the amount of our indebtedness. Our inability to secure adequate funds on a timely basis could result in the delay or cancellation of programs that we might otherwise pursue.

**We may incur significant costs in order to comply with environmental regulations or to defend claims arising from accidents involving the use of hazardous materials.**

We are subject to federal, state and local laws and regulations governing the use, discharge, handling and disposal of materials and wastes used in our operations. As a result, we may be required to incur significant costs to comply with these laws and regulations. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities which exceed our resources. In addition, we cannot predict the extent of the adverse effect on our business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

**Changes in the U.S. and international health care industry could adversely affect our revenues.**

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. Cost containment measures, whether instituted by health care providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payors may challenge the price and cost effectiveness of our products.



In addition, in many major markets outside the U.S., pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

We may not be able to obtain or maintain our desired price for our products. Our products may not be considered cost effective relative to alternative therapies. As a result, adequate third-party reimbursement may not be available to enable us to maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed health care in the U.S. and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborative partners.

**As a result of our sale of convertible notes, we have a significant amount of debt and may have insufficient cash to satisfy our debt service obligations. In addition, the amount of our debt could impede our operations and flexibility.**

As a result of our sale of convertible notes with an aggregate principal amount of \$150 million in February 2000, we have a significant amount of debt and debt service obligations. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on the notes, including from cash and cash equivalents on hand, we will be in default under the terms of the indenture which could, in turn, cause defaults under our other existing and future debt obligations.

Even if we are able to meet our debt service obligations, the amount of debt we have could adversely affect us in a number of ways, including by:

- limiting our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes
- limiting our flexibility in planning for, or reacting to, changes in our business
- placing us at a competitive disadvantage relative to our competitors who have lower levels of debt
- making us more vulnerable to a downturn in our business or the economy generally, and
- requiring us to use a substantial portion of our cash to pay principal and interest on our debt, instead of applying those funds to other purposes such as working capital and capital expenditures.

**Our common stock price is volatile and an investment in our company could decline in value.**

Market prices for securities of biotechnology companies (including PDL) have been highly volatile so that investment in our securities involves substantial risk. Additionally, the stock market from time to time has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. The following are some of the factors that may have a significant effect on the market price of our common stock:

- developments or disputes as to patent or other proprietary rights
- disappointing sales of approved products
- approval or introduction of competing products and technologies
- results of clinical trials
- failures or unexpected delays in obtaining regulatory approvals or FDA advisory panel recommendations
- delays in manufacturing or clinical trial plans
- fluctuations in our operating results
- disputes or disagreements with collaborative partners
- market reaction to announcements by other biotechnology or pharmaceutical companies
- announcements of technological innovations or new commercial therapeutic products by us or our competitors
- initiation, termination or modification of agreements with our collaborative partners
- loss of key personnel
- litigation or the threat of litigation
- public concern as to the safety of drugs developed by us
- sales of our common stock held by collaborative partners or insiders

- comments and expectations of results made by securities analysts, and
- general market conditions.

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

## ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

### *(a) Exhibits*

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended Certificate of Incorporation
10.1	Letter Amendment dated as of June 2, 2000 (with certain confidential portions deleted and marked by notation indicating such deletion) to the Amended and Restated Agreement between the Company and Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd, dated as of October 20, 1999.
27.1	Financial Data Schedule

### *(b) Reports on Form 8-K*

None

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## PROTEIN DESIGN LABS, INC.

### SIGNATURES

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.

PROTEIN DESIGN LABS, INC.  
*(Registrant)*

Dated: August 14, 2000

By: /s/Laurence Jay Korn

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

By: /s/Robert Kirkman

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

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# **CERTIFICATE OF INCORPORATION OF PROTEIN DESIGN LABS**

FIRST: The name of the Corporation is Protein Design Labs, Inc. (hereinafter sometimes referred to as the "Corporation").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 410 South State Street, in the City of Dover, County of Kent. The name of the registered agent at that address is Incorporating Services, Inc.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of Delaware.

FOURTH: This Corporation is authorized to issue two classes of shares to be designated respectively Preferred Shares ("Preferred Shares") and Common Shares ("Common Stock"). The total number of shares of Preferred Shares this Corporation shall have authority to issue is 2,146,667, par value one cent (\$.01) per share, and the total number of shares of Common Stock this Corporation shall have authority to issue is 4,200,000, par value one cent (\$.01) per share. The Preferred Shares authorized by this Certificate of Incorporation shall be issued in series. The first such series shall be designated Series A Preferred Stock ("Series A Preferred Stock") and shall consist of seven hundred thousand (700,000) shares. The second such series shall be designated Series B Preferred Stock ("Series B Preferred Stock") and shall consist of one million four hundred sixty-six thousand six hundred sixty-seven (1,466,667) shares. The Series A Preferred Stock and Series B Preferred Stock are collectively referred to herein as the "Preferred Stock." The relative rights, preferences, privileges, restrictions and other matters relating to the respective classes of the shares of capital stock of the Corporation or the holders thereof are as follows:

1. Definitions. For purposes of this Article FOURTH "Junior Shares" shall mean all Common Stock and any other shares of the Corporation other than the Preferred Stock.

2. Dividend Rights of Preferred Stock. The holders of the Preferred Stock shall be entitled to receive in any fiscal year, when and as declared by the Board of Directors, out of any assets at the time legally available therefor, dividends in cash at the rate per annum of \$0.06 per share of Series A Preferred Stock and \$0.135 per share of Series B Preferred Stock payable in preference and priority to any payment of any dividend on Junior Shares. The right to such dividends on the Preferred Stock shall not be cumulative, and no right shall accrue to holders of Preferred Stock by reason of the fact that dividends on such shares are not declared or paid in any prior year. No dividends shall be paid on any Junior Shares unless an equal dividend is paid with respect to all outstanding shares of Preferred Stock in an amount for each such share of Preferred Stock equal to the aggregate amount of such dividends for all Junior Shares into which each such share of Preferred Stock could then be converted.

3. Liquidation Preference.

(a) In the event of any liquidation, dissolution or winding up of the Corporation, either voluntary or involuntary, the holders of the Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Corporation to the holders of the junior Shares by reason of their ownership thereof, (i) the amount of \$1.00 per share for each share of Series A Preferred Stock then held by them and (ii) the amount of \$2.25 per share for each share of Series B Preferred Stock then held by them and, in addition, an amount equal to all declared but unpaid dividends on the Preferred Stock as provided in Section 2 of this Article FOURTH. If upon the occurrence of such event the assets and funds thus distributed among the holders of the Preferred Stock shall be insufficient to permit the payment to such holders of the full preferential amount aforesaid, then the entire assets and funds of the Corporation legally available for distribution shall be distributed ratably among the holders of the Preferred Stock in proportion to the number of shares of Preferred Stock held by such holders. After payment has been made to the holders of the Preferred Stock of the full amounts to which they shall be entitled as aforesaid, all remaining assets and funds of the Corporation shall be distributed ratably among the holders of the Preferred Stock and the holders of the Junior Shares, with the holders of the Preferred Stock being deemed to hold the number of shares of Junior Shares to which they would have been entitled to receive upon conversion of such Preferred Stock.

(b) For purposes of this Section 3 of Article FOURTH, a liquidation, dissolution or winding up of the Corporation shall be deemed to be occasioned by, or to include, the Corporation's sale of all or substantially all of its assets or the acquisition of this Corporation by another entity by means of merger or consolidation resulting in the exchange of the outstanding shares of this Corporation for securities or consideration issued, or caused to be issued, by the acquiring corporation or its subsidiary.

(c) The Corporation shall not consummate any proposed action of the types described in subsections (a) and (b) of this Section 3 of Article FOURTH without the written consent of the holders of fifty percent (50%) of the outstanding shares of Preferred Stock voting as a single class.

(d) In the event the Corporation shall propose to take any action of the types described in subsections (a) and (b) of this Section 3 of which will involve the distribution of assets other than cash, the Corporation shall promptly engage independent competent appraisers to determine the value of the assets to be distributed to the holders of shares of Preferred Stock. The Corporation shall, upon receipt of such appraiser's valuation, give prompt written notice of each holder of shares of Preferred Stock of the appraiser's valuation. All notices pursuant to this Section 3 hereof shall be deemed given upon personal delivery or upon deposit in a United States Post office by registered or certified mail.

4. Conversion. The holders of the Preferred Stock shall have conversion rights as follows (the "Conversion Rights"):

(a) Right to Convert and Automatic Conversion.

(i) Each share of Preferred Stock shall be convertible, at the option of the holder thereof at any time after the date of issuance of such share at the office of the Corporation or any transfer agent for the Preferred Stock, into fully paid and nonassessable shares of Common Stock at the Conversion Rate (as hereinafter defined) in effect at the time of conversion. The number of shares of Common Stock into which each share of Series A Preferred Stock and Series B Preferred Stock may be converted are hereinafter referred to as the "Series A Conversion Rate" and "Series B Conversion Rate," respectively. The initial Series A Conversion Rate and Series B Conversion Rate shall each be one (1), and such initial Conversion Rates shall be subject to the adjustments described below. Any adjustment of the Series A or Series B Conversion Rate shall also cause an appropriate adjustment of the Series A or Series B Conversion Price (as hereinafter defined) respectively, calculated by dividing the adjusted Series A Conversion Rate into \$1.00 and/or the adjusted Series B Conversion Rate into \$2.25.

(ii) Each share of Preferred Stock shall automatically be converted into shares of Common Stock at its then effective Conversion Rate in the event of the closing of a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of Common Stock for the account of the Corporation to the public at a net selling price per share of Common Stock (as constituted on the date hereof) of not less than \$5.00 and resulting in the receipt by the Corporation of at least \$5,000,000 of net proceeds (after applicable discounts, commissions and expenses). In the event of such an offering, the person(s) entitled to receive the Common Stock issuable upon such conversion of Preferred Stock shall not be deemed to have converted such Preferred Stock until immediately prior to the closing of such sale of securities.

(iii) No fractional shares of Common Stock shall be issued upon conversion of Preferred Stock. Any shares of Series A Preferred Stock or Series B Preferred Stock surrendered for conversion which would otherwise result in a fractional share of Common Stock shall be redeemed for \$1.00 (in the case of the Series A) or \$2.25 (in the case of the Series B) per share respectively, payable as promptly as possible whenever funds are legally available therefor.

(b) Mechanics of Conversion. Before any holder of Preferred Stock shall be entitled to convert the same into shares of Common Stock, he shall surrender the certificate or certificates therefor, duly endorsed, at the principal office of the Corporation or of any transfer agent for the Preferred Stock, and shall give written notice to the Corporation at such office that he elects to convert the same and shall state therein the name or names in which he wishes the certificate or certificates for shares of Common Stock to be issued; said conversion notice shall contain such representations as may reasonably be required by the Corporation, to the effect that the shares to be received upon conversion are not being acquired and will not be transferred in any way which might violate then applicable laws. The Corporation shall, as soon as practicable thereafter, issue and deliver at such office to such holder of Preferred Stock, or to his nominee or nominees, a certificate or certificates for the number of shares of Common Stock to which he shall be entitled as aforesaid. Except as set forth in subsection

4(a)(ii) of this Article FOURTH, such conversion shall be deemed to have been made immediately prior to the close of business on the date of such surrender of the shares of Preferred Stock to be converted, and the person or persons entitled to receive the shares of Common Stock issuable upon such conversion shall be treated for all purposes as the record holder or holders of such shares of Common Stock on such date.

(c) Adjustment for Combinations or Consolidations. In the event the Corporation at any time or from time to time after the effective date of a written agreement by the Corporation for the initial sale of Preferred Stock (hereinafter referred to as the "Original Issue Date") effects a subdivision or combination of its outstanding Common Stock into a greater or lesser number of shares without a proportionate and corresponding subdivision or combination of its outstanding Preferred Stock, then and in each such event each respective Conversion Rate shall be increased or decreased proportionately.

(d) Adjustment for Dividends, Distributions and Common Stock Equivalents. In the event the Corporation at any time or from time to time after the Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive a dividend or other distribution payable in additional shares of Common Stock, or other securities or rights (hereinafter referred to as "Common Stock Equivalents") convertible into or entitling the holder thereof to receive additional shares of Common Stock without payment of any consideration by such holder for such Common Stock, then and in each such event the maximum number of shares (as set forth in the instrument relating thereto without regard to any provisions contained therein for a subsequent adjustment of such number) of Common Stock issuable in payment of such dividend or distribution or upon conversion or exercise of such Common Stock Equivalents shall be deemed to be issued and outstanding as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date. In each such event each respective Conversion Rate shall be increased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying such Conversion Rate by a fraction,

(i) the numerator of which shall be the total number of shares of Common Stock issued and outstanding or deemed to be issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution or upon conversion or exercise of such Common Stock Equivalents; and

(ii) the denominator of which shall be the total number of shares of Common Stock issued and outstanding or deemed to be issued and outstanding immediately prior to the time of such issuance or the close of business on such record date; provided, however (A) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, each Conversion Rate shall be recomputed accordingly as of the close of business on such record date and thereafter each Conversion Rate shall be adjusted pursuant to this Section 4(d) of Article FOURTH as of the time of actual payment of such dividends or distributions; (B) if such Common Stock Equivalents provide, with the passage of time or otherwise, for any decrease in the number of shares of Common Stock issuable upon conversion or exercise thereof (or upon the occurrence of a record date with respect thereto), and any subsequent adjustments based thereon, each Conversion Rate shall, upon any such decrease

becoming effective, be recomputed to reflect such decrease insofar as it affects the rights of conversion or exercise of the Common Stock Equivalents then outstanding; (C) upon the expiration of any rights or conversion or exercise under any unexercised Common Stock Equivalents, each Conversion Rate computed upon the original issue thereof (or upon the occurrence of a record date with respect thereto), and any subsequent adjustments based thereon, shall, upon such expiration, be recomputed as if the only additional shares of Common Stock issued were the shares of such stock, if any, actually issued upon the conversion or exercise of such Common Stock Equivalents; and (D) in the case of Common Stock Equivalents which expire by their terms not more than sixty (60) days after the date of issuance thereof, no adjustment in any Conversion Rate shall be made until the expiration or exercise of all such Common Stock Equivalents, whereupon such adjustments shall be made in the manner provided in clause (C) above.

(e) Adjustment of Conversion Rates for Diluting Issues. The Series A Conversion Rate and Series B Conversion Rate shall be subject to the following adjustment, in addition to those set forth above. The amount obtained by dividing \$1.00 by the Series A Conversion Rate shall be called the "Series A Conversion Price" and the amount obtained by dividing \$2.25 by the Series B Conversion Rate shall be called the "Series B Conversion Price". Except as otherwise provided in this subsection (e) of Article FOURTH and subject to the provisions of Section 4(a)(iii) of Article FOURTH, in the event the Corporation sells or issues any Common Stock or Common Stock Equivalents at a per share consideration (as defined below) less than the Conversion Price for Series A Preferred Stock or Series B Preferred Stock, respectively, then in effect, then the Conversion Rate and Conversion Price then in effect with respect to such respective series shall be adjusted as provided in subsections (i), (ii) and (iii) hereof. For the purposes of the foregoing, the per share consideration with respect to the sale or issuance of Common Stock shall be the price per share received by the Corporation, prior to the payment of any expenses, commissions, discounts and other applicable costs. With respect to the sale or issuance of Common Stock Equivalents which are convertible into or exchangeable for Common Stock without further consideration, the per share consideration shall be determined by dividing the maximum number of shares of Common Stock issuable with respect to such Common Stock Equivalents (as set forth in the instrument relating thereto without regard to any provisions contained therein for subsequent adjustment of such number) into the aggregate consideration received by the Corporation upon the sale or issuance of such Common Stock Equivalents. With respect to the issuance of other Common Stock Equivalents, the per share consideration shall be determined by dividing the maximum number of shares of Common Stock issuable with respect to such Common Stock Equivalents into the total aggregate consideration received by the Corporation upon the sale or issuance of such Common Stock Equivalents plus the minimum aggregate amount of additional consideration receivable by the Corporation upon the conversion or exercise of such Common Stock Equivalents. The issuance of Common Stock or Common Stock Equivalents for no consideration shall be deemed to be an issuance at a per share consideration of \$.01. In connection with the sale or issuance of Common Stock and/or Common Stock Equivalents for non-cash consideration, the amount of consideration shall be determined by the Board of Directors of the Corporation.

As used herein, "Additional Shares of Common Stock" shall mean either shares of Common Stock issued subsequent to the Original Issue Date or, with respect to the issuance of Common Stock Equivalents, the maximum number of shares of Common Stock issuable in exchange for, upon conversion of, or upon exercise of such Common Stock Equivalents.

The Conversion Prices and Conversion Rates shall be determined and adjusted once only with respect to any single offering of the Corporation's securities for financing purposes, provided that all closings with respect to any such offering occur within a period of no more than 120 days. (i) Upon each issuance of Additional Shares of Common Stock for a per share consideration less than the Series A Conversion Price or the Series B Conversion Price in effect on the date of such issuance, the Conversion Rate of such series of Preferred Stock in effect on such date will be adjusted by multiplying it by a fraction:

(x) the numerator of which shall be the number of shares of Common Stock (assuming conversion of all outstanding Preferred Shares) outstanding immediately prior to the issuance of such Additional Shares of Common Stock, plus the number of such Additional Shares of Common Stock issued, and

(y) the denominator of which shall be the number of shares of Common Stock (assuming conversion of all outstanding Preferred Shares) outstanding immediately prior to the issuance of such Additional Shares of Common Stock plus the number of shares of Common Stock which the aggregate net consideration received by the Corporation for the total number of such Additional Shares of Common Stock so issued would purchase at the Conversion Price for such series of Preferred Stock then in effect.

(ii) Upon each issuance of Common Stock Equivalents, exchangeable without further consideration into Common Stock, for a per share consideration less than the respective Conversion Price in effect on the date of such issuance, the Conversion Rate for such series of Preferred Stock in effect on such date will be adjusted as in subsection (i) immediately above on the basis that the related Additional Shares of Common Stock are to be treated as having been issued on the date of issuance of the Common Stock Equivalents, and the aggregate consideration received by the Corporation for such Common Stock Equivalents shall be deemed to have been received for such Additional Shares of Common Stock.

(iii) Upon each issuance of Common Stock Equivalents other than those described in subsection (ii) immediately above, for a per share consideration less than the respective Conversion Price in effect on the date of such issuance, the Conversion Rate of such series of Preferred Stock in effect on such date will be adjusted as in subsection (i) immediately above on the basis that the related Additional Shares of Common Stock are to be treated as having been issued on the date of issuance of such Common Stock Equivalents, and the aggregate consideration received and that receivable by the Corporation on conversion or exercise of such Common Stock Equivalents shall be deemed to have been received for such Additional Shares.

(iv) Once any Additional Shares of Common Stock have been treated as having been issued for the purpose of this subsection 4(e) of Article FOURTH, they shall be treated as issued and outstanding shares of Common Stock whenever any subsequent calculations must be made pursuant hereto; provided that on the expiration of any options, warrants or rights to purchase Additional

Shares of Common Stock, the termination of any rights to convert or exchange for Additional Shares of Common Stock, or the expiration of any options or rights related to such convertible or exchangeable securities on account of which an adjustment in a Conversion Rate has been made previously pursuant to this subsection 4(e) of Article FOURTH, such Conversion Rate shall forthwith be readjusted to such Conversion Rate as would have obtained had the adjustment made upon the issuance of such options, rights, securities or options or rights related to such securities been made upon the basis of the issuance of only the number of shares of Common Stock actually issued upon the exercise of such options or rights, upon the conversion or exchange of such securities or upon the exercise of the options or rights related to such securities.

(v) The foregoing notwithstanding, no adjustment of any Conversion Rate or Conversion Price shall be made as a result of the issuance of:

-- up to 2,036,000 shares (or such larger number of shares as is approved by the Board of Directors of the Corporation) (as adjusted for splits, recombinations and the like and net of repurchases) of Common Stock (or any options, warrants or rights to purchase such shares of Common Stock) issued or issuable to officers, directors, employees or consultants of the Corporation pursuant to any stock option plan, stock incentive or purchase plan or agreement approved by the Board of Directors of the Corporation;

-- any shares of Common Stock pursuant to which any Conversion Rate and Conversion Price are adjusted under subsections (c) or (d) of this Section 4 of Article FOURTH;

-- any shares of Common Stock pursuant to the exchange, conversion, or exercise of any Common Stock Equivalents which have previously been incorporated into computations hereunder on the date when such Common Stock Equivalents were issued; or any shares of Common Stock issued upon conversion of the Preferred Stock;

(f) No adjustment in a Conversion Rate and Conversion Price need be made if such adjustment would result in a change in the Conversion Price of less than \$.01. Any adjustment of less than \$.01 which is not made shall be carried forward and shall be made at the time of and together with any subsequent adjustment which, on a cumulative basis, amounts to an adjustment of \$.01 or more in a Conversion Price.

(g) No Impairment. The Corporation will not, by amendment of its Certificate of Incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Corporation, but will at all times in good faith assist in the carrying out of all the provisions of this Section 4 of Article FOURTH and in the taking of all such action as may be necessary or appropriate in order to protect the Conversion Rights of the holders of the Preferred Stock against impairment.

(h) Certificate as to Adjustments. Upon the occurrence to each adjustment or readjustment of a Conversion Rate pursuant to this Section 4 of Article FOURTH, the Corporation at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and prepare and furnish to each holder of Preferred Stock a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, upon the written request at any time of any holder of Preferred Stock, furnish or cause to be furnished to such holder a like certificate setting forth (i) such adjustments and readjustments, (ii) the applicable Conversion Rate at the time in effect, and (iii) the number of shares of Common Stock and the amount, if any, of other property which at the time would be received upon the conversion of such series of Preferred Stock.

(i) Notices of Record Date. In the event of any taking by the Corporation of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend (other than a cash dividend) or other distribution, any Common Stock Equivalents or any right to subscribe for, purchase or otherwise acquire any shares of stock of any class or any other securities or property, or to receive any other right, the Corporation shall mail to each holder of Preferred Stock at least twenty (20) days prior to the date specified therein, a notice specifying the date on which any such record is to be taken for the purpose of such dividend, distribution or rights, and the amount and character of such dividend, distribution or right. Failure to give such notice, or any defect therein, shall not affect the legality or validity of any such action.

(j) Reservation of Stock Issuable Upon Conversion. The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of effecting the conversion of the shares of the Preferred Stock, such number of its shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding shares of the Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purpose.

(k) Notices. Any notice required by the provisions of this Section 4 of Article FOURTH to be given to the holders of shares of Preferred Stock shall be deemed given if deposited in the United States mail, postage prepaid, and addressed to each holder of record at the address appearing on the books of the Corporation.

## 5. Voting Rights.

(a) Each share of Preferred Stock issued and outstanding shall have the number of votes equal to the number of shares of Common Stock into which such shares of Preferred Stock could be converted on the record date for the vote or consent of stockholders and shall have voting rights and powers equal to the voting rights and powers of the Common Stock. The holder of each share of

Preferred Stock shall be entitled to notice of any stockholders' meeting in accordance with the bylaws of the Corporation. The holders of Preferred Stock shall vote with holders of the Common Stock upon any matters submitted to a vote of stockholders, except those matters required by law, subsection 5(b) of this Article FOURTH or any other Article of this Certificate of Incorporation to be submitted to a class vote.

(b) The holders of Common Stock, voting as a single class, shall be entitled to elect the Class A director provided for in Article SIXTH and to remove from office such director and to fill any vacancy caused by the resignation, death or removal of such director (to the exclusion of the vote of the holders of Preferred Stock). The holders of Preferred Stock, voting as a single class, shall be entitled to elect the Class B directors provided for in Article SIXTH to the Board of Directors and to remove from office any or all of them and to fill any vacancy or vacancies caused by the resignation, death or removal of any or all of them (to the exclusion of the vote of the holders of Common Stock).

6. Covenants. In addition to any other rights provided by law, so long as any Preferred Stock shall be outstanding, the Corporation shall not, without first obtaining the affirmative vote or written consent of the holders of not less than fifty percent (50%) of such outstanding shares of Preferred Stock:

(a) Amend or repeal any provision of, or add any provision to, the Corporation's Certificate of Incorporation or bylaws if such action would alter or change the preferences, rights, privileges or powers of, or the restrictions provided for the benefit of, any series of Preferred Stock, or increase or decrease the number of shares of any series of Preferred Stock authorized hereby, or change the number of authorized directors of the Corporation from seven (7);

(b) Authorize or issue shares of any class of stock having any rights, preferences or privileges superior to or on a parity with the Preferred Stock or authorize or issue shares of stock of any class or any bonds, debentures, notes or other obligations convertible into or exchangeable for, or having option rights to purchase, any shares of stock of the Corporation having any rights, preferences or privileges superior to or on a parity with the Preferred Stock;

(c) Reclassify any outstanding shares into shares having any rights, preferences or privileges superior to or on a parity with the Preferred Stock;

(d) Pay or declare any dividends on any Junior Stock without paying or declaring an equal dividend on the Preferred Stock;

(e) Repurchase, acquire or retire any shares of Preferred Stock or Junior Shares, except from employees of this Corporation upon termination; or

(f) Undertake or effect any consolidation or merger of the Corporation with or into another corporation or the conveyance of all or substantially all of the assets of the Corporation to another person.

FIFTH: The following provisions are inserted for the management of the business and the conduct of the affairs of the Corporation, and for further definition, limitation and regulation of the powers of the Corporation and of its directors and stockholders:

A. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authority expressly conferred upon them by Statute or by this Certificate of Incorporation or the bylaws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

B. The directors of the Corporation need not be elected by written ballot unless the bylaws so provide.

SIXTH: The number of directors shall initially be seven and, thereafter, shall be fixed from time to time exclusively by the stockholders pursuant to a resolution adopted by a majority of the outstanding Common Stock (on an as-converted basis) and by a majority of the Preferred Stock, voting separately as a single class. The directors shall be divided into three classes: Class A, Class B and Class C. There shall be one Class A director, who shall be nominated and elected solely by the holders of Common Stock voting as a single class (to the exclusion of the vote of the holders of Preferred Stock). The Class A director shall be entitled to two votes on any matter before the Board of Directors. There shall be two Class B directors who shall be nominated and elected solely by the holders of Preferred Stock voting as a single class (to the exclusion of the vote of the holders of Common Stock). The Class B directors shall be entitled to one vote each on any matter before the Board of Directors. The remaining four directors shall be Class C directors who shall be nominated and elected by the holders of Common Stock and Preferred Stock voting as a single class (on an as-converted basis). The Class C directors shall be entitled to one vote each on any matter before the Board of Directors. Class A and Class B directors may only be removed from office by, and vacancies caused by the resignation, death or removal of such directors may only be filled by, the holders of Common Stock and the holders of Preferred Stock, respectively. A majority of the remaining directors, with the Class A director, if any, having two votes, may fill any vacancy among the Class C directors. The Board of Directors is expressly empowered to adopt, amend or repeal bylaws of the Corporation other than those bylaws regarding the election or voting powers of directors. Any adoption, amendment or repeal of bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the total number of directors then in office, with the Class A director, if any, having two votes. The stockholders shall have the power to adopt, amend or repeal all bylaws of the Corporation.

SEVENTH: A director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the

director derived any improper personal benefit. If the Delaware General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended. Any repeal or modification-of the foregoing paragraph by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

EIGHTH: The name and mailing address of the sole incorporator are as follows:

Name	Mailing Address
	Paul R. Anderson
	c/o Ware & Freidenrich
	400 Hamilton Avenue
	Palo Alto, CA 94301

I, THE UNDERSIGNED, being the incorporator, for the purpose of forming a corporation under the laws of the State of Delaware, do make, file and record this Certificate of Incorporation, do certify that the facts herein stated are true, and, accordingly, have hereto set my hand this 22nd day Of July, 1986.

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Paul R. Anderson

#### **CERTIFICTE OF AMENDMENT OF CERTIFICATE OF INCORPORATION OF PROTEIN DESIGN LABS, INC.**

Protein Design Labs, Inc., a corporation duly organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify that:

I. The amendment to the Corporation's Certificate of Incorporation set forth below was duly adopted in accordance with the provisions of Section 242 and has been consented to by the stockholders at a meeting called in accordance with Section 222 of the General Corporation Law of the State of Delaware:

II. The first paragraph of Article FOURTH of the Corporation's Certificate of Incorporation is amended to read in its entirety as follows:

This Corporation is authorized to issue a total of one hundred million (100,000,000) shares of stock in two classes, designated Preferred Stock ("Preferred Stock") and Common Stock ("Common Stock"). The total number of shares of Preferred stock this Corporation shall have authority to issue is ten million (10,000,000), par value one cent (\$0.01) per share, and the total number of shares of Common Stock this Corporation shall have authority to issue is ninety million (90,000,000), par value one cent (\$0.01) per share.

IN WITNESS WHEREOF, Protein Design Labs, Inc. has caused this Certificate to be executed by Douglas O. Ebersole, its authorized officer, on this 6th day of July, 2000.

/s/Douglas O. Ebersole  
-----  
Senior Vice President and  
Secretary



June 2, 2000

Hoffmann-La Roche Inc.  
340 Kingsland Street  
Nutley, New Jersey 07110  
Attn: Mr. Georges Gemayel  
Vice President, Specialty  
Business Operations

Re: Amendment of Amended and Restated Agreement

Dear Mr. Gemayel:

The purpose of this letter is to amend certain provisions of the Amended and Restated Agreement (the "Agreement") dated October 20, 1999 among Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd and Protein Design Labs, Inc. Capitalized terms used in this letter have the meanings given to them in the Agreement. This letter amendment pertains to the manufacture and supply of Daclizumab for clinical and formulation development under Section 3C.1 of the Agreement.

A. Right to Manufacture. Roche and PDL agree that PDL shall have the right to manufacture Daclizumab to provide clinical and development supplies in addition to the supply to be provided by Roche under Section 3C.1. Accordingly:

1. The second paragraph of Section 1.14 is amended to read as follows:

"Roche Know-How shall also include all Daclizumab Know-How which is rightfully held by Roche or its Affiliates as of the Signing Date, or which is developed or acquired by Roche or its Affiliates with the right to license or sublicense during the term of this Amended and Restated Agreement, and which Daclizumab Know-How is reasonably required or useful for manufacturing Daclizumab."

2. Section 2.3 is amended to add a new sentence following the first sentence, which shall read as follows:

"In addition, Roche grants to PDL and to PDL's Affiliates nonexclusive rights to the Roche Know-How, Roche Patents, PDL Know-How, and PDL Patents to the extent reasonably required or useful to make and have made Daclizumab in the Territory for the sole purpose of conducting development and seeking registration of Daclizumab in Autoimmune Indications as contemplated by this Amended and Restated Agreement."

3. The first sentence of Section 3C.1(a) is amended to delete the word "exclusively".

4. Roche will deliver to PDL within thirty (30) days after the date of this letter amendment (or, with respect to item 2 on Exhibit A1, as soon as available) the items listed in Exhibit A1 to this letter

Right to Roll-Over Supplies.

[CONFIDENTIAL TREATMENT REQUESTED]

If the foregoing amendments are acceptable to Roche, please have the enclosed copies of this letter amendment signed and have one fully signed copy returned to me. Thank you.

Sincerely,

PROTEIN DESIGN LABS, INC.

By: \_\_\_\_\_  
Douglas O. Ebersole  
Senior Vice President, Legal  
and Licensing

The foregoing amendment of the Agreement is hereby accepted and agreed to, effective as of the above date of this letter amendment.

HOFFMANN-LA ROCHE INC.

F. HOFFMANN-LA ROCHE LTD.

By:

By:

Title:

Title:

Exhibit A1

[CONFIDENTIAL TREATMENT REQUESTED]

Note: PDL is not initially requesting documents included in the Roche Know-How for the purposes of PDL conducting process development and manufacturing of Daclizumab. If such information later becomes necessary, PDL will notify Roche. Roche shall have no liability to PDL if despite Roche's commercially reasonable efforts, it is unable to locate any such Roche Know-How.

Mr. Georges Gemayel CONFIDENTIAL

June 2, 2000 TREATMENT - EDITED COPIES

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CONFIDENTIAL

TREATMENT - EDITED COPIES

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM  
THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS AND IS QUALIFIED  
IN ITS ENTIRETY BY REFERENCE TO SUCH CONSOLIDATED FINANCIAL STATEMENTS.

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	DEC-31-2000	
	Jan-01-2000	
	Jun-30-2000	
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