SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Quarterly Period Ended September 30, 2004

OR

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

Commission File Number: 0-19756

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3023969**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

Yes ☒ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of Act). Yes ☒ No o

As of October 29, 2004, there were 95,506,327 shares of the Registrant's Common Stock outstanding.

PROTEIN DESIGN LABS, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Revenues:				
Royalties	$ 17,131	$ 8,758	$ 63,872	$ 43,808
License and other	2,653	567	9,323	9,265
Total revenues	19,784	9,325	73,195	53,073
Costs and expenses:				
Research and development	27,326	21,812	92,364	58,323
General and administrative	7,664	6,963	23,182	19,465
Acquired in-process research and development	—	—	—	37,834
Total costs and expenses	34,990	28,775	115,546	115,622
Operating loss	(15,206)	(19,450)	(42,351)	(62,549)
Interest and other income, net	2,822	4,291	7,689	13,151
Interest expense	(1,193)	(3,705)	(3,929)	(7,346)
Impairment loss on investment	—	—	—	(150)
Loss before income taxes	(13,577)	(18,864)	(38,591)	(56,894)
Provision for income taxes	12	11	68	60
Net loss	$ (13,589)	$ (18,875)	$ (38,659)	$ (56,954)
Net loss per basic and diluted share	$ (0.14)	$ (0.20)	$ (0.41)	$ (0.62)
Shares used in computation of net loss per basic and diluted share:	95,196	93,665	94,771	92,049

See accompanying notes.

PROTEIN DESIGN LABS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS
(unaudited)
(In thousands, except per share data)

	September 30, 2004	December31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 130,900	$ 341,768
Marketable securities, including $6.8 million and $7.4 million of restricted investments at September 30, 2004 and December 31, 2003, respectively	288,209	149,863
Other current assets	5,911	11,893
Total current assets	425,020	503,524
Land, property and equipment, net	227,027	155,513
Intangible assets, net	31,972	32,311
Restricted investments	6,688	13,362
Other assets	7,073	7,320

Convertible note receivable	30,000	30,000
Total assets	$ 727,780	$ 742,030
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,444	$ 3,576
Accrued compensation	7,245	5,903
Accrued clinical trial costs	850	1,759
Accrued interest	874	3,204
Other accrued liabilities	14,169	19,351
Deferred revenue	17,760	161
Current portion of long-term obligations	1,048	1,222
Total current liabilities	46,390	35,176
Convertible subordinated notes	249,998	250,000
Notes payable	154	595
Other long-term debt	7,521	7,928
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value $0.01 per share, 250,000 shares authorized; 95,402 and 93,886 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	954	939
Additional paid-in capital	682,110	666,793
Accumulated deficit	(258,950)	(220,291)
Accumulated other comprehensive income (loss)	(397)	890
Total stockholders' equity	423,717	448,331
Total liabilities and stockholders' equity	$ 727,780	$ 742,030

See accompanying notes.

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

	Nine months ended September 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	$ (38,659)	$ (56,953)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	37,834
Depreciation and amortization	8,613	5,759
Amortization of convertible notes offering costs	905	786
Stock-based compensation expense	878	255
Amortization of intangible assets	1,839	353
Loss on disposal of fixed assets	515	—
Impairment loss on investment	—	150
Non-cash license and other revenue	(4,000)	—
Non-cash in-licensing research and development expenses	3,000	—
Changes in assets and liabilities:		
Interest receivable	(844)	2,019
Other current assets	5,982	(1,552)
Other assets	(657)	(6,195)
Accounts payable	868	4,335
Accrued liabilities	(7,079)	5,432
Deferred revenue	17,099	374
Total adjustments	27,119	49,550
Net cash used in operating activities	(11,540)	(7,403)
Cash flows from investing activities:		
Purchases of marketable securities	(312,228)	(110,068)
Maturities of marketable securities	172,849	199,000
Cash acquired in acquisition of Eos	—	2,453
Maturities (purchases) of restricted investments	7,313	(20,754)
Purchases of land, property and equipment	(80,693)	(59,027)
Net cash provided by (used in) investing activities	(212,759)	11,604
Cash flows from financing activities:		
Proceeds from issuance of capital stock	14,453	2,449
Proceeds from issuance of convertible subordinated notes	—	250,000
Payments on other long-term obligations	(1,022)	(1,041)

Net cash provided by financing activities	13,431	251,408
Net increase (decrease) in cash and cash equivalents	(210,868)	255,609
Cash and cash equivalents at beginning of period	341,768	287,730
Cash and cash equivalents at end of period	$ 130,900	$ 543,339

See accompanying notes.

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
September 30, 2004
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

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

Basis of Presentation and Responsibility for Quarterly Financial Statements

The accompanying consolidated condensed financial statements are unaudited, but include all adjustments (consisting only of normal recurring adjustments), which we consider necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in our financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

The information included in this quarterly report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2003. The Consolidated Condensed Balance Sheet as of December 31, 2003 included herein is derived from our audited consolidated financial statements.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim consolidated condensed financial statements may not be indicative of results for any other interim period or for the entire year. For example, we receive a substantial portion of our royalty revenues on sales of the product *Synagis*® marketed by MedImmune. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters.

Principles of Consolidation

The consolidated condensed financial statements include the accounts of Protein Design Labs, Inc. and its wholly owned subsidiaries after elimination of inter-company accounts and transactions.

Reclassifications

Certain reclassifications of prior-year amounts have been made to conform to the current-year presentation.

Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the use of management's estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition

We currently recognize revenues resulting from the licensing and use of our technology and from services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." These revenues are typically derived from our proprietary patent portfolio covering the humanization of antibodies for use as drugs, in drug development and production.

If we determine that separate elements exist under Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

Revenues, and their respective treatment for financial reporting purposes, are as follows:

Royalties

Under some of our patent license agreements, we receive royalty payments based upon our licensees' net sales of products. Generally, we receive royalty reports from our licensees approximately one quarter in arrears; that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured. Accordingly, we recognize royalty revenue in the quarter reported to us by our licensees (i.e., generally royalty revenue is recognized one quarter following the quarter in which sales by our licensees occurred).

License and Other

We include revenue recognized from upfront licensing and license maintenance fees, milestone payments and reimbursement of development expenses in License and Other revenues.

Upfront License and License Maintenance Fees

We generally recognize revenue from upfront fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Revenues recognized from upfront fees typically relate to patent license and patent rights agreements. Generally there are three types of collaboration arrangements PDL enters into under which we provide access to our proprietary patent portfolio covering the humanization of antibodies.

- Under Patent License Agreements, the licensee typically obtains a non-exclusive license to one or more of our patents. In this arrangement, the licensee is responsible for all of the development work on its product. The licensee has the technical ability to perform the humanization of the antibody it is developing using our patented technology, but needs to obtain a license from us to avoid infringing our patents. We have no future performance obligations under these agreements. Consideration that we receive for patent license agreements is recognized upon execution and delivery of the patent license agreement and when payment is reasonably assured. Nonrefundable upfront licensing fees, including certain guaranteed, time-based payments that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue either (a) ratably over the development period if development risk is significant, or (b)

ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.

- Under Patent Rights Agreements, the licensee purchases a research patent license in exchange for an upfront fee. In addition, the licensee has the right to obtain, in exchange for consideration separate from the upfront fee, patent licenses for commercial purposes for a specified number of drug targets to be designated by the licensee subsequent to execution of the agreement. The licensee performs all of the research, and we have no further performance obligations with respect to the research patent license and the grant of the right to obtain commercial patent licenses; therefore, upon delivery of the patent rights agreement, the earnings process is complete. When a licensee exercises its right to obtain patent licenses to certain designated drug targets for commercial purposes, we recognize the related consideration as revenue upon the licensee's exercise of such right, execution and delivery of the associated patent license agreement and when payment is reasonably assured.

- Under Humanization Agreements, the licensee typically pays an upfront fee for us to humanize an antibody. These upfront fees are recognized as the humanization work is performed, which is typically over three to six months.

Under Patent License Agreements and Humanization Agreements, we may also receive annual license maintenance fees, payable at the election of the licensee to maintain the license in effect. We have no performance obligations with respect to such fees. Maintenance fees are recognized as they are due and when payment is reasonably assured.

Milestones

We enter into patent license and humanization agreements that may contain milestones related to reaching particular stages in product development. We recognize revenues from milestones when we have no further obligation with respect to the activities under the agreement and when we have confirmed that the milestone has been achieved. Where we have continuing involvement obligations in the form of development, manufacturing or other commercialization efforts, we recognize revenues from milestones either (a) ratably over the development period if development risk is significant, or (b) ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated. Generally, there are three types of agreements under which a customer would owe us a milestone payment:

- Humanization Agreements provide for the payment of certain milestones to us after the completion of services to perform the humanization process. These milestones generally include delivery of a humanized antibody meeting a certain binding affinity and, at the customer's election, delivery of a cell line meeting certain criteria described in the original agreement.

- Patent License Agreements and Humanization Agreements sometimes require our licensees to make milestone payments to us when they achieve certain progress, such as FDA approval, with respect to the licensee's product.

- We may also receive certain milestone payments in connection with licensing technology to or from our partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when they or we achieve certain levels of development with respect to the licensed technology.

Reimbursement of Development Costs

Reimbursement of development costs from our collaborators is recognized as revenue as the related costs are incurred.

Stock-Based Compensation

As of September 30, 2004, we had six stock-based employee compensation plans. We account for our plans under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations. During the three and nine

months

ended September 30, 2004, we recognized approximately $17,000 and $380,000, respectively, in stock-based compensation expense with respect to modifications to certain employee stock option awards. The tables below illustrate the effect on net loss and net loss per share if we had applied the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), as amended by FASB Statement No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure," to our stock-based employee compensation plans.

During the preparation of the notes to the consolidated condensed financial statements for the quarter ended June 30, 2004, we determined that the calculation of our pro forma net loss reported under SFAS 123 for the years ended December 31, 2001, 2002 and 2003, as previously reported, was understated primarily as a result of our having inadvertently excluded the fair value of (and, therefore, the amortization expense related to) options granted during 1998 through 2001. In addition, we found that amortization expense was incorrectly calculated in 2001, 2002 and 2003 due primarily to inaccuracies in the computation of the weighted-average expected life used to calculate the fair value of stock options granted during 2000 through 2003. Accordingly, pro forma net loss reported under SFAS 123 for the three and nine months ended September 30, 2003, presented in the tables below, has been revised. These revisions had no effect on our previously reported consolidated results of operations or financial condition.

(In thousands, except per share data)	Three Months Ended September 30,		Nine months ended September 30,	
	2004	2003 (Revised)	2004	2003 (Revised)
Net loss, as reported	$ (13,589)	$ (18,875)	$ (38,659)	$ (56,954)
Add: Stock-based employee compensation expense included in reported net loss	17	—	380	—
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards	(4,427)	(6,016)	(13,931)	(20,307)
Pro forma net loss	$ (17,999)	$ (24,891)	$ (52,210)	$ (77,261)
Basic and diluted net loss per share:				
As reported	$ (0.14)	$ (0.20)	$ (0.41)	$ (0.62)
Pro forma	$ (0.19)	$ (0.27)	$ (0.55)	$ (0.84)
Impact of revision on previously reported:				
Pro forma net loss		$ (969)		$ (6,655)
Pro forma net loss per share		$ (0.01)		$ (0.07)

For the periods presented in the table below, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Expected life, in years (revised, except 2004 periods)	2.2	2.7	2.4	2.7
Risk-free interest rate	2.6%	2.9%	2.6%	2.9%
Volatility	61%	70%	64%	72%
Dividend yield	0	0	0	0

On March 31, 2004, the FASB issued the Exposure Draft "Share Based Payment," which will require all equity-based awards to employees to be recognized in the statement of operations based on their fair values. We will be required to adopt the final standard on July 1, 2005, and we expect that the FASB will issue the final standard by the end of 2004.

We account for stock options granted to non-employees at fair value using the Black-Scholes option-pricing model in accordance with EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Stock options granted to non-employees are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense over the service period in which the non-employee provides services to the Company. We recognized stock-based compensation expense related to stock options issued to non-employees of approximately $301,000 and $498,000 for the three and nine months ended September 30, 2004, and approximately $56,000 and $255,000 for the three and nine months ended September 30, 2003, respectively.

Segment and Concentrations Disclosure

In accordance with FASB Statement No. 131, "Disclosure About Segments of an Enterprise and Related Information," we are required to report operating segments and related disclosures about our products, services, geographic areas and major customers. We have no product revenue and have only one segment with facilities located primarily within the United States. The majority of our revenues are earned in the United States.

Revenues from Genentech in the third quarters of 2004 and 2003 accounted for 70% and 68% of total revenues, respectively, and revenues from Genentech in the first three quarters of 2004 and 2003 accounted for 45% and 33% of total revenues, respectively. Revenues from MedImmune in the third quarters of 2004 and 2003 accounted for 8% and 16% of total revenues, respectively, and revenues from MedImmune in the first three quarters of 2004 and 2003

accounted for 37% and 44% of total revenues, respectively. No other revenue from any other source exceeded 10% of total revenues for all periods presented.

Capitalized Software

During the first quarter of 2004, we adopted Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use" (SOP 98-1). Pursuant to SOP 98-1, we recognize costs incurred in the preliminary planning phase of software development as expense as the costs are incurred. Software development costs incurred in the application development phase are capitalized and are included in property and equipment. Once the developed software is placed into service, these costs are amortized into expense over the estimated useful life of the software.

2. Net Loss Per Share

In accordance with FASB Statement No. 128, "Earnings Per Share," basic and diluted net loss per share amounts have been computed using the weighted-average number of shares of common stock outstanding during the periods presented. For all periods presented, we incurred a net loss, and as such, we did not include the effect of outstanding stock options or outstanding convertible notes in the diluted net loss per share calculations, as their effect would be anti-dilutive.

The total number of shares excluded from the calculations of diluted net loss per share for outstanding convertible notes was 12,415,450 for the three and nine months ended September 30, 2004 and 16,389,000 for the three and nine months ended September 30, 2003. The total number of shares excluded from the calculation of diluted net loss per share for stock options was 2,599,253 and 2,063,000 for the three months ended September 30, 2004 and 2003 and 3,103,716 and 1,555,000 for the nine months ended September 30, 2004 and 2003, respectively.

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and the change in unrealized gains and losses on our available-for-sale securities. The following table presents the calculation of our comprehensive loss, in thousands:

	Three Months Ended September 30,		Nine months ended September 30,	
(In thousands)	**2004**	**2003**	**2004**	**2003**
Net loss	$ (13,589)	$ (18,875)	$ (38,659)	(56,954)
Other comprehensive income (loss):				
Increase (decrease) in unrealized gains on marketable securities	980	(1,005)	(1,287)	(3,875)
Total comprehensive loss	$ (12,609)	$ (19,880)	$ (39,946)	(60,829)

4. Other Accrued Liabilities

At September 30, 2004 and December 31, 2003, other accrued liabilities consisted of the following:

(In thousands)	**September 30, 2004**	**December 31, 2003**
Construction-in-process	$ 7,976	$ 14,568
Consulting and services	4,871	2,409
Other	1,322	2,374
	$ 14,169	$ 19,351

5. Collaborations

In July 2004, we entered into an agreement with Morphotek, Inc. in which we granted patent rights and a commercial license under our humanization patents in exchange for broad access to Morphotek's MORPHODOMA® and Suppressor of Immunoglobulin Production technology. Under the agreement, Morphotek has the right to obtain additional patent licenses upon payment of additional fees. Upon the future commercialization of the products, Morphotek will pay us royalties on product sales.

In accordance with APB Opinion No. 29, "Accounting for Nonmonetary Transactions" (APB 29), we established the value of the technology that we acquired from Morphotek based on the fair value of the patent rights and commercial license granted to Morphotek. We deemed the fair value of the patent rights granted to Morphotek to be $1.0 million and the fair value of the commercial license to be $0.5 million, which is based on

the terms of similar agreements that we have signed with third parties. As this technology has broad application across multiple preclinical and clinical programs, in accordance with FASB Statement No. 2, "Accounting for Research and Development Costs," we have capitalized the $1.5 million in Intangible Assets on the Consolidated Condensed Balance Sheet and we will amortize it over five years, the term of the agreement. During the third quarter of 2004, we recognized $75,000 in amortization expense related to this asset.

As we have culminated the earnings process as proscribed under APB 29 and have satisfied revenue recognition criteria under SAB 104 and EITF 00-21 for the patent rights, we recognized revenue of $1.0 million in the third quarter of 2004 upon the execution of the agreement. The remaining $500,000 has been recorded as deferred revenue, and we will recognize this amount once the commercial license is delivered to Morphotek.

In September 2004, we entered into a Co-Development and Commercialization Agreement (the Collaboration Agreement) with Hoffman-La Roche (Roche) for the joint development and commercialization of daclizumab (*Zenapax*®) for the treatment of asthma and other respiratory diseases. Under the terms of the

Collaboration Agreement, we and Roche will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the United States. Outside the United States, we will receive royalties on net sales by Roche or its licensees of the product in asthma.

Under the terms of the Collaboration Agreement, we received a $17.5 million upfront payment from Roche in the third quarter of 2004, and we may receive up to $187.5 million in development and commercialization milestones in the future for successful further development of daclizumab. As we have continuing obligations under the Collaboration Agreement, we recorded the $17.5 million as deferred revenue, of which we recognized approximately $240,000 in License and Other revenue during the third quarter of 2004. We will amortize the remaining amount over a period of approximately six years, which is the expected development period. We also recognized approximately $960,000 as reimbursable research and development expenses during the third quarter of 2004.

6. Restructuring and Other Charges

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials, in June 2004 management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased office facility. As a result of the restructuring plan and in accordance FASB Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," we incurred a charge of approximately $288,000, included in research and development expenses in the Statement of Operations, in the nine months ended September 30, 2004. The restructuring charge included approximately $97,000 of severance-related amounts, $169,000 of committed cost for our New Jersey leased facility, primarily related to lease expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned at the facility. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005. The workforce reductions were completed by the end of the second quarter of 2004.

During the third quarter of 2004, we recognized an additional $42,000 in restructuring charges, which related to $67,000 in additional severance, authorized and paid in August 2004, in connection with the workforce reductions at the end of the second quarter of 2004 offset against $25,000 in proceeds expected to be received from a short-term sublease of our New Jersey facility. As of September 30, 2004, we had made payments totaling approximately $164,000 for severance-related restructuring charges and $31,000 for facility-related charges. We expect to pay the balance of the facility-related costs of approximately $113,000 through October 2005. Actual future cash requirements may differ materially from the accrual at September 30, 2004.

In the second quarter of 2004, we completed the first phase of a physical inventory of substantially all of our laboratory equipment at our Fremont facilities. As a result, we recorded a charge to research and development

expenses of $300,000, which represents the estimated amount of net book value of assets that are no longer in use. We plan to complete the physical inventory of these assets by the end of 2004.

7. Postretirement Benefit Plan

In June 2003, we established a postretirement health care plan, which covers medical, dental and vision coverage for certain of our former officers and their dependents. During the three and nine months ended September 30, 2004, we recognized net periodic benefit cost of approximately $77,000 and $177,000, respectively. During the three months ended September 30, 2003, we recognized net periodic benefit cost of approximately $62,000. This expense includes service cost, interest cost, and amortization of prior service cost.

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

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

OVERVIEW

We are a recognized leader in the discovery and development of humanized monoclonal antibodies for the treatment of disease. All of our revenues are derived from licensing, humanization and royalty arrangements. During the third quarter of 2004, we received royalties on seven marketed products, with approximately 57% of our royalty revenues derived from the *Herceptin*® antibody product marketed by Genentech and the *Synagis*® antibody product marketed by MedImmune. We do not currently anticipate having proprietary marketed products prior to 2007. Accordingly, our revenues and related cash flows continue to depend substantially on the success of our licensees and our ability to enter into new licensing and royalty arrangements.

Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of September 30, 2004, we had an accumulated deficit of approximately $259.0 million. We expect that our expenses will increase over the next several years because of the extensive resource commitments required to identify, develop and manufacture antibody candidates, to achieve regulatory approval and to market potential products for commercial success. Since we or our collaborative partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. Although we have had some profitable reporting periods, we do not expect to achieve sustained profitability until we are able to market and sell products. Since our goal is to launch our first product or products into the North American market by 2007, our ability to achieve profitability or a cash-flow positive position would not occur sooner than that, even if we were successful.

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

In the absence of substantial revenues from new corporate collaborations or patent rights or patent licensing or humanization agreements, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses and may require additional capital to fully execute our business strategy.

Significant Events

In September 2004, we entered into a Co-Development and Commercialization Agreement (the Collaboration Agreement) with Roche for the joint development and commercialization of daclizumab (*Zenapax*®) for the treatment of asthma and other respiratory diseases. Under the terms of the Collaboration Agreement, we, together with Roche, will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the United States. Outside the United States, we will receive royalties on net sales by Roche or its licensees of the product in asthma.

Under the terms of the Collaboration Agreement, we received a $17.5 million upfront payment from Roche in the third quarter of 2004, and we may receive up to $187.5 million in development and commercialization milestones in the future for successful further development of daclizumab. As we have continuing obligations under the Collaboration Agreement, we recorded the $17.5 million as deferred revenue, of which we recognized approximately $240,000 in License and Other revenue during the third quarter of 2004. We will amortize the remaining amount over a period of approximately six years, which is the expected development period. We also recognized approximately $960,000 as reimbursable research and development expenses during the third quarter of 2004.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

We believe there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2004 as compared to what was previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission on March 8, 2004.

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition

We currently recognize three types of revenues resulting from the licensing and use of our technology, and from services we sometimes perform in connection with the licensed technology. These revenues are typically derived from our proprietary patent portfolio covering the development, use, sale and importation of humanized antibodies.

We enter into patent license and humanization agreements that may contain other elements, such as royalties and milestones related to the achievement of particular stages in product development. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element. We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement and when payment is reasonably assured. In addition, we may enter into nonmonetary transactions in connection with our patent licensing arrangements, and management must use estimates and judgments when considering the fair value of the technology rights acquired and the patent licenses granted under these arrangements. When available, the fair value of the nonmonetary transaction is based on vendor-specific objective evidence of fair value of each significant element of the patent license agreement. Otherwise, management uses other methods of calculating the fair value, such as current pricing information within the Company. Therefore, the fair value of the technology right(s) acquired from the licensee is typically based on the fair value of the patent license and other consideration granted to the licensee.

Under our humanization agreements, the licensee typically pays an upfront fee for us to “humanize” an antibody. These upfront fees are recognized as the humanization work is performed, which is typically over three to six months. We follow this method because we can reliably estimate the progress of each project based on information from our scientists. Due to our extensive experience in humanizing antibodies, coupled with the short-term nature of the humanization contracts, the likelihood that the actual progress is materially different than that reflected in our revenues at the end of any particular reporting period is low. Historically, revenues recognized have approximated actual progress under each humanization agreement.

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential drugs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, direct

expenses related to each patient enrolled in a clinical trial are recognized on an estimated cost-per-patient basis as services are performed. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from contract research organizations (CROs), such as estimated costs per patient, to calculate our accrual for direct clinical expenses at the end of each reporting period. For indirect expenses, which relate to site and other administrative costs to manage our clinical trials, we rely on information provided by the CRO, including costs incurred by the CRO as of a particular reporting date, to calculate our indirect clinical expenses. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial, which we confirm directly with the CRO. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred; however, our experience has been that our estimates at the end of any particular reporting period have been materially accurate.

Intangible Assets

The valuation in connection with the initial acquisition and the ongoing evaluation for impairment of intangible assets requires significant management estimates and judgment. The value ascribed to each asset requires management estimates and judgment as to expectations for various products and business strategies. For example, we estimate future probability-adjusted cash flows and certain discount rates as well as assumed commercialization dates for future potential products. These estimations affect the allocation between charges to acquired in-process research and development and capitalization of intangible assets. If any of the significant assumptions differ from the estimates and judgments used by management, this could result in different valuations for intangible assets.

Once the values for intangible assets are established, we must test intangible assets with definite useful lives for impairment in accordance with Financial Accounting Standards Board (FASB) Statement No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” When we conduct our impairment tests for intangibles, factors that are considered important in determining whether impairment might exist include significant changes in our underlying business and product candidates or other factors specific to each asset being evaluated. Any changes in key assumptions about the business and its prospects, or changes in market conditions or other externalities, could result in an impairment charge and such a charge could have a material adverse effect on our consolidated results of operations.

RESULTS OF OPERATIONS

Three and Nine months ended September 30, 2004 and 2003

Revenues

	Three Months Ended September 30,			Nine months ended September 30,		
(In thousands)	2004	2003	% Change	2004	2003	% Change
Royalties	$ 17,131	$ 8,758	96%	$ 63,872	$ 43,808	46%
License and other	2,653	567	368%	9,323	9,265	1%
Total revenues	$ 19,784	$ 9,325	112%	$ 73,195	$ 53,073	38%

Royalties

Royalty revenues recognized under agreements with Genentech, MedImmune, Roche and Wyeth increased during the first three quarters of 2004 compared to the comparable period in 2003 due primarily to royalties recognized on sales of three additional products that were launched in the second half of 2003 and the first quarter of 2004: Genentech’s *Xolair*, *Raptiva* and *Avastin* products. Royalty payments from sales of Genentech’s products accounted for 81% and 49% of total royalty revenues in the three and nine months ended September 30, 2004, up from 73% and 40% in the comparable periods of 2003.

To a lesser extent, the increase in royalty revenues is attributable to higher reported product sales for all products in our royalty portfolio during the first three quarters of 2004 as compared to the first three quarters of 2003. The largest portion of this increase relates to Genentech’s *Herceptin* and MedImmune’s *Synagis* humanized antibody products. Royalty payments from sales of *Herceptin* and *Synagis* accounted for 48% and 9% of our royalty revenues for the three months ended September 30, 2004 as compared to 73% and 17% in the comparable period in 2003. Royalty payments from sales of *Herceptin* and *Synagis* accounted for 36% and 42% of our royalty revenues for the nine months ended September 30, 2004 as compared to 40% and 53% in the comparable periods in 2003.

We expect that royalty revenues will continue to increase as the number of drugs from which we receive royalty revenues has increased from four to seven over the past five quarters and sales of these products continue to increase. Further, we expect to continue to experience quarterly fluctuations in royalty revenues due to the seasonality of sales of *Synagis*, which results in higher royalty revenues reported to us in the first and second quarters of the year as compared to the third and fourth quarters.

License and Other

License and other revenues recognized during the third quarters of 2004 and 2003 primarily consisted of upfront licensing and patent rights fees and license maintenance fees. License and other revenues increased during the third quarter of 2004 primarily due to the timing of the execution of a patent licensing agreement and the execution of the Collaboration Agreement with Roche in September 2004, with no such comparable agreements in the third quarter of 2003. In connection with an agreement signed with Morphotek, Inc. in which we granted patent rights in exchange for broad access to Morphotek's MORPHODOMA and Suppressor of Immunoglobulin Production technology, we recognized $1.0 million of license revenue, which we determined to be the fair value of the patent rights provided to Morphotek. With respect to the Collaboration Agreement signed with Roche, we recognized approximately $1.2 million, which consists of approximately (a) $240,000 as the amortized portion of the $17.5 million upfront fee we received during the third quarter of 2004 and (b) $960,000 as reimbursable research and development expenses.

License and other revenues recognized during the first three quarters of 2004 and 2003 primarily consisted of upfront licensing and patent rights fees, milestone payments and license maintenance fees. License and other revenues were relatively flat from the prior-year period due to significant licensing activity during the first and third quarters of 2004 and the first two quarters of 2003.

License and other revenues recognized in the first quarter of 2004 included an upfront license fee from Genentech for its *Avastin* product following approval by the FDA and a milestone payment. In addition, in connection with certain agreements signed with Seattle Genetics, Inc. (SGI) in which we granted patent rights and a patent license as partial consideration for expanded access to SGI's drug conjugate and linker technology, we recognized license revenue of $3.0 million, which we determined to be the fair value of the patent rights and patent license.

License and other revenues recognized in the first quarter of 2003 primarily consisted of an upfront licensing fee from Actinium Pharmaceuticals, Inc. for certain development rights to our SMART M195 (*Zamyl*™) antibody conjugated to alpha-emitting radioisotopes and a milestone payment associated with a product licensing agreement. During the second quarter of 2003, we recognized revenue related to the exercise of an option by Wyeth to acquire a patent license and a milestone payment associated with a patent license agreement.

Costs and Expenses

(In thousands)	Three Months Ended September 30, 2004	2003	% Change	Nine months ended September 30, 2004	2003	% Change
Research and development	$ 27,326	$ 21,812	25%	$ 92,364	$ 58,323	58%
General and administrative	7,664	6,963	10%	23,182	19,465	19%
Acquired in-process research and development	—	—	—	—	37,834	—
Total costs and expenses	$ 34,990	$ 28,775	22%	$ 115,546	$ 115,622	—

Research and Development

Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. The increase in the third quarter of 2004 compared to the third quarter of 2003 was primarily due to an increase in research and development personnel headcount of approximately 90 employees from September 30, 2003 to September 30, 2004 and associated costs of approximately $3.3 million, contract manufacturing services of $2.2 million, and an increase in facility-related costs of $1.6 million, partially offset by a decrease of approximately 2.0 million of direct clinical trial expenses due to the winding down of certain clinical trials during the third quarter of 2004.

The increase in research and development costs during the first nine months of 2004 compared to the comparable period in 2003 was primarily due to an increase in research and development personnel headcount with associated costs of approximately $14.0 million, contract manufacturing services of $7.8 million, an increase in in-licensing costs of $4.1 million, and an increase in facility-related costs of $5.7 million. We expect our research and development expenses will increase further as we advance our product candidates into later stages of development and add new product candidates.

In addition, during the second and third quarters of 2004 we incurred approximately $0.3 million in restructuring charges related to the closure of our New Jersey facility and $0.3 million for the write-off of certain assets (see Restructuring and Other Charges below), and approximately $0.6 million related to stock-based compensation for non-employees and modifications to certain employee stock options, all of which were included in research and development expenses.

Below is a summary of products and the related stages of development for each product in clinical development, including the research and development expenses recognized in connection with each product.

Product	Description/Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the Nine months ended September 30, 2004	2003
Current Product Candidates						
Daclizumab					$ 22,907	$ 11,325
	Asthma	Phase IIa	Roche	2004 (1)		
	Ulcerative colitis (2)	Phase II	—	2004		
HuZAF	Crohn's disease	Phase IIa		2004	6,441	17,815

Nuvion	Severe steroid-refractory ulcerative colitis	Phase I/II	—	2005	15,902	6,494
M200 (3)	Solid tumors	Phase I	—	2004	15,834	1,764
***Other* (4)**			—		31,280	20,925
	Total Research and Development Expenses				**$ 92,364**	**$ 58,323**

(1) Study completed during the third quarter of 2004.

(2) Clinical trial for daclizumab in ulcerative colitis was discontinued during the second quarter of 2004.

(3) Anti-$\alpha_5\beta_1$ integrin product acquired as part of Eos acquisition in April 2003.

(4) No single clinical product included in "other" constitutes more than 5% of the total research and development expenses for the periods presented.

The information in the column labeled "Estimated Completion of Phase" is our current estimate of the timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates provided in the table. The clinical development portion of these programs may span as many as 7 to 10 years and any further estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing biopharmaceutical products, including significant and changing government regulation, the uncertainty of future preclinical and clinical study results and uncertainties associated with process development and manufacturing as well as marketing. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the "Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we can not accurately predict the timing and level of such expenses," "If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products," "Our clinical trial strategy may increase the risk of clinical trial difficulties," "If we do not attract and retain key employees, our business could be impaired," and "We may be unable to obtain or maintain regulatory approval for our products" sections of our Risk Factors.

Restructuring and Other Charges included in Research and Development Expenses

As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the conduct of clinical trials in June 2004, management approved a formal plan pursuant to which we closed our New Jersey office, which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of nine employees, which represents less than 2% of the Company's total workforce, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, we incurred charges of approximately $330,000, included in research and development expenses in the Statement of Operations, in the quarters ended June 30, 2004 and September 30, 2004. The restructuring charge included approximately $164,000 of severance-related amounts, $144,000 of committed cost for our New Jersey leased facility, primarily related to lease expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned at the facility. The estimated cost of abandoning our leased facilities was based on the contractual lease payments from the date of our abandonment of the facility through the term of the lease, which expires in October 2005, offset against expected proceeds from a short-term sublease entered into during October 2004. The workforce reductions were completed by the end of the second quarter of 2004. We expect to pay the balance of the facility-related costs of approximately $113,000 through October 2005. Actual future cash requirements may differ materially from the accrual at September 30, 2004, particularly if we sublease the facility.

Also in the second quarter of 2004, we completed the first phase of a physical inventory of substantially all of our laboratory equipment at our Fremont facilities. As a result, we recorded a charge to research and development expenses of $300,000, which represents the estimated amount of net book value of assets that are no longer in use. We plan to complete the physical inventory of these assets by the end of 2004.

General and Administrative Expenses

General and administrative costs include costs of personnel, professional services, consulting and other expenses related to our administrative functions and an allocation of facility costs. General and administrative expenses for the three months ended September 30, 2004 increased slightly from the comparable period in 2003 primarily due to increased outside services expenses of $0.9 million and higher facility-related costs of $0.3 million, partially offset by lower legal costs related to our intellectual property, licensing and other matters of $0.4 million.

The increase in general and administrative expenses for the nine months ended September 30, 2004 as compared to the 2003 period was primarily due to increased personnel-related expenses of approximately $1.9

million, primarily resulting from the resignation of Dr. Laurence Jay Korn as Chairman of the Board and an employee of the Company (see below), increased outside services expenses of approximately $1.7 million and increased facilities-related costs of approximately $0.7 million, partially offset by lower legal costs related to our intellectual property, licensing and other matters of approximately $0.3 million. We expect that general and administrative expenses will increase slightly for the last quarter of 2004, as compared to the third quarter of 2004.

In connection with Dr. Korn's resignation as Chairman of the Board and an employee of the Company, Dr. Korn received a severance payment of $515,000 in addition to the acceleration of an additional 12 months' of vesting of certain stock options previously granted to him. During the second quarter of 2004, we recognized $515,000 for his severance payment, which was paid in July 2004, and approximately $40,000 in stock-based compensation expense in connection with the accelerated vesting of stock options as provided under the amended Agreement. Additionally, Dr. Korn will continue to receive certain fringe benefits for a period of one year from his resignation date and 112,500 of his unvested, outstanding stock options as of September 30, 2004 will

continue to vest under the terms of the original stock option agreements. As this represents a change in the status in grantee status under FASB Statement No. 44, "Accounting for Certain Transactions Involving Stock Compensation," we expect to recognize stock-based compensation expense over the next two years as the stock options vest under the fair value method of accounting as proscribed by SFAS 123.

Acquired In-Process Research and Development

In connection with the April 2003 acquisition of Eos, we recorded charges for acquired in-process research and development of $37.8 million due to Eos' incomplete research and development programs that had not yet reached technological feasibility as of April 4, 2003 and had no alternative future use as of that date. A summary and the status of these programs at the end of the third quarter of 2004 follows:

Program	Description	Status of Development	Value Assigned (in thousands)
Anti-angiogenesis (M200, Anti-$\alpha_5\beta_1$ Integrin Antibody)	Function-blocking antibody that targets a specific integrin for solid tumors, including melanoma, pancreatic, non-small lung and renal cell cancers	Phase I clinical trials initiated in June 2003, and Phase II clinical trials are expected to commence by the end of 2004	$ 24,067
Ocular Neovascularization (F200, Anti-$\alpha_5\beta_1$ Integrin Antibody)	Fab fragment of Anti-$\alpha_5\beta_1$ Integrin Antibody for ocular indications, including age-related macular degeneration	Phase I clinical trial expected in 2005*	$ 13,767

* Development progress may be affected by potential partnering discussions or commitment of resources to more advanced programs.

In addition, in 2003 we recorded a charge to acquired in-process research and development totaling approximately $48.2 million in connection with the amendment to our collaboration agreement with Roche in October 2003, pursuant to which we now have exclusive worldwide rights to market, develop, manufacture and sell *Zenapax*® (daclizumab) in all disease indications other than transplantation. This amount relates to the rights to autoimmune indications for daclizumab that were then being developed and tested in clinical studies, specifically to treat asthma and ulcerative colitis. Significant changes to the acquired in-process research and development daclizumab projects since December 31, 2003 are as follows:

- In March 2004, we reported positive results from the initial clinical study of daclizumab in patients with chronic, persistent asthma whose disease is not well controlled with high doses of inhaled corticosteroids. We currently expect that the next trial of daclizumab in asthma will be a Phase I trial in which daclizumab is administered subcutaneously, expected to commence by the first quarter of 2005.

- In May 2004, we reported results from a Phase II clinical study of daclizumab in patients with moderate-to-severe ulcerative colitis. Daclizumab did not meet primary or secondary endpoints in the trial, and we do not intend to develop it further for this indication.

Interest and Other Income, Interest Expense and Impairment Loss on Investment

(In thousands)	Three Months Ended September 30, 2004	2003	% Change	Nine months ended September 30, 2004	2003	% Change
Interest and other income, net	$ 2,822	$ 4,291	(34)%	$ 7,689	$ 13,151	(42)%
Interest expense	(1,193)	(3,705)	(67)%	(3,929)	(7,346)	(47)%
Impairment loss on investment	—	—	—	(150)	—	

Interest and Other Income and Expense

Interest income for the three and nine months ended September 30, 2004 decreased from the comparable periods in 2003 due to the reduced interest earned on our cash, cash equivalents and marketable securities balances primarily as a result of lower interest rates and lower invested balances.

Interest expense for the three months ended September 30, 2004 decreased from the comparable period in 2003 primarily due to both our 2.75%, $250 million convertible subordinated notes and our 5.50%, $150 million convertible subordinated notes being outstanding during the third quarter of 2003, compared to just our 2.75%, $250 million convertible subordinated notes being outstanding in the third quarter of 2004.

In addition to the above, interest expense further decreased during the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 because we capitalized more interest costs in connection with the development activities for our future manufacturing facilities during the 2004 period; we capitalized approximately $1.0 million and $2.7 million of our interest cost in the three and nine months ended September 30, 2004, compared to $0.6 million and $1.7 million in the three and nine months ended September 30, 2003, respectively. Further, interest expense decreased slightly from the same period in the prior year due to a lower interest rate on our outstanding 2.75%, $250 million convertible subordinated notes that were issued in July 2003, as compared to our 5.50%, $150 million convertible notes that were outstanding during the first quarter of 2003 but redeemed in the fourth quarter of 2003, partially offset by the amortization of slightly higher issuance costs associated with our 2.75%, $250 million convertible subordinated notes.

Impairment Loss on Investment

During the second quarter of 2003, we recorded an impairment charge of $150,000 related to a complete write-down of shares of Signature BioScience, Inc. convertible preferred stock that we acquired during 2002 in exchange for the sale of the assets of our small molecule research group.

Income Taxes

We have recorded a tax provision of approximately $68,000 for the nine months ended September 30, 2004, compared to $60,000 for the comparable period in 2003. Taxes during both periods primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee. We do not expect to record any tax provision for federal income taxes based upon our projected tax loss for fiscal 2004.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have financed our operations primarily through public and private placements of equity and debt securities, revenue under agreements with third parties and interest income on invested capital. At September 30, 2004, we had cash, cash equivalents, marketable securities and restricted investments in the aggregate of $425.8 million, compared to $505.0 million at December 31, 2003.

Net cash used in operating activities for the nine months ended September 30, 2004 was approximately $11.5 million, compared to net cash used in operating activities of $7.4 million in the comparable 2003 period. The change from the 2003 period was primarily due to a higher research and development expenses in the 2004 period as compared to the 2003 period, which was primarily the result of higher spending to support our ongoing preclinical and clinical efforts, including an approximate 20% increase in research and development personnel from September 30, 2003 to September 30, 2004. This higher spending was partially offset by a $17.5 million upfront payment received from Roche in the third quarter of 2004 in connection with the Collaboration Agreement.

Net cash used in investing activities was $212.8 million for the nine months ended September 30, 2004, compared to net cash provided by investing activities of $11.6 million in the comparable period in 2003. The change from the 2003 period was primarily the result of higher investment of our cash by way of larger purchases of our marketable securities, fewer maturities of our marketable securities, and higher capital expenditures in the first three quarters of 2004. Capital expenditures in the first nine months of 2004 and 2003 were primarily related to the development and construction activities for our manufacturing facility in Brooklyn Park, Minnesota.

Net cash provided by financing activities for the nine months ended September 30, 2004 was $13.4 million compared to $251.4 million in the comparable period in 2003. In July 2003, we issued our $2.75%, $250 million convertible subordinated notes. In both periods, other financing activities related to the exercise of employee stock options offset by payments on our long-term debt obligations.

We estimate that our existing capital resources will be sufficient to fund our current level of operations for at least the next four years. Our future capital requirements will depend on numerous factors, including, among others, interest income, royalties from sales of products by third-party licensees, including *Synagis*, *Herceptin*, *Xolair*, *Raptiva*, *Avastin*, *Zenapax* and *Mylotarg*; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; progress of product candidates in clinical trials; the ability of our licensees to obtain regulatory approval and successfully manufacture and market products licensed under our patents; the continued or additional support by our collaborative partners or other third parties of research and development efforts and clinical trials; investment in existing and new research and development programs; time required to gain regulatory approvals; significant resources we will devote to constructing our manufacturing facilities; our ability to obtain and retain funding from third parties under collaborative arrangements; our continued development of internal marketing and sales capabilities; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology. In order to develop and commercialize our potential products we may need to raise

substantial additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. No assurance can be given that such additional financing will be available on acceptable terms, if at all, and such financing may only be available on terms dilutive to existing stockholders.

Our material contractual obligations under lease, debt and construction agreements have not changed significantly from those at December 31, 2003, as disclosed in our Annual Report on Form 10-K filed on March 8, 2004.

In addition, as of September 30, 2004, we have made payments totaling $4.0 million to ICOS Corporation pursuant to a manufacturing agreement for the manufacture of supplies of clinical trial materials for one of our products. The aggregate amount of all committed future payments that we may make under that agreement is $3.4 million, payable in the remainder of 2004 and the first quarter of 2005.

RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Quarterly Report on Form 10-Q, including the risk factors listed below. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock.

Keep these risk factors in mind when you read forward-looking statements contained in this Quarterly Report on Form 10-Q and the documents incorporated by reference herein. These statements relate to our expectations about future events and time periods. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “intends,” “plans,” “believes,” “anticipates,” “expects,” “estimates,” “predicts,” “potential,” “continue” or “opportunity,” the negative of these words or words of similar import. Similarly, statements that describe our reserves and our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Forward-looking statements involve risks and uncertainties, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements.

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

In general, our expenses have exceeded revenues. As of September 30, 2004, we had an accumulated deficit of approximately $259.0 million. We expect our expenses to increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our partners or licensees may not be

able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain. We may be unable to achieve sustained profitability.

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

- some of our earlier stage potential products move into later stage clinical development;
- additional potential products are selected as clinical candidates for further development;
- we pursue clinical development of our potential products in new indications;
- we invest in additional manufacturing capacity;
- we build commercial infrastructure to market our products in North America;
- we defend or prosecute our patents and patent applications; and
- we invest in research or acquire additional technologies, product candidates or businesses.

In the absence of substantial revenues from new agreements with third-party business partners, significant royalties on sales of products licensed under our intellectual property rights, product sales or other uncertain sources of revenue, we will incur substantial operating losses and may require additional capital to fully execute our business strategy.

We have substantial outstanding indebtedness, which could adversely affect our financial condition and prevent us from fulfilling our obligations under our 2.75% $250 million convertible notes.

In connection with our sale of the 2.75% convertible notes, referred to as the Notes, in July 2003, we incurred $250.0 million of indebtedness, set to mature in August 2023, although callable by the holders as early as 2010. Our total consolidated long-term debt as of September 30, 2004 was $257.7 million. The indenture relating to the Notes does not restrict our ability to incur additional indebtedness, including debt that is senior to the Notes.

The degree to which we are leveraged could have important consequences, because:

- it could affect our ability to satisfy our obligations under the Notes;
- a substantial portion of our cash flow from operations will be required to be dedicated to interest and principal payments and may not be available for operations, working capital, capital expenditures, expansion, acquisition or general corporate or other purposes;

- our ability to obtain additional financing in the future may be impaired;
- we may be more highly leveraged than some of our competitors, which may place us at a competitive disadvantage;
- our flexibility in planning for, or reacting to, changes in our business and industry may be limited; and
- it may make us more vulnerable in the event of a downturn in our business, our industry or the economy in general.

Our ability to make payments on and, if necessary, to refinance our debt, including the Notes, will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, business, financial, competitive, legislative, regulatory and other factors that are beyond our control.

We cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available in an amount sufficient to enable us to pay our debt, including the Notes, or to fund our other liquidity needs. We may need to refinance all or a portion of our debt, including the Notes, on or before maturity. We cannot assure you that we would be able to refinance any of our debt, including the Notes, on commercially reasonable terms or at all.

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

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

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

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

In addition, our expenses or other operating results may fluctuate due to the accounting treatment of securities we own or may purchase or securities we have issued or may issue. For example, we expect to recognize expense for employee stock options beginning in the third quarter of 2005, and as a result, we will incur significantly higher losses. In addition, we hold a $30.0 million five-year convertible note receivable we

purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the change in the value of the Exelixis stock

in our financial statements such that changes in the Exelixis stock price contribute to fluctuations of our operating results from quarter to quarter.

Our humanization patents are being opposed and a successful challenge or refusal to take a license could limit our future revenues.

Most of our current revenues are related to our humanization patents and the related licenses that third parties enter into with us for rights to those patents. If our rights are successfully challenged or third parties decline to take licenses for the patents, our future revenues would be adversely affected.

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European humanization patent. We appealed this decision. In November 2003, the Technical Board of Appeal of the European Patent Office decided to uphold our appeal and to set aside the Opposition Division's decision. The Board of Appeal ordered that certain claims be remitted to the Opposition Division for further prosecution and consideration of issues of patentability (novelty, enablement and inventive step). The claims remitted by the Board of Appeal cover the production of humanized antibody light chains that contain amino acid substitutions made under our antibody humanization technology. Regardless of the Opposition Division's decision on these claims, such decision could be subject to further appeals. Until the opposition 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 the opponents are successful, 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; and, whether the antibodies are manufactured in a country outside of Europe where they are covered by one or more of our patents, and if so, on the terms of our license agreements. Also, the Opposition Division's decision could encourage challenges to our related patents in other jurisdictions, including the United States. This decision may lead some of our licensees to stop making royalty payments or lead potential licensees not to take a license, either of which might result in us initiating formal legal actions to enforce our rights under our humanization patents. In such a situation, a likely defensive strategy to our action would be to challenge our patents in that jurisdiction. During the opposition process with respect to our first European patent, if we were to commence an infringement action in Europe to enforce that patent, such an action would likely be stayed until the opposition is decided by the European Patent Office. As a result, we may not be able to successfully enforce our rights under our European or related U.S. and Japanese patents.

With respect to our second European antibody humanization patent, eight notices of opposition were filed. We have filed a response with the European Patent Office. The European Patent Office has scheduled oral hearings for February 2005.

In Japan, three opposition statements were filed with the Japanese Patent Office with respect to our Japanese humanization patent. The Japanese Opposition Board's subsequent decision supported one aspect of the position of the opponents, to which we filed two responses. Ultimately, we received a final determination from the Japanese Patent Office affirming the Opposition Board's earlier decision. We appealed this decision to the Tokyo High Court. A hearing was held in April 2003, and the Tokyo High Court recently notified us that the Opposition Board's decision was upheld. We have appealed this decision to the Japanese Supreme Court.

We intend to vigorously defend the European patents and the Japanese patent in these proceedings. We may not prevail in the opposition proceedings or any litigation contesting the validity of these patents. If the outcome of the European or Japanese opposition proceedings or any litigation involving our antibody humanization patents were to be unfavorable, our ability to collect royalties on existing licensed products and to license our patents relating to humanized antibodies may be materially harmed. In addition, these proceedings or any other litigation to protect our intellectual property rights or defend against infringement claims by others could result

in substantial costs and diversion of management's time and attention, which could harm our business and financial condition.

Our ability to maintain and increase our revenues from licensing is dependent upon third parties entering into new patent licensing arrangements, exercising rights under existing patent rights agreements, and paying royalties under existing patent licenses with us. To date, we have been successful in obtaining such licensing arrangements, and in receiving royalties on product sales, from parties whose products may be covered by our patents. However, we have experienced challenges in our licensing efforts, including the disagreement we had with Genentech in 2003 over whether its *Xolair* antibody product was covered under our humanization patents. There can be no assurance that we will continue to be successful in our licensing efforts in the future. Additionally, although we have reached an amicable settlement with Genentech that is intended to resolve such disagreements, Genentech or other companies may, in the

future, seek to challenge our U.S. patents through litigation or patent office proceedings, such as re-examinations or interferences. If we experience difficulty in enforcing our patent rights through licenses, or if our licensees, or prospective licensees, challenge our antibody humanization patents, our revenues and financial condition could be adversely affected, and we could be required to undertake additional actions, including litigation to enforce our rights. Such efforts would increase our expenses and could be unsuccessful.

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

Our pending patent applications may not result in the issuance of valid patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology. A number of companies, universities and research institutions have filed patent applications or received patents in the areas of antibodies and other fields relating to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of our patents or result in a significant reduction in the scope of our issued patents.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings. 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. 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 in claim scope could reduce our ability to negotiate or collect royalties or to negotiate future collaborative research and development agreements based on these patents. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

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

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

Celltech has been granted a European patent covering humanized antibodies, which we have opposed. At an oral hearing in September 2000, the Opposition Division of the European Patent Office decided to revoke this patent. Celltech appealed that decision, but the Technical Board of Appeal recently rejected the appeal. As a result, the decision revoking the patent is final; no further appeals are available. However, Celltech has a second issued divisional patent in Europe, which has claims that may be broader in scope than its first European patent, and which we have opposed. An Oral Hearing is scheduled to take place in January 2005. In addition, Celltech has a third divisional application currently drafted with broad claims directed towards humanized antibodies. We cannot predict whether Celltech’s second European patent will be modified or revoked in any future opposition proceedings, or whether it will be able to obtain the grant of a patent from the pending divisional application with claims broad enough to generally cover humanized antibodies. Celltech has also been issued a corresponding U.S. patent that contains claims that may be considered broader in scope than their first European patent. In addition, Celltech was recently issued a second U.S. patent with claims that may be considered broader than its first U.S. 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. While this agreement expires in December 2004, we currently are negotiating an extension that, if agreed, would extend the term of the current agreement to December 2014. Notwithstanding this agreement, if our humanized antibodies were covered by Celltech’s European or U.S. patents and if we need more than the three licenses under those patents currently available to us under the agreement, we would

be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

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

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

If our research efforts are not successful, we may not be able to effectively develop new products.

We are engaged in research activities intended to identify antibody product candidates that we may enter into clinical development. These research activities include efforts to discover and validate new targets for antibodies in our areas of therapeutic focus. We obtain new targets through our own drug discovery

efforts and through in-licensing targets from institutions or other biotechnology or pharmaceutical companies. Our success in identifying new antibody product candidates depends upon our ability to discover and validate new targets, either through our own research efforts, or through in-licensing or collaborative arrangements. In order to increase the possibilities of identifying antibodies with a reasonable chance for success in clinical studies, part of our business strategy is to identify a number of potential targets. If we are unsuccessful in our research efforts to identify and obtain rights to new targets, our ability to develop new products could be harmed.

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

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

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

To obtain regulatory approval for the commercial sale of any of our potential products or to promote these products for expanded indications, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in indications for which approval is requested. We have had, and may in the future have, clinical setbacks that prevent us from obtaining regulatory approval for our potential products. Most recently, in May 2004, we announced that daclizumab, our humanized antibody that binds to the interleukin-2 (IL-2) receptor, did not meet the primary endpoint in a Phase II clinical trial in patients with moderate-to-severe ulcerative colitis. As a result, we terminated further development of daclizumab in this indication. Further development of daclizumab in asthma is ongoing.

Early clinical trials such as Phase I and II trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed.

Larger or later stage clinical trials may not produce the same results as earlier trials. Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials. As an example, the daclizumab Phase II clinical trials in moderate-to-severe ulcerative colitis, which did not

meet the primary endpoint in May 2004, were based on earlier Phase I physician-sponsored clinical trials that indicated safety and biological activity for a small number of patients in this indication.

Even when a drug candidate shows evidence of efficacy in a clinical trial, it may be impossible to further develop or receive regulatory approval for the drug if it causes an unacceptable incidence or severity of side effects, or further development may be slowed down by the need to find dosing regimens that do not cause such side effects.

In addition, we may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise because we have a relatively large number of potential products in clinical development. Additionally, regulatory review of our clinical trial protocols may cause us in some cases to delay or abandon our planned clinical trials. Our potential inability to commence or continue clinical trials, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of our potential products, further adds to the uncertainty of regulatory approval for our potential products.

Our clinical trial strategy may increase the risk of clinical trial difficulties.

Research, preclinical testing and clinical trials may take many years to complete and the time required can vary depending on the indication being pursued 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, our current projection for regulatory approval of Nuvion in the United States in 2007 depends upon regulatory approval to initiate potential registration studies in 2005. We anticipate that only some of our potential products may show safety and efficacy in clinical trials and some may encounter difficulties or delays during clinical development.

We may be unable to enroll sufficient patients in a timely manner in order 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, including those in clinical development;

- availability of clinical drug supply;
- availability of clinical trial sites;
- design of the protocol;
- proximity of and access by patients to clinical sites;
- patient referral practices of physicians;
- eligibility criteria for the study in question; and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may result in our being unable to successfully achieve our projected development timelines, or potentially even lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication. For example, our current expectations for registrational studies and regulatory approval for Nuvion are dependent on our ability to timely enroll a worldwide clinical program.

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

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

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

We intend to market and sell a number of our products either directly or through sales and marketing partnership arrangements with partners. To market products directly, we must establish an internal marketing and sales group, contract for these services, or obtain the assistance of another company. Pursuant to the terms of our revised collaboration agreement with Hoffmann-La Roche Inc. (Roche), we have a reversion right, exercisable in 2006, but effective in 2007, to repurchase all rights, including marketing rights, in transplant indications, unless earlier elected by Roche. If we elect to exercise this right, or Roche elects to transfer such rights to us, we will be responsible for the marketing and commercialization of *Zenapax* in all indications worldwide. While Roche must notify us at least six months prior to a transfer of *Zenapax* to us, there can be no assurance that we will be able to establish marketing, sales and distribution capabilities for *Zenapax* in a timely manner. Further, we may not be able to establish such capabilities for our other products 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 could largely depend on these partners' marketing and promotion efforts.

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

To be successful we must attract additional and retain qualified clinical, manufacturing, scientific and management personnel. If we are unsuccessful in attracting and retaining qualified personnel, our business could be impaired.

Manufacturing difficulties could delay commercialization of our products.

Of the products that we currently have in clinical development, Roche and its affiliates are responsible for manufacturing *Zenapax* (daclizumab). In connection with the restructuring of our collaboration agreement with Roche, we have a reversion right, exercisable in 2006, but effective in 2007, to repurchase all rights, including the rights to manufacture *Zenapax*, unless earlier elected by Roche. Our ability to successfully market and develop *Zenapax*, in particular in transplantation, depends upon our success in manufacturing *Zenapax* at commercial scale. We have not manufactured this product in the past and we will need to show comparability with material used by Roche. There can be no assurance that we will successfully and in a timely manner be capable of manufacturing *Zenapax* following the transfer of *Zenapax* to us by Roche.

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 and/or the inability to produce sufficient quantities of such products in a commercially viable manner. Our collaborative partners and we 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.

We do not have experience in manufacturing commercial supplies of our potential products, nor do we currently have sufficient facilities to manufacture all of our potential products on a commercial scale. To obtain regulatory approvals and to create capacity to produce our products for commercial sale at an acceptable cost, we will need to improve and expand our manufacturing capabilities. Our current plans are to validate and use our new manufacturing plant in Brooklyn Park, Minnesota in order to manufacture initial commercial supplies of Nuvion and daclizumab. Our ability to file for, and to obtain, regulatory approvals for such products, as well as the timing of such filings, will depend on our ability to successfully operate our existing manufacturing plant. We may be unable to do so, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis. Failure to do so could delay commercialization of our products.

In addition, as we implement construction and validation of our new Brooklyn Park, Minnesota manufacturing facility, we are implementing an enterprise resource management software platform to support the operations of the Company, including our new manufacturing facility. These efforts will involve

substantial costs and resource commitments. Any construction, validation or other delays could impair our ability to obtain necessary regulatory approvals and to produce adequate commercial supplies of our potential products on a timely basis. Failure to do so could delay commercialization of some of our products and could impair our competitive position.

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

Potential competitors have developed and are developing human and humanized antibodies or other compounds for treating autoimmune and inflammatory diseases, transplantation, asthma and cancers. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our antibody technology platform. 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 our collaborative partners or we succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply

commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, markets Simulect® (basiliximab), a product competitive with *Zenapax*, in the United States and Europe. Novartis has acquired a significant interest in Roche.

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

All of our products in development are subject to risks associated with applicable government regulations. The manufacturing, testing and marketing of our products are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, pharmaceutical products are subject to rigorous FDA regulation. Additionally, other federal, state and local regulations govern the manufacture, testing, clinical and non-clinical studies to assess safety and efficacy, approval, advertising and promotion of pharmaceutical products. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires a number of years and the expenditure of substantial resources.

Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

As part of the regulatory approval process, we must demonstrate the ability to manufacture the pharmaceutical product. Accordingly, the manufacturing process and quality control procedures must conform to rigorous guidelines in order to receive FDA approval. Pharmaceutical product manufacturing establishments are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the United States, 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.

In addition, during 2003 the FDA completed the transfer of regulatory responsibility, review and continuing oversight for many biologic therapeutic products, including antibody therapeutics, from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This transfer of responsibility could result in new regulatory standards, which could result in delays in development or regulatory approvals for our potential products. In addition, when we assume responsibility for manufacturing *Zenapax*, we will be required to demonstrate that the material manufactured by Roche is comparable to the material we produce at our manufacturing facilities. New regulations resulting from the transfer of regulatory responsibility from CBER to CDER could make it more difficult for us to show comparability which could delay development and regulatory approval of *Zenapax* in new indications or reduce or interrupt commercial sales of *Zenapax* for the prevention of acute kidney transplant rejection.

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

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

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

Manufacturing of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. If we make changes in the manufacturing process, we may be required to demonstrate to the FDA and corresponding foreign authorities that the changes have not caused

the resulting drug material to differ significantly from the drug material previously produced. Additionally, when we assume responsibility for manufacturing *Zenapax*, we will be required to demonstrate that the material manufactured by Roche does not differ significantly from the material we produce at our manufacturing facilities. Showing

comparability between the material we produce before and after manufacturing changes, and in the case of *Zenapax*, between the material produced by Roche and the drug material produced by us, 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, and in the case of *Zenapax*, between the our material and the Roche material, we may be required to conduct additional animal studies or human clinical trials to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material. We have made manufacturing changes and are likely to make additional manufacturing changes for the production of our products currently in clinical development. These manufacturing changes or an inability to immediately show comparability between the Roche material and our material could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

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

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

produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

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

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

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

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

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

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. Cost containment measures, whether instituted by health care providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payors may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, 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 United States and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborative partners.

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

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

- developments or disputes as to patent or other proprietary rights;
- disappointing sales of approved products;
- approval or introduction of competing products and technologies;
- results of clinical trials;

- failures or unexpected delays in obtaining regulatory approvals or unfavorable FDA advisory panel recommendations;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- disputes or disagreements with collaborative partners;
- market reaction to announcements by other biotechnology or pharmaceutical companies;

- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- initiation, termination or modification of agreements with our collaborative partners;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by collaborative partners or insiders;
- comments and expectations of results made by securities analysts; and
- general market conditions.

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

We may not have the ability to repurchase the 2.75% $250 million convertible notes on the repurchase date or to finance any repurchase offer required by the indenture.

In August 2010, August 2013 and August 2018, holders of our $250 million convertible notes (the Notes) may require us to repurchase all or a portion of their notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of notes to be repurchased in August 2013 and August 2018, at our option, in cash, shares of our common stock or a combination of cash and shares of our common stock. In addition, if a repurchase event occurs (as defined in the indenture), each holder of the Notes may require us to repurchase all or a portion of the holder's notes. We cannot assure you that there will be sufficient funds available for any required repurchases of these securities. In addition, the terms of any agreements related to borrowing which we may enter into from time to time may prohibit or limit our repurchase of notes or make our repurchase of notes an event of default under certain circumstances. If a repurchase event occurs at a time when a credit agreement prohibits us from purchasing the Notes, we could seek the consent of the lender to purchase the Notes or could attempt to refinance the debt covered by the credit agreement. If we do not obtain a consent, we may not purchase the Notes. Our failure to purchase tendered notes would constitute an event of default under the indenture, which might also constitute a default under the terms of our other debt. In such circumstances, our financial condition and the value of our securities could be materially harmed.

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

Future changes in financial accounting standards, including proposed changes in accounting for stock options, may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty for companies such as ours and insurance costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply

with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Prior and future acquisitions could be difficult to integrate, disrupt our business, dilute stockholder value and harm our operating results.

In April 2003, we completed the acquisition of a privately owned company, Eos Biotechnology, Inc. We expect to continue to review opportunities to acquire other businesses, products or technologies that would complement our current products, expand the breadth of our markets or enhance our technical capabilities, or that may otherwise offer growth opportunities. In our acquisition of Eos, we issued stock as all of the consideration. The issuance of stock in these and any future transactions will dilute stockholders' percentage ownership.

Other risks associated with acquiring the operations of other companies include:

- problems assimilating the purchased operations, technologies or products;

- unanticipated costs and liabilities associated with the acquisition;
- diversion of management's attention from our existing business;
- the potential loss of key collaborators of the acquired companies;
- lack of synergy, or the inability to realize expected synergies, resulting from the acquisition;
- adverse effects on existing relationships with other third-party business partners;
- risks associated with entering markets in which we have no, or limited, prior experience; and
- potential loss of key employees of acquired organizations.

We cannot assure that we would be successful in overcoming problems encountered in connection with such acquisitions, and our inability to do so could significantly harm our business. In addition, to the extent that the economic benefits associated with such acquisitions diminish in the future, we may be required to record write downs of goodwill, intangible assets or other assets associated with such acquisitions.

If we are unable to favorably assess the effectiveness of internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment, our stock price could be adversely affected.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and beginning with our Annual Report on Form 10-K for the year ending December 31, 2004, our management will be required to report on, and our independent auditors to attest to, the effectiveness of our internal controls over financial reporting as of the end of 2004. The rules governing the standards that must be met for management to assess the effectiveness of our internal controls over financial reporting are new and complex and require significant documentation, testing and possible remediation. We are currently in the process of reviewing, documenting and testing our internal controls over financial reporting, which has and may continue to result in increased expenses and the devotion of significant management resources. We may encounter problems or delays in completing the implementation of any changes necessary to make a favorable assessment of our internal controls over financial reporting. In addition, in connection with the attestation process by our independent auditors, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment, investor confidence and our stock price could be adversely affected.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We maintain a non-trading investment portfolio of investment grade, highly liquid, debt securities, which limits the amount of credit exposure to any one issue, issuer, or type of instrument. We do not use derivative financial instruments for speculative or trading purposes. We hold a $30.0 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis

stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the value of the Exelixis stock in our financial statements. Such a requirement could cause changes in the Exelixis stock price to contribute to fluctuation of our operating results from quarter to quarter. The securities in our investment portfolio are not leveraged and are classified as available-for-sale and therefore are subject to interest rate risk. We do not currently hedge interest rate exposure. As of September 30, 2004, there has been no material change in our interest rate exposure from that described in the Company's Annual Report on Form 10-K for the year ended December 31, 2003.

Because we translate foreign currencies into United States dollars for reporting purposes, currency fluctuations can have an impact on our results. For the nine months ended September 30, 2004 and 2003, there was no material currency exchange impact on our Consolidated Condensed Statements of Operations from our intercompany transactions. As of September 30, 2004, we did not engage in foreign currency hedging activities.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation as of September 30, 2004, our chief executive officer and chief financial officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q.

Changes in internal controls. There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2004, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Item 3 of our Annual Report on Form 10-K for the period ended December 31, 2003. No significant changes in the status of disclosed items have occurred since December 31, 2003.

ITEM 6. EXHIBITS

10.1	Co-Development and Commercialization Agreement between the Company and Hoffman-La Roche, dated September 14, 2004 (with certain confidential portions deleted and marked by notation indicating such deletion).
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of Protein Design Labs, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

SIGNATURES

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

Dated: November 3, 2004

PROTEIN DESIGN LABS, INC.
(Registrant)

/s/ Mark McDade
Mark McDade
Chief Executive Officer
(Principal Executive Officer)

/s/ Glen Sato
Glen Sato
Senior Vice President and Chief
Financial Officer
(Principal Accounting Officer)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Co-Development and Commercialization Agreement is entered into as of September 14, 2004 (the **"Effective Date"**), by and among PROTEIN DESIGN LABS, INC., a Delaware corporation having offices at 34801 Campus Drive, Fremont, California 94555 (**"PDL"**), and HOFFMANN-LA ROCHE INC., a New Jersey corporation having offices at 340 Kingsland Street, Nutley, New Jersey 07110 (**"Roche-Nutley"**) and F. HOFFMANN-LA ROCHE LTD of Basel, Switzerland (**"F. Roche**") (Roche-Nutley and F. Roche are hereinafter individually and collectively referred to as **"Roche**").

RECITALS

WHEREAS, Roche currently markets a humanized antibody against the interleukin-2 (IL-2) receptor (Daclizumab), under the trademark Zenapax®, for the prevention of acute organ rejection in patients receiving kidney transplants;

WHEREAS, pursuant to that certain Amended and Restated Worldwide Agreement between PDL and Roche dated October 1, 2003 (the **"Worldwide Daclizumab Agreement"**), certain rights previously granted to Roche reverted to PDL, and PDL acquired, among other rights, the sole and exclusive worldwide rights to develop, market and sell Daclizumab for autoimmune and other non-transplant indications, including asthma, and PDL has the obligation to make certain royalty payments to Roche; and

WHEREAS, PDL and Roche now wish to enter into a worldwide collaboration for the joint development and commercialization of Daclizumab for the treatment of asthma and other respiratory diseases.

NOW THEREFORE, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 "Affiliate" means any corporation or other business entity controlled by, controlling, or under common control with another entity, with **"control"** meaning direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock of, or more than a fifty percent (50%) interest in the income of, such corporation or other business entity. Notwithstanding anything to the contrary in this paragraph, Genentech, Inc., a Delaware corporation, and Chugai Pharmaceutical Company, a Japanese company, shall not be deemed an Affiliate of Roche unless Roche provides written notice to PDL of its desire to include Genentech and/or Chugai as an Affiliate.

1.2 "Asthma Field" means the treatment and/or prevention of asthma or other respiratory diseases.

1.3 "Autoimmune Indications" or **"AI"** means all indications that involve pathogenic consequences, including tissue injury, produced by autoantibodies or autoreactive T lymphocytes interacting with self epitopes, i.e., autoantigens. Autoimmune Indications shall include, without limitation, asthma, psoriasis, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, juvenile rheumatoid arthritis, polymytosis, Type I diabetes, sarcoidosis, Sjogrens syndrome, chronic active non-pathogenic hepatitis, non-infectious uveitis (Behcets), aplastic anemia, regional non-pathogenic enteritis (including ulcerative colitis, Crohn's Disease and inflammatory bowel disease), Kawasaki's disease, post-infectious encephalitis, multiple sclerosis, and tropic spastic paraparesis.

1.4 "Change of Control" shall mean a transaction in which a Party: (a) sells, conveys or otherwise disposes of all or substantially all of its property or business; or (b)(i) merges or consolidates with any other entity (other than a wholly-owned subsidiary of such Party); or (ii) effects any other transaction or series of transactions; in each case of clause (i) or (ii), such that the stockholders of such Party immediately prior thereto, in

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the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving entity following the closing of such merger, consolidation, other transaction or series of transactions.

1.5 "Collaboration Inventions" means all inventions that (a) relate to or are useful with **[*]** that **[*]** the **[*]** and (b) are made during the term of this Agreement by employees of Roche or persons contractually required to assign or license patent rights covering such inventions to Roche, in the course of performing Roche's obligations, or exercising Roche's rights, under this Agreement.

1.6 "Combination Product" means a Licensed Product that contains one or more therapeutically active ingredients in addition to Daclizumab.

1.7 "Commercial Supply Agreement" shall have the meaning set forth in Section 8.2.

1.8 "Commercialization Plan" shall have the meaning set forth in Section 6.1.

1.9 "Controlled" means, with respect to any intellectual property right, that the Party has a license to such intellectual property right and has the ability to grant to the other Party a sublicense to such intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such sublicense.

1.10 "Co-Promotion Term" shall have the meaning set forth in Section 6.4.

1.11 "Cost of Goods Sold" or **"COGS"** means, with respect to a Licensed Product (in bulk, vialed or finished product form, as the case may be), the sum of the following, all of which shall be calculated in accordance with U.S. generally accepted accounting principles consistently applied by PDL to all of its products:

(a) [*]

provided, however, that Cost of Goods Sold shall not include any costs or expenses included or includible in Distribution Expenses.

1.12 "Daclizumab" means that certain humanized murine monoclonal antibody directed against the p55 component of IL-2R and given the generic name "Daclizumab" by the United States Adopted Names Council. Daclizumab does not include fragments of such antibody or any antibodies having a different amino acid sequence from such antibody.

1.13 "Data Services" shall have the meaning set forth in Section 7.6(b).

1.14 "Detail" or "Detailing" shall mean a **[*]** presentation by a Party's sales representative, to one or several medical professional(s) having prescribing authority in the U.S. Territory in the Asthma Field, as well as to other individuals or entities that have significant impact or influence on prescribing decisions in the U.S. Territory in the Asthma Field, as identified in the Commercialization Plan approved by the JDC (collectively, the **"Target Audience"**), in which the principal objective of such presentation is to emphasize the features and function of such Licensed Product in the Asthma Field. **[*]**

1.15 "Development" means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of a Licensed Product in the Asthma Field or (b) developing the ability to manufacture the same. This includes, without limitation, (i) preclinical testing, toxicology, formulation, manufacturing-related technology development, and clinical studies of a Licensed Product in the Asthma Field; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a governmental authority to obtain and/or maintain Regulatory Approval of a Licensed Product in the Asthma Field, and outside counsel regulatory legal services related thereto; and (iii) manufacturing process development and scale-up, bulk production and fill/finish work associated with the supply of Licensed Products

for preclinical and clinical studies, and related quality assurance technical support activities.

1.16 "Development Expenses" shall have the meaning set forth in Exhibit A.

1.17 "Development Plan" shall have the meaning set forth in Section 4.1.

1.18 "Diligent Efforts" means the carrying out of obligations or tasks in a diligent, sustained manner using efforts equivalent to the efforts a Party devotes to a product of similar market potential, profit potential and strategic value resulting from its own research efforts, based on conditions then prevailing. Diligent Efforts requires that the Party: (a) promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives. The Parties acknowledge that Roche does not, as of the Effective Date, develop, register, market, and sell its products in every country in the Territory, and it is understood that the exercise by Roche of Diligent Efforts shall be judged in light of this fact.

1.19 "Distribution Expenses" means the costs, excluding administration costs, incurred by a Party or for its account, specifically attributable to the distribution of a Licensed Product in the U.S. Territory, to be calculated in the manner set forth in Exhibit A.

1.20 "Dollars" or "$" means the legal tender of the U.S.

1.21 "Drug Approval Application" means a Biologics License Application or an equivalent application for Regulatory Approval required before commercial sale or use of a Licensed Product in the Asthma Field in a regulatory jurisdiction.

1.22 "European Union" means all countries that are officially recognized as member states of the European Union. There are twenty-five (25) such member states

as of the Effective Date, namely: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Finland, France, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

1.23 "Exclusive Field" means, with respect to Roche, Roche's Exclusive Field and, with respect to PDL, PDL's Exclusive Field.

1.24 "Executive Officers" means, for Roche, the Head of the Roche Pharma Division (or such individual's designee), and, for PDL, the Chief Executive Officer of PDL (or such individual's designee). If either position is vacant or either position does not exist, then the person having the most nearly equivalent position (or such individual's designee) shall be deemed to be the Executive Officer of the relevant Party.

1.25 "Failure to Supply" shall have the meaning set forth in Section 8.2.

1.26 "FDA" means the U.S. Food and Drug Administration or any successor agency thereto.

1.27 "First Commercial Sale" means, for each Licensed Product in each country, the first sale to a Third Party of the Licensed Product in the Asthma Field in the country by a Party, its Affiliate, or its sublicensee, after the granting by the relevant governing authorities of all Regulatory Approvals required for commercial sale of the Licensed Product in the Asthma Field in such country.

1.28 "FTE" means the equivalent of one employee working full time in a Development-related capacity, for or on behalf of a Party for one 12-month period.

1.29 "Generic Product" means a Third Party product (a) that contains Daclizumab or an antibody with a substantially identical amino acid sequence, whether or not the glycosylation pattern of such antibody is identical to Daclizumab; and (b) that has received Regulatory Approval for use in the Asthma Field through an expedited regulatory approval process governing approval of generic biologics. Notwithstanding

the foregoing, Generic Products do not include Licensed Products sold by either Party's sublicensees or distributors pursuant to this Agreement or the Worldwide Daclizumab Agreement or otherwise sold for use outside of the Asthma Field.

1.30 "Global Net Sales" means PDL Net Sales plus Roche Net Sales.

1.31 "Gross Margin" means, with respect to a particular calendar quarter during the Co-Promotion Term, PDL Adjusted Gross Sales for such quarter minus COGS for Licensed Products sold in the U.S. Territory during such quarter.

1.32 "Incremental Development Expenses" means the expenses incurred by Roche or for its account that are attributable to Development performed solely in support of Regulatory Approval with respect to the ROW Territory and that were not requested by the JDC to support Regulatory Approval with respect to the U.S. Territory or the European Union. Such expenses shall include the transfer price paid by Roche, pursuant to Section 8.1(c), for Licensed Product supplied by PDL for such Development.

1.33 "Information" means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, physical, biological, chemical, biochemical, toxicological, clinical and veterinary test data, analytical and quality control data, stability data, studies and procedures, dosage regimens and control assays, financial information, procurement requirements, purchasing information, manufacturing information, customer lists, business and contractual relationships, business forecasts, sales and merchandising information, marketing plans, and patent and other legal information or descriptions.

1.34 "Joint Development Committee" or **"JDC"** shall have the meaning set forth in Section 3.6.

1.35 "Joint Finance Committee" or **"JFC"** means that subcommittee of the JSC established pursuant to Section 3.3(g).

1.36 "Joint Inventions" means any inventions:

(a) related to humanized or chimeric antibodies that bind to IL-2R, whether patented or not, that are jointly made during the period beginning on January 31, 1989 and continuing until the Effective Date by at least one (1) PDL employee or person contractually required to assign or license patent rights covering such inventions to PDL and at least one (1) Roche employee or person contractually required to assign or license patent rights covering such inventions to Roche; or

(b) related to antibodies that bind to IL-2R, whether patented or not, that are jointly made during the period beginning on the Effective Date and continuing until the expiration or termination of this Agreement by at least one (1) PDL employee or person contractually required to assign or license patent rights covering such inventions to PDL and at least one (1) Roche employee or person contractually required to assign or license patent rights covering such inventions to Roche.

1.37 "Joint Patent Committee" or **"JPC"** means that subcommittee of the JSC established pursuant to Section 3.3(f).

1.38 "Joint Roche-PDL Patents" means all patent applications and patents claiming Joint Inventions.

1.39 "Joint Steering Committee" or **"JSC"** shall have the meaning set forth in Section 3.1.

1.40 "Know-How" means all inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results related to antibodies that bind to IL-2R, and improvements thereon, including any information regarding the physical, chemical, biological, toxicological, pharmacological, clinical, and veterinary data, dosage regimens, control assays and specifications of Licensed Products.

1.41 "Licensed Product" shall mean any pharmaceutical product having as an active ingredient Daclizumab.

1.42 "**Major Pharmaceutical Company**" shall mean any entity that, together with its Affiliates, has annual worldwide pharmaceutical sales of **[*]** or more for the last full fiscal year preceding the date of consummation of a Change of Control.

1.43 "Major Regulatory Jurisdiction" means the U.S., the United Kingdom, France, Italy, Germany, Spain and Japan.

1.44 "Non-Registrational Trial" means a clinical trial in the Asthma Field for a Licensed Product that (a) is initiated or ongoing after completion of the first Phase III Trial, and (b) is not conducted to obtain, maintain or expand Regulatory Approval of the Licensed Product in the Asthma Field. A Non-Registrational Trial shall be deemed initiated upon the enrollment of the first patient.

1.45 "Operating Expenses" shall have the meaning set forth in Exhibit A.

1.46 "Other Indications" means all indications other than Transplant Indications and Autoimmune Indications.

1.47 "Party" means PDL or Roche individually, and **"Parties"** means PDL and Roche collectively.

1.48 "PDL Adjusted Gross Sales" means the gross invoice price of Licensed Products sold or otherwise disposed of for consideration in the U.S. Territory by PDL, its Affiliates or sublicensees (other than Roche and its Affiliates hereunder) to independent Third Parties (not Affiliates of the seller) for use in the Asthma Field, reduced by the following amounts: (a) the amounts actually allowed as volume or quantity discounts, rebates, price reductions, or returns (including withdrawals and recalls); and (b) sales, excise and turnover taxes imposed directly on and actually paid by PDL, its Affiliates or sublicensees.

In the case of the sale by PDL, its Affiliates or sublicensees (other than Roche and its Affiliates hereunder) in the Asthma Field in the U.S. Territory of Combination Products for which a Licensed Product and each of the other therapeutically active ingredients contained in the Combination Product have established market prices when sold separately, PDL Adjusted Gross Sales shall be determined by multiplying the PDL Adjusted Gross Sales for each such Combination Product by a fraction, the numerator of which shall be the established market price for the form and formulation of the Licensed Product contained in the Combination Product, and the denominator of which shall be the sum of the established market prices for such form and formulation of the Licensed Product plus the other active ingredients contained in the Combination Product. When such separate market prices are not established, then the Parties shall negotiate in good faith to determine the method of calculating PDL Adjusted Gross Sales for such Combination Product.

If PDL or its Affiliates or sublicensees receive non-cash consideration for Licensed Products sold or otherwise transferred to an independent Third Party (not an Affiliate of the seller or transferor), the fair market value of such non-cash consideration on the date of the transfer will be the gross invoice price that PDL currently charges independent Third Parties and shall be deemed the PDL Adjusted Gross Sales for such Licensed Products sold or otherwise transferred.

1.49 "PDL House Marks" means the corporate name of PDL and associated logos and designs.

1.50 "PDL Inventions" means all inventions made during the term of this Agreement by employees of PDL or persons contractually required to assign or license patent rights covering such inventions to PDL, either alone or together with Third Parties, that (a) are not PDL Know-How or PDL Patents and (b) relate to Licensed Products or antibodies that bind to IL-2R.

1.51 "PDL Know-How" means, except as otherwise set forth in this Section 1.51, all Know-How that is possessed, as of the Effective Date, by PDL or by any entity

that is a PDL Affiliate as of the Effective Date, or that is developed during the term of this Agreement by PDL or by any entity while it is a PDL Affiliate, and which Know-How is Controlled by PDL or its Affiliates and is reasonably required or useful for seeking registration of, using or selling Licensed Products in the Asthma Field; provided, however, that PDL Know-How excludes any know-how of any kind concerning generic methods of manufacturing, designing, developing or preparing antibodies including, but not limited to, methods of humanizing antibodies, methods of reducing the immunogenicity of antibodies, and methods of increasing the affinity of antibodies.

1.52 "PDL Net Sales" means the amount determined by deducting **[*]** from PDL Adjusted Gross Sales to account for standard deductions from gross sales such as shipping, insurance, taxes (to the extent not included in calculations of PDL Adjusted Gross Sales).

1.53 "PDL Patents" means all patent applications owned or Controlled by PDL or its Affiliates alone or with a Third Party (**"Sole PDL Patents"**) and all Joint Roche-PDL Patents claiming Licensed Products or their manufacture or use in the Asthma Field, which are filed prior to or during the term of this Agreement in the U.S. or any foreign jurisdiction, including any addition, continuation, continuation-in-part or division thereof or any substitute application therefor; any patent issued with respect to such patent application, any reissue, extension or patent term extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; and any other U.S. or foreign patent or inventor's certificate covering Licensed Products in the Asthma Field.

1.54 "PDL Technology" means PDL Know-How and PDL Patents.

1.55 "PDL Trademarks" means all trademarks owned by PDL (except for any PDL House Marks or trade names) and used by PDL or its sublicensee(s) in connection with the marketing, promotion, and sale of Licensed Products in the Asthma Field and all trademark registrations and applications therefor, and all goodwill associated therewith. Prior to any assignment of the Zenapax Trademark to PDL pursuant to the

Worldwide Daclizumab Agreement, the PDL Trademarks shall not include the Zenapax Trademark. If the Zenapax Trademark is assigned to PDL pursuant to the Worldwide Daclizumab Agreement, then the term "PDL Trademarks" shall also include the trademark "Zenapax®," and all trademark registrations and applications therefor, and all goodwill associated therewith.

1.56 "PDL's Exclusive Field" means the Autoimmune Indications (excluding the Asthma Field), Other Indications and, upon the first to occur of the Reversion Effective Date or the Put Right Effective Date, the Transplant Indications.

1.57 "Phase III Trial" means a human clinical trial in the Asthma Field performed to gain evidence of the efficacy of a Licensed Product in a target population, and to obtain expanded evidence of safety for such Licensed Product that is needed to evaluate the overall benefit-risk relationship of such Licensed Product and provide an adequate basis for physician labeling, as described in 21 CFR 312.21(c). For the purposes of Section 9.2, a Phase III Trial shall be deemed initiated upon the dosing of the first patient.

1.58 "Phase IV Trial" means a clinical trial in the Asthma Field for a Licensed Product that (a) is initiated or ongoing after completion of the first Phase III Trial and (b) is not a Non-Registrational Trial. A Phase IV Trial shall be deemed initiated upon the enrollment of the first patient.

1.59 "Post-Launch Product R&D Expenses" shall have the meaning set forth in Exhibit A.

1.60 "Promotion" or **"Promote"** shall mean the marketing and advertising of a Licensed Product in the Asthma Field in the U.S. Territory in accordance with the Commercialization Plan, including medical education, information and communication, market development and medical liaison activities, but not including Detailing.

1.61 "Put Right Effective Date" shall have the meaning set forth in Section 5.3(a) of the Worldwide Daclizumab Agreement.

1.62 "Queen Patents" means those PDL Patents claiming priority under 35 U.S.C. § 120 to U.S. Patent Application Serial No. 07/290,975, filed December 28, 1988.

1.63 "Region" shall mean each region set forth in Exhibit G, provided that such Exhibit may be modified by Roche with PDL's written consent, such consent not to be unreasonably withheld, if Roche modifies the regions that it uses to generally manage its pharmaceuticals business.

1.64 "Regulatory Approval" means all approvals (including pricing and reimbursement approvals), product and/or establishment licenses, registrations or authorizations of any regional, federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the manufacture, use, storage, import, export, transport or sale of Licensed Products in the Asthma Field in a regulatory jurisdiction.

1.65 "Reversion Effective Date" shall have the meaning set forth in Section 5.2(b) of the Worldwide Daclizumab Agreement.

1.66 "Roche Adjusted Gross Sales" means the gross invoice price of Licensed Products sold or otherwise disposed of for consideration in the ROW Territory by Roche, its Affiliates or sublicensees (other than PDL and its Affiliates hereunder) to independent Third Parties (not Affiliates of the seller) for use in the Asthma Field, reduced by the following amounts: (a) the amounts actually allowed as volume or quantity discounts, rebates, price reductions, returns (including withdrawals and recalls); and (b) sales, excise and turnover taxes imposed directly on and actually paid by Roche, its Affiliates or sublicensees.

When calculating the Roche Adjusted Gross Sales, the amount of such sales in foreign currencies shall be converted into Dollars at the average rate of exchange at the time for the applicable calendar quarter in accordance with Roche's then-current standard practices. Roche shall provide reasonable documentation of the calculation

and reconciliation of the conversion figures on a country-by-country basis as part of its report of Roche Adjusted Gross Sales for the period covered under the report.

In the case of the sale by Roche, its Affiliates or sublicensees (other than PDL and its Affiliates hereunder) in the Asthma Field in the ROW Territory of Combination Products for which a Licensed Product and each of the other therapeutically active ingredients contained in the Combination Product have established market prices when sold separately, Roche Adjusted Gross Sales shall be determined by multiplying the Roche Adjusted Gross Sales for each such Combination Product by a fraction, the numerator of which shall be the established market price for the form and formulation of the Licensed Product contained in the Combination Product, and the denominator of which shall be the sum of the established market prices for such form and formulation of the Licensed Product plus the other active ingredients contained in the Combination Product. When such separate market prices are not established, then the Parties shall negotiate in good faith to determine the method of calculating Roche Adjusted Gross Sales for such Combination Product.

If Roche or its Affiliates or sublicensees receive non-cash consideration for Licensed Products sold or otherwise transferred to an independent Third Party (not an Affiliate of the seller or transferor), the fair market value of such non-cash consideration on the date of the transfer will be the gross invoice price that Roche currently charges independent Third Parties and shall be deemed the Roche Adjusted Gross Sales for such Licensed Products sold or otherwise transferred.

1.67 "Roche Fill/Finish Costs" shall have the meaning set forth in Section 8.3(a).

1.68 "Roche Know-How" means, except as otherwise set forth in this Section 1.68, all Know-How that is possessed, as of the Effective Date, by Roche or by any entity that is a Roche Affiliate as of the Effective Date, or that is developed during the term of this Agreement by Roche or by any entity while it is a Roche Affiliate, and which Know-How is Controlled by Roche or its Affiliates and is reasonably required or useful

for seeking registration of, manufacturing, using or selling the Licensed Products; provided, however, that Roche Know-How excludes any Know-How of any kind concerning generic methods of manufacturing, designing, developing or preparing antibodies including, but not limited to, methods of humanizing antibodies, methods of reducing the immunogenicity of antibodies, and methods of increasing the affinity of antibodies.

1.69 "Roche Net Sales" means the amount determined by deducting **[*]** from Roche Adjusted Gross Sales to account for standard deductions from gross sales such as shipping, insurance, taxes (to the extent not included in calculations of Roche Adjusted Gross Sales).

1.70 "Roche Patents" means all patent applications owned or Controlled by Roche or its Affiliates (**"Sole Roche Patents"**) alone or with a Third Party, and all Joint Roche-PDL Patents claiming Licensed Products or their manufacture or use in the Asthma Field, which are filed prior to or during the term of this Agreement in the U.S. or any foreign jurisdiction, including any addition, continuation, continuation-in-part or division thereof or any substitute application therefor; any patent issued with respect to such patent application, any reissue, extension or patent term extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; and any other U.S. or foreign patent or inventor's certificate covering Licensed Products in the Asthma Field.

1.71 "Roche Technology" means Roche Know-How and Roche Patents.

1.72 "Roche's Exclusive Field" means the Transplant Indications. Notwithstanding the foregoing, upon the first to occur of the Reversion Effective Date or the Put Right Effective Date, the term "Roche's Exclusive Field" shall have no meaning.

1.73 "ROW Commercialization Activities" has the meaning set forth in Section 7.1.

1.74 "ROW Territory" means all parts of the Territory not included in the U.S. Territory.

1.75 "[*] Daclizumab" means a **[*]** humanized murine monoclonal antibody prepared against the p55 component of IL-2R **[*]** and covered by claims under **[*]**

1.76 "Sole PDL Patents" shall have the meaning set forth in Section 1.53.

1.77 "Sole Roche Patents" shall have the meaning set forth in Section 1.70.

1.78 "Successful GMP Audit" shall have the meaning set forth in Exhibit B.

1.79 "Territory" means all countries of the world.

1.80 "Third Party" means any person or entity other than a Party or its Affiliates.

1.81 "Third Party License" means (a) any of the license agreements set forth on Exhibit C and (b) any license agreement entered into by a Party with a Third Party after the Effective Date that the Parties agree in writing is necessary for the use, manufacture, sale, offering for sale, or importation of Licensed Product in the Asthma Field in the Territory under this Agreement.

1.82 "Transfer Price" means, with respect to a particular unit of Licensed Product, the amount paid by Roche to PDL for supply of such unit of Licensed Product pursuant to the Commercial Supply Agreement in either bulk or finished form.

1.83 "Transplant Indications" means all indications that involve the suppression of rejection of transplanted organs, bone marrow or other tissue, including, without limitation, solid organ transplantation (including tolerance induction and xenotransplantation), bone marrow transplantation, graft versus host disease and cell transplantation. In any event, if a given indication satisfies the criteria for both an Autoimmune Indication and a Transplant Indication, such indication shall be deemed a Transplant Indication and not an Autoimmune Indication, provided that an Autoimmune

Indication shall not be deemed a Transplant Indication merely because it may cause the need for a transplant (e.g., Type I diabetes, even if it causes the need for an organ transplant).

1.84 "U.S." means the United States of America.

1.85 "U.S. Territory" means the U.S. and its territories and possessions.

1.86 "Valid Claim" means a claim in any unexpired and issued patent in the PDL Patents or Roche Patents that has not been disclaimed, revoked, or held invalid or unenforceable by a final unappealable decision of a court or government agency of competent jurisdiction.

1.87 "Zenapax Trademark" means the trademark "Zenapax®," and all trademark registrations and applications therefor, and all goodwill associated therewith. If the Zenapax Trademark is assigned to PDL pursuant to the Worldwide Daclizumab Agreement, then the license set forth in Section 2.2(c) shall automatically terminate.

ARTICLE 2

LICENSES AND OPTION

2.1 Grants to Roche.

(a) U.S. Territory

(i) Technology License. Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche a co-exclusive license (together with PDL), under the PDL Technology, to develop Licensed Products in the Asthma Field with respect to the U.S. Territory and the European Union, in accordance with the Development Plan, and to import and use Licensed Products for such purposes. The foregoing licenses include the right to perform Development outside the U.S. Territory

and European Union in accordance with the Development Plan with respect to any Licensed Product solely in order to obtain Regulatory Approval of such Licensed Product in the Asthma Field in the U.S. Territory or the European Union.

(ii) Promotion Right. Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche a co-exclusive (together with PDL), non-transferable (subject to Section 19.1) right to Promote and Detail Licensed Products in the Asthma Field in the U.S. Territory during the Co-Promotion Term, in accordance with applicable law and the Commercialization Plan.

(iii) Sublicenses. The rights granted to Roche in Sections 2.1(a)(i) and 2.1(a)(ii) are sublicensable, without the prior written consent of PDL, only to Roche's Affiliates.

(b) ROW Territory

(i) Technology License. Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche and Roche's Affiliates the exclusive (even as to PDL) license, under the PDL Technology, to (1) develop Licensed Products in the Asthma Field in the ROW Territory (other than the European Union), (2) to use and import Licensed Products in the Asthma Field in the ROW Territory (other than the European Union) for such Development purposes, (3) offer for sale and sell Licensed Products in the Asthma Field in the ROW Territory, (4) to use and import Licensed Products in the Asthma Field in the ROW Territory for such commercialization purposes; provided, however, that the license granted under this Section 2.1(b)(i) with respect to the Queen Patents shall be nonexclusive. Notwithstanding the exclusivity of the foregoing license, PDL retains the right to perform Development activities in the ROW Territory (other than the European Union) with respect to the Licensed Product solely in order to obtain Regulatory Approval of the Licensed Product in the Asthma Field in the U.S. Territory or the European Union, in accordance with the Development Plan or as approved by the JSC.

(ii) Trademark License. Subject to the terms and conditions of this Agreement, PDL hereby grants to Roche, the exclusive right and license to use the PDL Trademarks solely in connection with the development, use, marketing, promotion, detailing, offer for sale and sale of Licensed Products in the Asthma Field in the ROW Territory; provided, however, that Roche's license under this Section 2.1(b)(ii) shall be co-exclusive (together with PDL) with respect to Development in the European Union. PDL agrees to execute any required documents, to provide on request any required records, and otherwise to cooperate fully with Roche as may be necessary to accomplish the recordation of the license set forth in this Section 2.1(b)(ii) in any jurisdiction in the ROW Territory that Roche seeks such recordation. In such event, the documented expenses for recordation (not including any PDL internal costs) will be borne by Roche.

(iii) Sublicenses. The licenses granted to Roche in Sections 2.1(b)(i) and 2.1(b)(ii) are sublicensable only with the prior written consent of PDL, which shall not be unreasonably withheld. It shall be deemed reasonable for PDL to withhold consent with respect to sublicense by Roche of the license set forth in Section 2.1(b)(i) to any other entity that is **[*]** (in at least one **[*]**, **[*]** in a **[*]** any **[*]** for **[*]** or any other **[*]** in the **[*]** for which the Parties are selling, developing or planning to develop the Licensed Product, where the term **[*]** means a **[*]** performed to gain **[*]**, and to establish **[*]**. Roche and its Affiliates may use Third Party distributors in the ROW Territory in accordance with their customary practices. The license granted to Roche in Section 2.1(b)(ii) is sublicensable only to a sublicensee of the licenses set forth in Section 2.1(b)(i).

2.2 Grants to PDL.

(a) Technology License. Subject to the terms and conditions of this Agreement, Roche hereby grants to PDL, under the Roche Technology, Collaboration Inventions, and all patents claiming Collaboration Inventions, (i) a co-exclusive license (together with Roche) to develop in accordance with the Development Plan and use

Licensed Products in the Asthma Field with respect to U.S. Territory and the European Union, (ii) a co-exclusive license (together with Roche) to import Licensed Products in the Asthma Field into the European Union for such Development purposes, (iii) an exclusive license to import, offer for sale and sell Licensed Products in the Asthma Field in the U.S. Territory, and (iv) an exclusive license to make Licensed Products in the Asthma Field in the Territory. The foregoing licenses include the right to perform Development outside the U.S. Territory and the European Union in accordance with the Development Plan with respect to any Licensed Product solely in order to obtain Regulatory Approval of such Licensed Product in the Asthma Field in the U.S. Territory or the European Union. The license granted to PDL in Section 2.2(a)(i) shall automatically convert from a co-exclusive license to an exclusive license with respect to the U.S. Territory at the end of the Co-Promotion Term. Roche hereby covenants that it and its Affiliates will not grant to any Third Party a license that overlaps with the scope of the licenses granted to PDL under Sections 2.2(a)(i) and 2.2(a)(ii) and that it and its Affiliates will not practice the Roche Technology and Collaboration Inventions within the scope of the licenses granted to PDL under Sections 2.2(a)(i) and 2.2(a)(ii) on behalf of or for the benefit of any Third Party.

(b) Additional Licenses to Collaboration Inventions. Subject to the terms and conditions of this Agreement, Roche hereby grants to PDL, under the Collaboration Inventions and all patents claiming Collaboration Inventions (i) a co-exclusive license to develop, make, use, import, offer for sale and sell products (other than Licensed Products or Excluded Products) containing antibodies that bind to IL-2R in the Asthma Field in the Territory; and (ii) a co-exclusive license to develop, make, use, import, offer for sale, and sell Licensed Products and other products containing antibodies that bind to IL-2R

(other than Excluded Products) in PDL's Exclusive Field in the Territory. For the purpose of this Section 2.2(b), the term **"Excluded Products"** shall have the meaning given to such term in Section 1.16 of the Worldwide Daclizumab Agreement. Roche hereby covenants that it and its Affiliates will not grant to any Third Party a license that overlaps with the scope of the licenses granted to PDL under Section 2.2(b)(i) and Section 2.2(b)(ii) and that it and its Affiliates will not practice the

Collaboration Inventions within the scope of the licenses granted to PDL under Sections 2.2(b)(i) and 2.2(b)(ii) on behalf of or for the benefit of any Third Party.

(c) Trademark License. Subject to the terms and conditions of this Agreement, Roche hereby grants to PDL, (i) the co-exclusive right and license (together with Roche) to use the Zenapax Trademark solely in connection with the development, use, marketing, promotion, and detailing of Licensed Products in the Asthma Field in the U.S. Territory, (ii) the co-exclusive right and license (together with Roche) to use the Zenapax Trademark solely in connection with the development of Licensed Products in the Asthma Field with respect to the European Union, and (iii) the exclusive right and license to use the Zenapax Trademark solely in connection with the offer for sale and sale of Licensed Products in the Asthma Field in the U.S. Territory. Roche agrees to execute any required documents, to provide on request any required records, and otherwise to cooperate fully with PDL as may be necessary to accomplish the recordation of the license set forth in this Section 2.2(c) in any jurisdiction in the U.S. Territory that PDL seeks such recordation. In such event, the expenses for recordation (not including any internal Roche expenses) will be borne by PDL. The license set forth in this Section 2.2(c) shall automatically terminate upon assignment of the Zenapax Trademark to PDL pursuant to the Worldwide Daclizumab Agreement. Subject to the preceding sentence, the license granted to PDL in Section 2.2(c)(i) shall automatically convert from a co-exclusive license to an exclusive license at the end of the Co-Promotion Term. Roche hereby covenants that it and its Affiliates will not grant to any Third Party a license that overlaps with the scope of the licenses granted to PDL under Sections 2.2(c)(i) and 2.2(c)(ii).

(d) Sublicenses. Prior to the end of the Co-Promotion Term, the license granted to PDL in Section 2.2(a) is sublicensable: (i) without the prior written consent of Roche, only to PDL's Affiliates; and (ii) with Roche's consent (such consent not to be unreasonably withheld) to subcontractors performing, on behalf of PDL, PDL's obligations under, and consistent with, the Development Plan or the Commercialization Plan. After the Co-Promotion Term, PDL may grant sublicenses under the license

granted to PDL in Section 2.2(a) without the consent of Roche. PDL may grant sublicenses under the license granted to PDL in Section 2.2(b) without the consent of Roche. The license granted to PDL in Section 2.2(c) is sublicensable only to a sublicensee of the licenses set forth in Section 2.2(a).

2.3 Negative Covenants

(a) Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to knowingly use or practice, directly or indirectly, any PDL Know-How, PDL Patents or PDL Trademarks for any other purposes other than those expressly permitted by this Agreement or any other written agreements between the Parties which are currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties; or

(b) PDL hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to: knowingly use or practice, directly or indirectly, any Roche Know-How, Roche Patents, Collaboration Inventions or Zenapax Trademark for any other purposes other than those expressly permitted by this Agreement or any other written agreements between the Parties which are currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties.

2.4 [*] Daclizumab. For the purpose of keeping Roche informed as to the status and results of any **[*]** involving **[*]** Daclizumab, PDL's presentation of an update on such matters shall be specifically listed as an agenda item for up to two (2) JDC meetings per year. When PDL first obtains **[*]** in the Asthma Field from a **[*]** for a product containing **[*]** Daclizumab, PDL shall notify Roche in writing and provide a detailed summary of such data to Roche. Upon Roche's request, Roche may **[*]** on **[*]** Daclizumab in the Asthma Field for up to **[*]**, and PDL shall reasonably cooperate with Roche with respect to such **[*]** activities. Upon Roche's further request, PDL and Roche shall **[*]**. If the Parties do not **[*]**, then PDL is **[*]**, provided that PDL does not **[*]** with respect to the **[*]** of such **[*]**. If Roche has previously provided **[*]** to PDL to **[*]** and the

Parties have not **[*]**, then within **[*]** of **[*]**, PDL shall **[*]**. Roche shall have **[*]** following receipt to notify PDL **[*]** that **[*]** For clarity, PDL shall not **[*]** until the earlier of: (i) expiration of the **[*]** period after Roche's receipt of PDL's summary of **[*]**, without Roche **[*]**, and (ii) expiration of the **[*]** after Roche's receipt of such summary, without **[*]** in the **[*]**.

ARTICLE 3

GOVERNANCE

3.1 Joint Steering Committee; Minutes. Within thirty (30) days after the Effective Date, PDL and Roche shall form a Joint Steering Committee (**"JSC"**) consisting of **[*]** representatives from PDL and **[*]** representatives from Roche. Each Party may replace its JSC representatives at any time upon prior written notice to the other Party. Roche shall have the right to designate the first chairperson of the JSC, whose term shall run until December 31, 2005, and such right shall thereafter alternate between the Parties on a calendar year basis. The JSC chairperson shall be responsible for providing an agenda for each JSC meeting at least ten (10) business days in advance of such meeting. The Party not chairing the JSC shall prepare written draft minutes of all JSC meetings in reasonable detail and distribute such draft minutes to all members of the JSC for comment and review within twenty (20) business days after the relevant meeting. The members of the JSC shall have ten (10) business days to provide comments. The Party preparing the minutes shall

incorporate timely received comments and distribute revised minutes to all members of the JSC for their final review and approval within thirty-five (35) business days of the relevant meeting.

3.2 Meetings of the JSC. The JSC shall meet at least **[*]**, on such dates and at such times as agreed to by Roche and PDL, with all scheduled in-person meetings to alternate between Fremont, California and a Roche site to be designated by Roche prior to such meeting, or at such other locations as determined by the Joint Steering

Committee. Meetings may be held by audio or video conference with the consent of each Party, provided that at least **[*]** per calendar year shall be held in person. Each Party may permit such visitors to attend meetings of the Joint Steering Committee. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating.

3.3 Responsibilities of the JSC. The JSC shall have the responsibility and authority to:

(a) define and oversee the implementation of the strategy for developing and commercializing Licensed Products in the Asthma Field;

(b) review the efforts of the JDC in the conduct of the development and commercialization programs for Licensed Products in the Asthma Field;

(c) review and revise, as required, the budget forecasts for the Development Plan and the Commercialization Plan, including any **[*]** with respect to **[*]**, all in accordance with the schedule set forth in Exhibit A.

(d) review and approve the Commercialization Plan and any proposed amendments or updates to the Development Plan or Commercialization Plan;

(e) review and approve the **[*]** and **[*]** of the **[*]** for Licensed Products in the Asthma Field, and the commercialization of Licensed Products in the Asthma Field in the U.S. Territory; and review the commercialization of Licensed Products in the Asthma Field in the ROW Territory, including the **[*]** of such **[*]** and such **[*]** and the **[*]** of the Licensed Products in the Asthma Field;

(f) create and oversee a Joint Patent Committee which will address intellectual property issues with respect to Licensed Products in the Asthma Field;

(g) create and oversee a Joint Finance Committee which will address **[*]** and related finance and accounting issues with respect to the Development Plan and Commercialization Plan;

(h) address disputes or disagreements arising in the JDC, JPC, or JFC;

(i) relax any deadlines and timeframes specified in this Article 3;

(j) select a Trademark in accordance with Section 13.1; and

(k) perform such other functions as the Parties may agree in writing.

3.4 Areas Outside the JSC's Authority. The JSC shall have no authority other than that expressly set forth in Section 3.3 and, specifically, shall have no authority to amend this Agreement. The JSC shall have no authority to make any decisions that would commit a Party to incur an expense that it had not previously agreed to incur or that would increase any expenses a Party is otherwise responsible for, without obtaining the agreement of that Party as evidenced by written notice of approval by the appropriate internal decision-making bodies of that Party. For clarity, each Party, by its entry into this Agreement, has agreed to pay **[*]** of those expenses, to the extent incurred, that are set forth in the budget associated with the Development Plan attached hereto as Exhibit D as of the Effective Date.

3.5 JSC Decisions.

(a) Consensus; Good Faith; Action Without Meeting. The JSC shall decide all matters by **[*]**, with each Party having **[*]**. Consistent with Section 3.12, the members of the JSC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the JSC. Action that may be taken at a meeting of the Joint Steering Committee also may be taken without a meeting if a written consent setting forth the action so taken is signed by all members of the Joint Steering Committee.

(b) Failure to Reach Consensus. In the event that the members of the JSC cannot come to consensus within thirty (30) days with respect to any matter over which the JSC has authority and responsibility, the JSC shall submit the respective positions of the Parties with respect to such matter for discussion in good faith by the **[*]**. If such **[*]** are not able to mutually agree upon the resolution to such matter within **[*]** of its submission to them, then PDL shall have the right to decide such matter in good faith, giving due consideration to the input of **[*]** and the economic interests of both Parties under this Agreement, except that any decision that primarily pertains to (i) the sale and marketing of Licensed Products in the Asthma Field in the ROW Territory, (ii) the Development of Licensed Products in the Asthma Field **[*]** that are not **[*]**, or (iii) the determination of a revised anticipated commercial launch date for the purpose of **[*]**, shall be decided by **[*]** in good faith, giving due consideration to the input of **[*]** and the economic interests of both Parties under this Agreement. Notwithstanding the foregoing, any decision to initiate a development program for **[*]** for Licensed Products in the Asthma Field or

[*] shall be made solely by **[*]**, and **[*]** shall have the right to make such decision if the JSC and the Executive Officers fail to reach agreement. Furthermore, nothing in this Section 3.5(b) shall be interpreted to limit Roche's rights under Section 17.3 as a result of a delay in Development.

3.6 Joint Development Committee; Minutes. Within thirty (30) days after the Effective Date, PDL and Roche shall form a Joint Development Committee (**"JDC"**) consisting of **[*]** representatives from PDL and **[*]** representatives from Roche, or such number(s) of representatives as set from time to time by the JSC. Each Party may replace its JDC representatives at any time upon prior written notice to the other Party. **[*]** shall have the right to designate the **[*]** the JDC, whose term shall run until **[*]**, and such right shall thereafter alternate between the Parties on a calendar year basis. The JDC chairperson shall be responsible for providing an agenda for each JDC meeting at least ten (10) business days in advance of such meeting. PDL shall prepare written draft minutes of all JDC meetings in reasonable detail and distribute such draft minutes to all members of the JDC for comment and review within twenty (20) business days after the relevant meeting. The members of the JDC shall have ten (10) business days

to provide comments. PDL shall incorporate timely received comments and distribute revised minutes to all members of the JDC for their final review and approval within thirty-five (35) business days of the relevant meeting.

3.7 Subcommittees. The JDC shall have the right to establish subcommittees, which may include, but will not be limited, to the following: a **[*]** subcommittee, a **[*]** subcommittee, a **[*]** subcommittee, a **[*]** subcommittee, and a **[*]** subcommittee.

3.8 Meetings of the JDC. The JDC shall meet as frequently as members of the Joint Development Committee determine is required (but in no event, less frequently than **[*]** following the Effective Date and **[*]** thereafter), on such dates and at such times as agreed to by Roche and PDL, with all scheduled in-person meetings to alternate between Fremont, California and a Roche site to be designated by Roche prior to such meeting, or at such other locations as determined by the JDC. Meetings may be held by audio or video conference with the consent of each Party, provided that at least **[*]** shall be held in person at locations to which both Parties have mutually consented. Each Party may permit such visitors to attend meetings of the Joint Development Committee as the Joint Development Committee determines. All out-of-pocket expenses incurred by a Party as a result of its participation in the JDC, to the extent not captured in the FTE rate set forth in Section 4.6(b) (which shall only apply to JDC members), shall be borne solely by such Party. Meetings of the JDC shall be effective only if at least **[*]** of each Party are present or participating.

3.9 Responsibilities of the JDC. The JDC shall have the responsibility and authority to:

(a) oversee all aspects of the execution of the JSC-approved Development and commercialization of Licensed Products in the Asthma Field;

(b) review and comment upon, and where appropriate, recommend to the JSC for approval, all updates or amendments to the Development Plan thereto, in accordance with Sections 4.1 and 4.2;

(c) review and comment upon, and where appropriate, recommend to the JSC for approval, the Commercialization Plan and amendments and updates thereto, in accordance with Section 6.1;

(d) monitor the Development of Licensed Products in the Territory against the applicable Development Plan;

(e) review the overall strategy for and design of all clinical trials and other studies conducted under the Development Plan;

(f) discuss the requirements for Regulatory Approval in applicable countries in the Territory and oversee and coordinate regulatory matters with respect to Licensed Products in the Territory;

(g) establish subcommittees pursuant to Section 3.7, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;

(h) oversee and approve a multi-year estimate of supply requirements to be used for capacity planning purposes;

(i) present disputes not resolvable by the JDC to the JSC for resolution;

(j) discuss Roche Development activities in the ROW Territory;

(k) select CROs and other non-manufacturing vendors needed to carry out the Development Plan, except for any CRO or other non-manufacturing vendor whose agreement with the relevant Party has, or is anticipated to have, **[*]**;

(l) propose and discuss possible manufacturing vendors to carry out activities associated with clinical or commercial supply of the Licensed Product (provided that **[*]** alone shall be responsible for ultimately selecting such manufacturing vendors);

(m) perform the functions set forth in Sections 1.14, 4.6(a), 4.6(c), 5.1(a), 5.6, 6.3(b), and 8.1(a) and Exhibits D and E; and

(n) perform such other functions as the Parties may agree in writing.

3.10 Areas Outside the JDC's Authority. The JDC shall have no authority other than that expressly set forth in Section 3.9.

3.11 JDC Decisions.

(a) Consensus; Good Faith; Action Without Meeting. The JDC shall decide all matters by consensus, with each Party having one collective vote. Consistent with Section 3.12, the members of the JDC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the JDC. Action that may be taken at a meeting of the JDC also may be taken without a meeting if a written consent setting forth the action so taken is signed by all of the JDC members.

(b) Failure to Reach Consensus. In the event that the members of the JDC cannot come to consensus within **[*]** with respect to any matter over which the JDC has authority and responsibility, the JDC shall submit the respective positions of the Parties with respect to such matter to the JSC for decision.

3.12 Operating Principles. The Parties hereby acknowledge and agree that the deliberations and decision-making of the JSC, JDC, JPC, JFC and any subcommittee established by the JDC shall be in accordance with the following operating principles:

(a) Time is of the essence in addressing the market for Licensed Products in the Asthma Field.

(b) The Parties' mutual objective is to maximize the clinical and commercial success of the Licensed Products in the Asthma Field, consistent with sound and ethical business and scientific practices.

ARTICLE 4

DEVELOPMENT

4.1 Development Plan. Development with respect to the U.S. Territory and the European Union shall be governed by an asthma development plan (**"Development Plan"**), which shall set forth all anticipated Development activities and timelines for obtaining, maintaining, or expanding (to the extent mutually agreed) Regulatory Approval in such countries or jurisdictions, allocate responsibility for carrying out such activities between PDL and Roche (including the anticipated minimum and maximum number of FTEs to be expended by each Party on Development with respect to the U.S. Territory and the European Union on a quarterly basis), include an associated twelve (12) month development budget, and specify the extent to which each Party is anticipated to use internal or external (i.e. subcontractors) resources to fulfill its obligations. As of the Effective Date, the Parties have agreed to an initial Development Plan, a copy of which is attached hereto as Exhibit D. The Parties anticipate that promptly following the Effective Date and the formation of the JDC and JSC, the JDC shall review in detail the initial Development Plan and propose appropriate revisions, if needed, for adoption by and approval of the JSC.

4.2 Updating the Development Plan. The JDC may decide from time to time to propose for approval by the JSC updates to the Development Plan on a rolling basis as necessary to reflect changes in the progress, strategy, or costs of Development with

respect to the U.S. Territory and the European Union. In any event, so long as the JSC intends to continue Development with respect to the U.S. Territory and the European Union, the JDC shall confirm, or propose for JSC approval an update to, the Development Plan in accordance with the schedule set forth in Exhibit A. Any proposed change shall, for the appropriate time period as determined by the JSC, set forth all anticipated Development activities and timelines for obtaining, maintaining, or expanding (to the extent mutually agreed) Regulatory Approval in such countries or jurisdictions, allocate responsibility for carrying out such activities between PDL and Roche (including a maximum number of FTEs to be expended by each Party on Development with respect to the U.S. Territory and the European Union on a quarterly basis), and include an associated development budget. All mutually agreed activities directed toward the expansion of Regulatory Approval with respect to the U.S. Territory and/or the European Union shall be included in the updated Development Plan. The JSC shall not approve an updated Development Plan that is inconsistent with or contradicts the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail.

4.3 Goals of Joint Development. The Parties hereby acknowledge and agree that the goals for joint development of Licensed Products hereunder will be to obtain and maintain Regulatory Approval for the treatment of asthma for the Licensed Product in the U.S. Territory and the European Union.

4.4 Standards of Conduct. Each Party shall perform, or shall ensure that its Third Party contractors perform, the Development activities for which it is responsible under the Development Plan or which it undertakes independent of the Development Plan in good scientific manner and in compliance with applicable laws, rules and regulations. At each JDC meeting, each Party will keep the JDC fully informed regarding the progress and results of such Party's Development activities with respect to Licensed Products in the Territory.

4.5 Diligent Development. Each of the Parties shall use Diligent Efforts to achieve the goals set forth in Section 4.3 and to execute and carry out the Development Plan within the associated budget. Roche shall use Diligent Efforts to obtain Regulatory Approval for the treatment of asthma for the Licensed Product in each country in the ROW Territory (other than the European Union). Roche's efforts in this regard shall be discussed with PDL through the JDC. Roche from time to time (but in any event no less frequently than yearly) shall provide PDL with written updates discussing in reasonable detail its clinical trial activities and plans with respect to Development for all countries of the ROW Territory outside the European Union for which Roche has current or contemplated activities and plans. Each of the Parties agrees to cooperate with the other in carrying out the Development Plan.

4.6 Development Expenses.

(a) All Development Expenses shall be shared **[*]** by the Parties as set forth in greater detail in Section 4.6(c). **[*]** shall be responsible for **[*]** of all Incremental Development Expenses. Any expenses incurred by a Party for Development activities that do not fall within the definitions of Development Expenses or Incremental Development Expenses shall be borne solely by such Party unless the JDC determines otherwise.

(b) The Development Expenses of each Party that are attributable to Development activities performed by its employees pursuant to the Development Plan shall be calculated on an FTE basis. Each Party shall keep accurate records of its FTEs expended with respect to such Development activities, and shall report such FTE expenditures to the JDC on a quarterly basis as part of the report filed pursuant to Section 4.6(c). All FTE expenditures shall be converted to Development Expenses at an initial rate of **[*]**, subject to **[*]** of **[*]** effective as of **[*]**, beginning **[*]**. There shall be no **[*]** until after the **[*]** of this Agreement.

(c) Each Party shall keep detailed records of the Development Expenses it incurs, including all supporting documentation for such expenses. Each

Party shall keep such records for at least **[*]** after the date that such expense was incurred. Within **[*]** after the end of each calendar quarter, each Party shall provide a report to the JDC (with a copy to the other Party) specifying and documenting, both in reasonable detail, such Party's Development Expenses during such quarter. Each Party shall promptly provide all additional information and documentation requested by the JDC to verify such Development Expenses. Within **[*]** after the end of each such calendar quarter, the JDC shall provide each Party with an accounting in reasonable detail of the Parties' Development Expenses for such quarter and the JDC shall send **[*]** during such quarter an invoice for an amount equal to **[*]**. Such Party shall pay the amount specified in such invoice to the other Party within **[*]** of its receipt of such invoice.

(d) To the extent a Party has previously paid a share of the cost of any item included in Development Expenses (including the cost of manufacturing clinical supply of Licensed Product), then that Party shall receive a credit for the amounts paid in the event that such item is subsequently used for **[*]** or **[*]**.

ARTICLE 5

REGULATORY

5.1 Drug Approval Applications in U.S. Territory.

(a) Consistent with the Development Plan but subject to the remainder of this Section 5.1, PDL shall be responsible for preparing and filing Drug Approval Applications and seeking Regulatory Approvals for Licensed Products in the Asthma Field in the U.S. Territory. All such Drug Approval Applications shall be filed in the name of PDL, and PDL alone shall be responsible for all communications and other dealings with the regulatory agencies relating to the Licensed Products in the Asthma Field in the U.S. Territory. The JDC shall develop and implement procedures for drafting and review of such Drug Approval Applications, which shall provide sufficient time for Roche to provide substantive comments. PDL shall be responsible for

obtaining appropriate regulatory approvals in the U.S. Territory for the manufacture of bulk Licensed Product by PDL or its Third Party manufacturer(s). Roche shall have the right of cross-reference to all such Drug Approval Applications for the purposes set forth in Section 5.2.

(b) After receipt of Regulatory Approval of the Drug Approval Application for the Licensed Product in the Asthma Field in the U.S. Territory hereunder, PDL shall retain primary responsibility for dealings with any regulatory agency with respect thereto, including filing all supplements and other documents with such agency with respect to such Drug Approval Application. Notwithstanding the foregoing, the reporting of all adverse drug experiences and other safety issues relating to Licensed Products shall be handled in accordance with Sections 5.3, 5.5 and 5.6. In the event that any regulatory agency threatens or initiates any action to remove a Licensed Product from the market in the Asthma Field in the U.S. Territory during the Co-Promotion Term, PDL shall notify Roche of such communication within one business day of receipt by PDL. PDL agrees to provide Roche with a copy (which may be wholly or partly in electronic form) of all filings to regulatory agencies with respect to Licensed Products in the Asthma Field in the U.S. Territory that it makes hereunder. PDL shall provide Roche with reasonable advance notice of any scheduled meeting with a regulatory agency relating to Development and/or a Drug Approval Application in the U.S. Territory, and Roche shall have the right to observe and, if the Parties mutually agree in advance, participate in any such meeting. PDL shall promptly furnish Roche with copies of all material correspondence or minutes of material meetings with any regulatory agency in each case relating to Development and/or a Drug Approval Application in the U.S. Territory. As between the Parties, PDL shall be the legal and beneficial owner of all Drug Approval Applications and related approvals in the U.S. Territory.

5.2 Drug Approval Applications in ROW Territory.

(a) Roche shall be responsible for preparing and filing Drug Approval Applications and seeking Regulatory Approvals for Licensed Products in the Asthma Field in the ROW Territory. The Parties intend that such Drug Approval Applications will be comprised of the Drug Approval Application submitted to the FDA, plus such additional data and reports not required to be submitted to the FDA. All such Drug Approval Applications shall be filed in the name of Roche, and Roche alone shall be responsible for all communications and other dealings with the regulatory agencies relating to the Licensed Products in the Asthma Field in the ROW Territory. The JDC shall develop and implement procedures for review of such Drug Approval Applications, which procedures shall be equivalent to those procedures developed pursuant to Section 5.1(a) with respect to Roche's review of Drug Approval Applications for the U.S. Territory and shall provide sufficient time for PDL to provide substantive comments. Roche shall be responsible for obtaining appropriate regulatory approvals in the ROW Territory for the manufacture of bulk Licensed Product by PDL or its Third Party manufacturer(s). PDL shall have the right of cross reference to all such Drug Approval Applications filed in the ROW Territory.

(b) If required to support Regulatory Approvals in the ROW Territory, PDL shall be responsible for providing to Roche, in the format required by the FDA, the data and information required to be submitted to the FDA, and such additional data and information relating to the Development activities for which it was responsible, including all clinical trials performed by it and all manufacturing and controls information.

(c) In connection with all Drug Approval Applications being prosecuted by Roche hereunder, Roche agrees to provide PDL with a copy (which may be wholly or partly in electronic form) of all filings to regulatory agencies in each Major Regulatory Jurisdiction that it makes hereunder. Roche will provide PDL with reasonable advance notice of any scheduled meeting with any regulatory agency relating to Development and/or any Drug Approval Application in the ROW Territory, and PDL shall have the right to observe and, if the Parties mutually agree in advance, participate in any such meeting. Roche also shall promptly furnish PDL with copies of all material

correspondence or minutes of material meetings with any regulatory agency in each case relating to Development and/or a Drug Approval Application in the ROW Territory. Within thirty (30) days following the end of each calendar quarter, Roche shall report to PDL regarding the status of each pending and proposed Drug Approval Application in the ROW Territory. In the event that any regulatory agency threatens or initiates any action to remove such Licensed Product from the market in any country in the Asthma Field in the ROW Territory, Roche shall notify PDL of such communication within one business day of receipt by Roche. As between the Parties, Roche shall be the legal and beneficial owner of all Drug Approval Applications and related approvals in the ROW Territory.

5.3 Adverse Event Reporting. Each Party shall notify the other of all information coming into its possession concerning any and all side effects, injury, toxicity, pregnancy or sensitivity event associated with commercial or clinical uses, studies, investigations or tests with Licensed Products, throughout the world, whether or not determined to be attributable to Licensed Products (**"Adverse Event Reports"**). Pursuant to the Worldwide Daclizumab Agreement, the Parties have already identified a person from each Party to coordinate the exchange of Adverse Event Reports (**"Report Coordinators"**) so as to enable timely reporting of such Adverse Event Reports to appropriate governmental and regulatory authorities consistent with all laws, rules and regulations. The Parties, through their Report Coordinators, have agreed in writing on formal procedures for such exchange, which are embodied in the PDL-Roche Procedure for the Exchange of Licensed Products Adverse Event Reports, dated December 2000 (**"Pharmacovigilance Agreement"**). Promptly after the Effective Date, Roche and PDL agree to cause their respective Report Coordinators to (a) review the Pharmacovigilance Agreement and (b) negotiate in good faith an amendment to the Pharmacovigilance Agreement to reflect the terms of this Agreement, if the Report Coordinators agree that such an amendment is required. Such Pharmacovigilance Agreement (as amended, if applicable) shall survive the end of the Co-Promotion Term.

5.4 Copies of Responses. Within a reasonable time frame prior to submission of responses to any regulatory authority on product safety issues regarding Licensed Products, a copy of a near final draft response will be provided to the other Party for review. Final copies of responses submitted to any regulatory authority will be provided to the other Party within **[*]** of document finalization.

5.5 Regulatory Actions. The Party responsible for interacting with regulators on a specific safety issue regarding Licensed Products must communicate any action requested by regulators to the other Party without delay. Such actions may include, for example, change in label, Dear Doctor letter, trial on hold for clinical safety reasons and the like.

5.6 Other Safety Issues. At the request of either Party, the JDC shall establish a subcommittee to handle the discussion of specific safety issues, advise each Party concerning the collection and evaluation of safety data, and respond to any significant safety issues raised, or requests made, by regulatory authorities. If the Parties have established a Joint Safety Committee pursuant to the Worldwide Daclizumab Agreement, they may agree to have such issues handled by the Joint Safety Committee rather than establishing a separate subcommittee of the JDC to do so.

ARTICLE 6

COMMERCIALIZATION IN U.S. TERRITORY

6.1 Commercialization Plan. During the Co-Promotion Term, all commercialization of Licensed Products in the Asthma Field in the U.S. Territory shall be conducted pursuant to a commercialization plan (the **"Commercialization Plan"**), which shall set forth the anticipated activities (including without limitation market studies, launch plans, Detailing and Promotion) and timelines, shall allocate responsibility for

carrying out such activities between PDL and Roche, and shall include an associated budget. No later than **[*]** after **[*]** for a Licensed Product, and on an annual basis thereafter until the end of the Co-Promotion Term, PDL (or, at the JDC's election, a subcommittee established by the JDC) shall submit to the JDC an initial or updated Commercialization Plan, which the JDC and JSC shall review and the JSC (after consulting with the JDC) shall approve or reject on a timely basis. It is understood that the initial Commercialization Plan may be very preliminary but nevertheless shall be effective for the purposes of commencing the Party's sharing of Operating Expenses. Each updated Commercialization Plan shall include the plan for Detailing and Promotion activities for the Licensed Product in the Asthma Field in the U.S. Territory for the next **[*]** and timelines for performing such activities. Once approved by the JSC, such updated Commercialization Plan shall become effective and supersede the previous Commercialization Plan as of the date of such approval or at such other time decided by the JSC. The JSC shall not approve an updated Commercialization Plan that is inconsistent with or contradicts the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Commercialization Plan and this Agreement, the terms of this Agreement shall prevail.

6.2 Commercialization in the U.S. Territory; Co-Promotion.

(a) PDL will be solely responsible for the booking of sales of Licensed Products in the Asthma Field in the U.S. Territory and the supply and distribution of Licensed Product in respect to such sales. PDL shall determine the U.S. Territory selling price (including volume discounts, rebates, and similar matters), credit terms, and return policies for all formulations of Licensed Products that are sold for use in the Asthma Field but not for use in the Transplant Indications.

(b) During the Co-Promotion Term, PDL and Roche will co-promote Licensed Products in the Asthma Field in the U.S. Territory in accordance with the Commercialization Plan. As part of this co-promotion, PDL shall contribute **[*]** of the Details required by the Commercialization Plan (measured as an average across each

calendar quarter), and Roche shall be responsible for the remaining **[*]** of such Details. Each Party's sales force shall promote the Licensed Product in the U.S. Territory in a manner that reflects such Party's capacities and that is consistent with such Party's promotional efforts for its own products of similar market potential.

(c) During the Co-Promotion Term, Roche and PDL agree to deploy their respective sales forces to Detail Licensed Product in the Asthma Field in the U.S. Territory (i) at such level of effort as is required pursuant to Section 6.2(b) and (ii) in a manner consistent with the Commercialization Plan and applicable law. The Parties shall agree upon a sales calling plan, which plan shall include mechanisms to address possible underperformance and failure to perform Detailing at the agreed upon levels.

(d) Each party agrees to permit its Detailing records to be examined by the other Party for the purpose of verifying each Parties' compliance with the Detailing requirements set forth in this Section 6.2. Such audit shall be performed at the request of either Party, but in any event shall not be performed more frequently than **[*]** per **[*]** nor more frequently than **[*]** with respect to Detailing records covering any specific period of time. The expense of any such examination shall be borne by the auditing Party unless such examination reveals a discrepancy of **[*]** or more in favor of the audited Party, in which case such expense shall be borne by the audited Party.

(e) Following the end of the Co-Promotion Term, PDL shall have sole responsibility and decision-making authority for the Detailing, marketing, Promotion, sale and distribution of Licensed Product in the Asthma Field in the U.S. Territory. Except as explicitly provided in Section 10.2, PDL shall owe Roche no consideration in respect to sales of Licensed Product in the Asthma Field in the U.S. Territory after the end of the Co-Promotion Term. In particular, PDL shall not have any obligation to make the payments specified in Section 7.2(c) of the Worldwide Daclizumab Agreement on account of any sales of Licensed Product for use in the Asthma Field in the U.S. Territory after the end of the Co-Promotion Term.

6.3 Sharing of Operating Expenses

(a) During the Co-Promotion Term, all Operating Expenses shall be shared **[*]**. **[*]** will be solely responsible for **[*]** Sales Force Expenses, unless the sales calling plan specifies otherwise **[*]**.

(b) During the Co-Promotion Term, each Party shall keep detailed records of the Operating Expenses it incurs, including all supporting documentation for such expenses, in accordance with procedures to be agreed upon between the Parties. Each Party shall keep such records for at least **[*]** after the date that such expense was incurred. Within **[*]** after the end of each calendar quarter during the Co-Promotion Term, each Party shall provide a report to the JDC (with a copy to the other Party) specifying and documenting, in reasonable detail, such Party's Operating Expenses during such quarter. Each Party shall promptly provide all additional information and documentation requested by the JDC to verify such Operating Expenses. Within **[*]** after the end of each such calendar quarter, the JDC shall provide each Party with an accounting of the Parties' Operating Expenses for such quarter and the JDC shall send **[*]** during such quarter an invoice for an amount equal to **[*]**. Such Party shall pay the amount specified in such invoice to the other Party within **[*]** of its receipt of such invoice.

(c) For each quarter during the Co-Promotion Term that falls (in whole or in part) in the period commencing on **[*]** in the U.S. Territory and ending on **[*]** in the U.S. Territory, if the budget for such quarter specifies that Operating Expenses will be greater than **[*]** and if **[*]** for such quarter exceed **[*]** for such quarter, then **[*]** an amount equal to **[*]** for such quarter and **[*]** for such quarter, which payment shall be due within **[*]** after **[*]** receipt of a written invoice from **[*]** specifying the amount of such payment. Payments advanced under this Section 6.3(c) shall be credited against any amounts owed by **[*]** under Section 6.3(b) for the quarter with respect to which **[*]**. Within **[*]** following the end of each calendar year to which this Section 6.3(c) applies, **[*]** shall **[*]** any payments **[*]** under this Section 6.3(c) during such calendar year **[*]**.

6.4 Co-Promotion Term. The Parties' co-promotion of the License Products in the U.S. Territory shall commence on the date that the first Operating Expense is incurred by a Party and shall initially continue until **[*]** after the First Commercial Sale of Licensed Product in the Asthma Field in the U.S. Territory, subject to any early termination in the U.S. Territory or the Territory pursuant to Section 17.2, 17.3, 17.4, 17.5 or 17.6. At the end of this initial term and each extension thereof, **[*]** may, at its option, elect to extend the co-promotion for an additional year, provided that **[*]** makes such election in writing to **[*]** no later than **[*]** prior to the end of the initial term or extension term (as the case may be) and provided further that **[*]** for the **[*]** prior to such election **[*]**. The initial term of co-promotion and any extensions thereof (in each case, taking into account any early termination in the U.S. Territory or the Territory pursuant to Section 17.2, 17.3, 17.4, 17.5 or 17.6) shall be referred to herein as the **"Co-Promotion Term."**

6.5 Sales Force Training. During the Co-Promotion Term, each Party's relevant U.S. Territory operating entities shall be responsible for the development and conduct of training programs specifically relating to the co-promoted Licensed Products for the sales representatives of such Party. The Parties agree to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy. The costs of transporting, housing and maintaining personnel of a Party for such training shall be treated as Sales Force Expenses of such Party and shall be borne **[*]** pursuant to Section

6.3(a). The Parties shall establish joint training programs as specified by the JSC and shall share the direct incremental cost of such training **[*]**. Information transmitted pursuant to this Section 6.5 shall be treated as Confidential Information of both Parties.

6.6 Joint U.S. Marketing Subcommittee. The joint U.S. marketing subcommittee of the JDC shall specify in detail each Party's obligations, consistent with Sections 6.1 through 6.5, with respect to Licensed Product Promotion and Detailing in the Asthma Field in the U.S. Territory during the Co-Promotion Term.

6.7 Negative Covenant. Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to **[*]** Licensed Products in the U.S. Territory **[*]**, except as expressly permitted by any other written agreement between the Parties which is currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties.

ARTICLE 7

COMMERCIALIZATION IN ROW TERRITORY

7.1 Commercialization by Roche in ROW Territory. Except as expressly set forth in this Article 7, Roche shall have sole responsibility and decision-making authority for the marketing, promotion, sale and distribution of the Licensed Product in the Asthma Field in the ROW Territory (collectively, the **"ROW Commercialization Activities"**), including post-registration clinical and marketing studies that are not conducted in order to obtain, expand (as mutually agreed with PDL) and/or maintain Regulatory Approval of a Licensed Product in the Asthma Field in the U.S. Territory or European Union. Roche shall be responsible for all costs and expenses associated with the ROW Commercialization Activities. Roche's sales force shall promote the Licensed Product in the ROW Territory in a manner that reflects Roche's capacities and that is consistent with Roche's promotional efforts for its own products of similar market potential.

7.2 Roche Diligence in ROW Territory.

(a) During the term of this Agreement, Roche will provide PDL with its draft plan for Roche's, its Affiliates' and sublicensees' commercialization of the Licensed Products in the Asthma Field in the ROW Territory. PDL shall have the opportunity to comment on such draft plan, and Roche shall take such comments into account when finalizing the plan. Roche shall comply and ensure the compliance of its Affiliates and

sublicensees with such finalized plan. Roche shall provide PDL, upon PDL's request, with reasonable documentation of such compliance.

(b) Roche, directly or through its Affiliates and/or sublicensees, shall use Diligent Efforts to commercialize the Licensed Products in the Asthma Field in each country in the ROW Territory. Roche shall provide PDL, upon PDL's request (such request not to be made more than once per calendar year), with a written summary specifying in reasonable detail, on a country-by-country basis, how it has used such Diligent Efforts.

7.3 Negative Covenant. Roche hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to, **[*]** Licensed Products in the ROW Territory **[*]**, except as expressly permitted by any other written agreement between the Parties which is currently in existence (including, without limitation, the Worldwide Daclizumab Agreement), or which may later be entered into by the Parties.

7.4 [*]. Roche and PDL shall cooperate fully under **[*]** to **[*]** and other **[*]** for the U.S. Territory and the ROW Territory in order to optimize global penetration of the Licensed Product in the Asthma Field.

7.5 [*] In order to most effectively establish a **[*]** for the Licensed Product with the benefit of Roche's experience in the areas of **[*]** the Licensed Product for Transplant Indications, the Parties may participate in discussions regarding the **[*]** of the Licensed Product within and outside the Asthma Field to the extent **[*]**.

7.6 Tracking of Sales. The Parties recognize that (i) pursuant to other agreements between the Parties, each Party has the right, as of the Effective Date, to market Licensed Products for certain mutually exclusive indications outside the Asthma Field; and (ii) Roche currently markets Licensed Products in the Territory under the trademark Zenapax® for the prevention of acute organ rejection in patients receiving kidney transplants. As a result, Licensed Products marketed by PDL and/or Roche now or in the future for indications outside the Asthma Field may nonetheless be sold in the

Asthma Field or in the other Party's Exclusive Field, and Licensed Products marketed by PDL and/or Roche now or in the future for indications in the Asthma Field may nonetheless be sold outside the Asthma Field (collectively, **"Cross-Field Sales"**). In order to detect and limit these Cross-Field Sales of Licensed Products, the Parties agree as follows:

(a) If at any time during the term of this Agreement, a Party, its Affiliate, licensee or sublicensee (the **"Marketing Party"**) has filed in a Major Regulatory Jurisdiction to obtain regulatory approval for or is marketing a Licensed Product for an indication in its Exclusive Field (an **"Exclusive Field Product"**) or in the Asthma Field (an **"Asthma Field Product"**) in a particular territory, and the other Party (the **"Non-Marketing Party"**) believes that (i) sales of an Exclusive Field Product or Asthma Field Product (as the case may be) are occurring or will occur for use in the Exclusive Field of the Non-Marketing Party; or (ii) solely with respect to territories in which the Non-Marketing Party has the right to sell Licensed Product in the Asthma Field, sales of the Exclusive Field Product are occurring or will occur for use in the Asthma Field, then the Non-Marketing Party may provide notice to the Marketing Party of its desire to track sales of the Exclusive Field Product or Asthma Field Product (as the case may be) for the relevant indications in such territory.

(b) Upon receipt of notice under Section 7.6(a), PDL and Roche shall meet and agree upon a method of tracking sales of each such product for use in its respective indications including (i) the acquisition of one or more **[*]** (including, by way of example, **[*]**) or other **[*]** (including, for example, **[*]**) generally recognized in the pharmaceutical industry as having a **[*]** in the tracking of sales of pharmaceutical products that have a similar nature as and are prescribed by similar physicians as such Exclusive Field Product or Asthma Field Product (as the case may be) in the U.S. Territory and, if applicable, outside the U.S. Territory (the **"Data Services"**), and (ii) the methodology for applying any such **[*]** to determine the extent to which sales of the Exclusive Field Product or Asthma Field Product (as the case may be) are Cross-Field Sales in the relevant territory.

(c) All costs associated with the acquisition and application of such **[*]** shall be shared by the Parties **[*]**. In addition, the Parties shall also meet and confer with respect to: (i) how to account for prescriptions to patients with multiple afflictions (e.g. transplant patients with asthma), both within and outside the indications for which the Exclusive Field Product or Asthma Field Product (as the case may be) has received Regulatory Approval; (ii) the right for each Party to audit, on a periodic basis, the application of the **[*]**; and (iii) a mechanism for addressing prescriptions that are tracked back to sole source purchasing agreements.

(d) If in the course of applying the foregoing **[*]** to track sales of the Exclusive Field Product or Asthma Field Product (as the case may be) pursuant to this Section 7.6, or in the course of performing an audit of such application by the other Party, a Party determines that Cross-Field Sales are occurring at **[*]** of annual sales in **[*]**, or **[*]** annually for sales in **[*]**), the Parties shall confer regarding an appropriate method either to curtail such Cross-Field Sales and/or to compensate any affected Party for the economic effects thereof.

(e) In the event of any unresolved issues, dispute or disagreement under this Section 7.6, the Parties will submit such dispute, issue or disagreement for resolution pursuant to Article 18.

7.7 Transplant Indications.

(a) The Parties anticipate that under the Worldwide Daclizumab Agreement, the right to market and sell Daclizumab, which is a Licensed Product, in the Transplant Indications will revert to PDL in **[*]**. Accordingly, the Parties intend to continue to maintain the competitive vitality and value of Daclizumab in the Transplant Indications and to facilitate eventual transfer of such marketing and selling activities to PDL. To that end, the Parties have agreed to further discussions and collaboration regarding the **[*]** Daclizumab (as such term is defined in the Worldwide Daclizumab Agreement) in the Transplant Indications in the U.S. Territory. This collaboration will allow PDL to form a nascent commercial organization before the reversion of

Daclizumab with a view to providing customer and product support in a rapid and effective manner at the time of transfer of ownership to PDL of Daclizumab as provided under the Worldwide Daclizumab Agreement.

(b) The Parties desire to contribute their respective product and marketing expertise to best position Daclizumab competitively. To that end, the Parties agree to establish a process for discussion of the positioning of Daclizumab (as such term is defined in the Worldwide Daclizumab Agreement) in accordance with this Section 7.7. In order to facilitate these discussions, if at any time prior to the earliest of (i) **[*]** or **[*]** and (ii) **[*]**, Roche desires to **[*]** for Daclizumab for the **[*]** in the U.S. Territory, then Roche shall notify PDL immediately in writing and the Parties shall meet in person within a reasonable time period following notification to discuss the **[*]**. Roche shall give due consideration to any recommendations or opinions offered by PDL regarding the impact of the **[*]**. The Parties shall have a period of up to **[*]** to further confer, but Roche shall have the right to effect such **[*]** unless PDL notifies Roche in writing, supported by a **[*]**, of its request for further consideration pursuant to subparagraph (c) below.

(c) If PDL notifies Roche in writing that it wishes further consideration of its views, then the Parties shall refer the matter for discussion by a specially constituted subcommittee of the JDC consisting of **[*]** members from each of PDL and Roche with experience in sales and marketing in the Transplant Indications (the "JDC Special Committee"). The JDC Special Committee shall prepare an analysis of the impact of the **[*]** for Daclizumab on the Licensed Product. The JDC Special Committee shall have access to information and personnel from both Parties reasonably required to prepare its analysis and assessment for review by the full JDC. The analysis shall be prepared as soon as practically feasible, in no event later than **[*]** of the date of notification from Roche hereunder. The full JDC shall consider such analysis and assessment and agree upon a recommendation to the JSC within a reasonable period of time after receipt of such analysis and assessment. Thereafter, the JSC shall review and consider the recommendation of the JDC. If the JSC is unable to agree on the **[*]**,

then the matter shall be submitted for discussion and resolution by **[*]** and **[*]** (the "Officers"). The JSC shall within **[*]** days prepare an executive summary for submission to the Officers. The Officers shall then, within a reasonable period of time, meet to resolve the matter. If the Officers are unable to agree on appropriate resolution within **[*]** thereafter, then **[*]** shall have the sole right to effect the **[*]** for Daclizumab.

(d) The term "**[*]**" in Section 7.7(b) shall mean proposals to: **[*]** in the U.S. Territory; proceed with development of **[*]**; change by more than **[*]** for the U.S. Territory to the **[*]**, other than in response to **[*]** by a **[*]** or in response to **[*]**; use a **[*]** for Daclizumab other than **[*]**; change **[*]** other than in accordance with **[*]** applicable to similar products; or change in **[*]**.

(e) As of the Effective Date, Roche shall have no further diligence obligations in the U.S. Territory under Section 4.6 of the Worldwide Daclizumab Agreement. In addition, the Parties agree to discuss in good faith the possibility of amending the Worldwide Daclizumab Agreement to provide for a Reversion Exercise Fee (as such term is defined in the Worldwide Daclizumab Agreement) that is independent of AAGS (as such term is defined in the Worldwide Daclizumab Agreement).

(f) The Worldwide Daclizumab Agreement shall be deemed to be amended as necessary to give effect to the provisions of this Section 7.7.

ARTICLE 8

MANUFACTURE AND SUPPLY

8.1 Clinical Supply.

(a) With respect to Licensed Product, PDL shall supply the Active Pharmaceutical Ingredient (**"API"**), Investigational Medicinal Product (**"IMP"**), and

placebo for Development purposes in accordance with the Development Plan, which shall set forth appropriate milestones to ensure conformance with the Development Plan. These milestones, in general, will be based on **[*]** to conduct the planned clinical trials in accordance with the projected schedule at each stage in the Development Plan. A milestone based on **[*]** should include the quantities of and specifications for **[*]** for Development purposes and an approximate delivery schedule therefor. PDL shall review current and proposed manufacturing subcontractors for clinical supply with the JDC. The JDC shall consider using Roche as a subcontractor for various clinical manufacturing steps, including formulation, filling, finishing, and distribution. This consideration of Roche as the formulation, filling, finishing and/or distribution subcontractor for the clinical supply shall be based on capacity, quality, compliance, cost, capability, distribution, and the strategic needs of the Parties, and subject to the normal supplier qualification process at PDL. If Roche is selected as a subcontractor, the Parties shall negotiate in good faith to enter into an appropriate toll manufacturing agreement.

(b) The COGS associated with supplying all API, IMP, and placebo pursuant to this Section 8.1 for the purposes of obtaining Regulatory Approval in the U.S. Territory and the European Union shall be **[*]**, consisting of **[*]** for such clinical supplies for the phase I and phase II clinical program (the **"Phase I/II [*] Price"**) and **[*]** for such clinical supplies for the phase III clinical program (the **"Phase III [*] Price"**). The Phase I/II **[*]** Price shall be included as a Development Expense in **[*]** in the **[*]** beginning with **[*]**. The Phase III **[*]** Price shall be included as a Development Expense in **[*]** in the **[*]** after Roche decides to proceed with phase III development (i.e., such decision is currently identified as the Roche "Full Development Decision Point [FDDP]" determination as approved by the "Life Cycle Committee [LCC]"). Roche shall promptly inform PDL of its decision whether or not to proceed with phase III development. If the non-manufacturing aspects of the initial Development Plan are modified in any manner that results in an increase in the quantity of API, IMP, or placebo to be manufactured for purposes of obtaining Regulatory Approval in the U.S. Territory and the European Union, then the Parties shall **[*]** in the Phase I/II **[*]** Price and/or Phase III **[*]** Price, as

appropriate, or agree upon an alternative method of **[*]** the costs resulting from such change.

(c) With respect to API, IMP, or placebo supplied by PDL to Roche pursuant to this Section 8.1 for use in any Development activities not required to obtain Regulatory Approval in the U.S. Territory or the European Union, Roche shall pay PDL, within the later of **[*]** of acceptance of the shipment or **[*]** of receipt of the applicable invoice, a transfer price equal to (i) **[*]**, as the case may be, minus (ii) **[*]** for the production of such material. Such amount shall be deemed an Incremental Development Expense.

8.2 Commercial Supply. Within **[*]** after the Effective Date, Roche and PDL shall negotiate in good faith a definitive commercial supply agreement (the **"Commercial Supply Agreement"**) that will govern the exact terms and conditions of the commercial supply of API or other finished form of Licensed Product by PDL to Roche for sale in the ROW Territory for use in the Asthma Field. The Parties acknowledge and agree that the Commercial Supply Agreement will address Roche's remedies in the event that PDL is unable to supply or have supplied API or other finished form of Licensed Product in quantities desired by Roche (a **"Failure to Supply"**). All such remedies set forth in the Commercial Supply Agreement shall be Roche's sole remedies with respect to a Failure to Supply.

8.3 Transfer Price for Commercial Supply of API.

(a) If Roche desires to perform the fill/finish step of the manufacturing process of Licensed Product for sale in the Asthma Field in the ROW Territory, it shall notify PDL of its desire and commitment based on capacity, quality, compliance, cost, capability and the strategic needs of the Parties. The Parties shall discuss and agree upon the amounts which Roche would **[*]** for the fill/finish step under different reasonably contemplated supply requirements if Roche were to perform such fill/finish (the **"Roche Fill/Finish Cost"**). If **[*]** provides a corresponding fill/finish cost that is **[*]**, based on the same assumptions with respect to the calculations of such cost, then **[*]**

shall perform such fill/finish step and the Parties shall agree upon the appropriate commitment for continued fill/finish by **[*]** (including the frequency and lead times with which **[*]**) with a view to ensuring uninterrupted supply of Licensed Product in the ROW Territory.

(b) Roche will pay PDL a Transfer Price based on **[*]** calculated as follows: Transfer Price = **[*]**), where the Target Price is determined based on the **[*]** as shown below. The total **[*]** is determined by combining **[*]** with **[*]**. For **[*]** intermediate to those shown below, **[*]** will be used to determine the Target Price. If total **[*]** are **[*]** or **[*]**, the Target Price will be **[*]**.

Target Price	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*]	**[*]**
[*]	**[*]**
[*]	**[*]**
[*]	**[*]**

The Transfer Price for API will be fixed **[*]** as described in the Commercial Supply Agreement to be negotiated between the Parties.

8.4 Transfer Price for Commercial Supply of Finished Product. If PDL or its subcontractor performs the fill/finish step, then Roche will pay PDL a Transfer Price based on the **[*]** Licensed Product **[*]** calculated as follows: Transfer Price = **[*]**, where

the Target Price is determined based on the **[*]** as shown below. The total **[*]** is determined by combining **[*]** with **[*]**. For **[*]** intermediate to those shown below, **[*]** will be used to determine the Target Price. If total annual order quantities are **[*]** or **[*]**, the Parties will **[*]**. For the purpose of all calculations under this Section 8.4, finished Licensed Product **[*]** shall be handled separately from finished Licensed Product **[*]**.

[*]	Target Price for [*]	Target Price for [*]
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**

For the purpose of this Section 8.4:

(a) the term **[*]** indicates a **[*]** that contains **[*]**, which would be labeled and bulk packaged for shipment only;

(b) the term **[*]** indicates a **[*]** that contains **[*]** (exact package to be determined), which would be labeled and bulk packaged for shipment only.

(c) In the event that the **[*]** configurations differ from those specified above, the Parties shall negotiate in good faith a new Target Price table.

(d) The Transfer Price for finished Licensed Product will be fixed **[*]** in accordance with the procedure described in the Commercial Supply Agreement to be negotiated between the Parties.

8.5 Transfer Price Following Expiration of Royalty Obligations. Following expiration of Roche's royalty obligations in a given country in the ROW Territory pursuant to Section 10.3(b), PDL will continue to supply Licensed Product to Roche under the terms of the Commercial Supply Agreement, except that the Transfer Price shall be **[*]**

8.6 Delivery Terms. The Parties acknowledge and agree that the Target Prices set forth in Sections 8.3 and 8.4, and the Transfer Price set forth in Section 8.5, (a) are based on PDL delivering API or other finished form Ex Works (Incoterms 2000) PDL's or its Third Party manufacturer's facilities and (b) do not include the cost of any shipping fees, freight charges, insurance, import and export compliance fees, consumption taxes, withholding taxes, customs, duties and other taxes imposed by any government taxing authority in connection with API or other finished form supplied by PDL for the ROW Territory.

8.7 Transition Services After Expiration. If Roche or its Affiliate or sublicensee is still selling the Licensed Product in the ROW Territory in the Asthma Field at the time of expiration of this Agreement and Roche wishes to assume the responsibility for supplying the Licensed Product for such sales, then Roche shall notify PDL in writing at least **[*]** prior to the expiration of this Agreement and PDL for a reasonable transition period thereafter shall supply Licensed Product to Roche and provide Roche with certain transition services related to the transfer of manufacturing from PDL to Roche or its designee, all under the terms of (and subject to the execution of) a separate written agreement to be negotiated by the Parties in good faith.

ARTICLE 9

R&D REIMBURSEMENT PAYMENT AND DEVELOPMENT PAYMENTS

9.1 [*]. Roche shall pay to PDL a non-refundable, non-creditable payment of Seventeen Million Five Hundred Thousand Dollars ($17,500,000) **[*]** within **[*]** after the Effective Date.

9.2 Development Payments. Roche shall pay to PDL the following non-refundable and non-creditable amounts no later than **[*]** after the later of (i) first occurrence of the indicated event with respect to a Licensed Product in the Asthma Field or (ii) receipt by Roche of an invoice for such amount:

Event	Payment
(a) **[*]** (as defined and specified in Exhibit E)	**[*]**
(b) **[*]** (as defined and specified in Exhibit E)	**[*]**
(c) **[*]** (as described in Exhibit B) prior to **[*]**	**[*]**
(d) **[*]**	**[*]**
(e) **[*]**	**[*]**
(f) **[*]**	**[*]**
(g) **[*]**	**[*]**

If Roche is responsible for achieving an event listed in this Section 9.2, then Roche shall provide PDL with written notice of the first occurrence of such event within **[*]** of such occurrence. If Roche fails to provide such notice within such **[*]** period, then Roche's associated payment shall be due no later than **[*]** after such event. If any of the payments specified in **[*]** have not been made at the time the payment specified in

[*] becomes due and payable, then Roche shall make all such unpaid payments no later than the due date for the payment specified in Section **[*]**, regardless of whether the events specified in **[*]** have occurred.

ARTICLE 10

PAYMENTS BASED ON SALES OF PRODUCTS

10.1 Profit Share in the U.S. Territory. PDL shall pay Roche, within **[*]** after the end of each calendar quarter during the Co-Promotion Term, an amount equal to **[*]** of the **[*]** for such calendar quarter. The Parties acknowledge and agree that the payments set forth in this Section 10.1 are in lieu of, rather than in addition to, any payments that would otherwise have been due to Roche pursuant to Section 7.2(c) of the Worldwide Daclizumab Agreement on account of the **[*]**.

10.2 [*] in the U.S. Territory.

(a) For each of the **[*]** following the **[*]**, PDL shall pay to Roche **[*]** on a quarterly basis on PDL Net Sales of the Licensed Product **[*]**, at the following rates:

Year	Royalty Rate
For the **[*]** following the **[*]**	**[*]**
For the **[*]** following the **[*]**	**[*]**
For the **[*]** following the **[*]**	**[*]**

If in the U.S. Territory, sales of units of Generic Products in the aggregate total at least **[*]** of the aggregate sales of units of all Generic Products and Licensed Products as measured **[*]**, then PDL shall have the right to **[*]** due under **[*]** by **[*]** in the **[*]**, **[*]** in the **[*]**, and **[*]** in the **[*]** (in each case rounded to the nearest **[*]**). For clarity, if such **[*]** are

applicable, then the actual **[*]** paid by PDL shall be **[*]** in the **[*]**, **[*]** in the **[*]**, and **[*]** in the **[*]**.

(b) For clarity, the **[*]** specified in Section 10.2(a) are **[*]**), the first of which commences on **[*]**. The Parties acknowledge and agree that the payments set forth in Section 10.2(a) are in lieu of, rather than in addition to, any payments that would otherwise have been due to Roche pursuant to Section 7.2(c) of the Worldwide Daclizumab Agreement on account of **[*]**.

10.3 Royalties in the ROW Territory.

(a) For each calendar year or portion thereof during the term specified below, Roche shall pay to PDL incremental royalties on Roche Net Sales, at a royalty rate determined by annual Roche Net Sales of all Licensed Products as follows:

Annual Roche Net Sales (US$)	Royalty Rate
Up to and including **[*]**	**[*]**
Above **[*]** but not exceeding **[*]**	**[*]**
Above **[*]**	**[*]**

Roche shall have the right to deduct from any royalties payable under this Section 10.3(a) the following: (i) **[*]** for Licensed Products sold in the ROW Territory (on a first-in, first-out basis) during the royalty reporting period for which such royalties are due; and (ii) any **[*]** for Licensed Product sold in the ROW Territory (on a first-in, first-out basis) during the royalty reporting period for which such royalties are due.

(b) Roche's obligation to pay a royalty under Section 10.3(a) for a particular Licensed Product shall expire, on a country-by-country basis, on the later of (i) **[*]** following the First Commercial Sale of such Licensed Product in such country and (ii)

the last date on which the making, using, selling, or importing of Licensed Product, but for the licenses granted herein, would infringe a Valid Claim. If required by law, the First Commercial Sale in the European Union will be considered the First Commercial Sale in each country of the European Union.

(c) The Parties acknowledge and agree that no payments will be owed to Roche pursuant to Section 7.2(c) of the Worldwide Daclizumab Agreement on account of those sales of Licensed Products included in Roche Net Sales hereunder.

10.4 Adjustments Related to Third Party Competition. If in a country of the ROW Territory sales of units of Generic Products in aggregate total at least **[*]** of the aggregate sales of units of all Generic Products and Licensed Products as measured **[*]**, then Roche shall have the right to **[*]** any royalties due under Section 10.3 (after the applicable **[*]**, if applicable) by: (a) **[*]** in the **[*]** in which such Generic Product sales achieve such sales levels; (b) **[*]** in the **[*]**, and (c) **[*]** in the **[*]** and all subsequent such years during the royalty term (in each case rounded to the nearest **[*]**).

10.5 Adjustments for Third Party Licenses. Roche and PDL shall share all costs associated with Third Party Licenses in the ROW Territory as set forth in this Section 10.5. Roche shall be responsible for **[*]** of all payments under Third Party Licenses that are not included in the Transfer Price and are allocable to the use, development, sale, manufacture, or import of Licensed Products in the ROW Territory, including without limitation all payments under Third Party Licenses (a) calculated based on sales of Licensed Products in the ROW Territory; (b) made on account of the achievement of particular events relating to development or commercialization of Licensed Products in the ROW Territory; and (c) as consideration for a grant of a license or other rights in the ROW Territory (collectively, **"ROW License Payments"**). PDL shall be responsible for the remaining **[*]** of ROW License Payments. The Parties shall, within **[*]** after the end of each **[*]**, reimburse each other to effect the sharing of ROW License Payments set forth in this Section 10.5. For each license agreement that is included in Third Party Licenses pursuant to Section 1.81(b) and that is also

necessary for the use, manufacture, sale, offering for sale, or importation of products outside the Asthma Field, the Parties will **[*]** of payments under such license agreement to determine the portion of such payments **[*]**, which portion alone shall be includable in ROW License Payments. This Section 10.5 shall supersede Section 7.4 of the Worldwide Daclizumab Agreement to the extent Section 7.4 of the Worldwide Daclizumab Agreement is applicable to any ROW License Payments.

10.6 [*] Payments. Roche shall pay to PDL the following one-time, non-refundable and non-creditable amounts within **[*]** after the later of (i) the first achievement of the indicated events with respect to **[*]** of all Licensed Products in the Territory, and (ii) receipt by Roche of an invoice for such amount:

Event	Payment
[*]	**[*]**
[*]	**[*]**
[*]	**[*]**

For clarity, if more than one of the indicated **[*]** events occurs in the same calendar year, then Roche shall pay PDL the sum of all payments corresponding to such **[*]** events. Roche shall provide PDL with written notice of the first achievement of each event listed in this Section 10.6 within **[*]** of such achievement. If Roche fails to provide such notice within such **[*]** period, then Roche's associated payment shall be due no later than **[*]** after such event.

ARTICLE 11

PAYMENT; REPORTS; AUDITS

11.1 Roche Quarterly Royalty Payments and Reports.

(a) Until the expiration of Roche's royalty obligations under Section 10.3, Roche agrees to make payments and written reports to PDL within **[*]** after the end of each calendar quarter covering all sales of the Licensed Products in the Asthma Field in the ROW Territory by Roche, its Affiliates or sublicensees (except PDL, its Affiliates and sublicensees) for which invoices were sent during such calendar quarter, each such written report stating for the period in question:

(i) for Licensed Products disposed of by sale, the description of Licensed Products and the calculation of Roche Net Sales,

(ii) for Licensed Products disposed of other than by sale, the description and nature of the disposition, and

(iii) the calculation of the amount due to PDL for such quarter pursuant to Sections 10.3, 10.4, 10.5 and 10.6.

(b) The information contained in each report under Section 11.1(a) shall be considered Confidential Information of Roche. Concurrent with the delivery of each quarterly report, Roche shall make the payment due PDL hereunder for the calendar quarter covered by such report.

(c) It is understood that only one royalty payment under Article 10 shall be payable on a given unit of Licensed Product disposed of under this Agreement. In the case of transfers or sales of any Licensed Product between Roche and an Affiliate sublicensee of Roche, such royalty shall be payable with respect to, the sale of such Licensed Product to (i) an independent Third Party not an Affiliate of the seller or (ii) if the end user is an Affiliate of the seller, then such end user.

11.2 PDL Quarterly Royalty Payments and Reports.

(a) During the **[*]** period of PDL's royalty obligations under Section 10.2, PDL agrees to make payments and written reports to Roche within **[*]** after the end of each calendar quarter covering all sales of the relevant Licensed Product in the Asthma Field in the U.S. Territory by PDL for which invoices were sent during such calendar quarter, or, in the case of royalties from the PDL Net Sales of PDL's Affiliates or sublicensees (except Roche, its Affiliates and sublicensees), within **[*]** following the end of the quarter in which PDL receives the royalty report from the Affiliate sublicensee. Each report shall state for the period in question:

(i) for such Licensed Products disposed of by sale, the description of Licensed Products and the calculation of PDL Net Sales therefor,

(ii) for such Licensed Products disposed of other than by sale, the description and nature of the disposition, and

(iii) the calculation of the amount due to Roche for such quarter pursuant to Section 10.2.

(b) The information contained in each report under Section 11.2(a) shall be considered Confidential Information of PDL. Concurrent with the delivery of each quarterly report, PDL shall make the payment due Roche hereunder for the calendar quarter covered by such report.

(c) It is understood that only one royalty payment under Section 10.2 shall be payable on a given unit of Licensed Product disposed of under this Agreement. In the case of transfers or sales of any Licensed Product between PDL and an Affiliate sublicensee of PDL which is subject to royalties under Section 10.2, such royalty shall be payable with respect to the sale of such Licensed Product to (i) an independent Third Party not an Affiliate of the seller or (ii) if the end user is an Affiliate of the seller, then such end user.

11.3 Gross Margin Reports. Along with the payment specified in Section 10.1, PDL shall provide Roche with a written report (the **"Gross Margin Report"**) containing the PDL Adjusted Gross Sales, COGS and the calculation of the amount due to Roche. The information contained in each report under this Section 11.3 shall be considered Confidential Information of the Parties.

11.4 Other Reports. The Parties' reporting obligations with respect to Development Expenses and Operating Expenses are set forth in Sections 4.6(c) and 6.3(b). The information contained in such reports shall be considered Confidential Information of both Parties.

11.5 Accounting.

(a) Product Sales Records. Each Party (the **"Royalty Paying Party"**) agrees to keep full, clear and accurate records for a period of at least **[*]** after the relevant payment is owed pursuant to this Agreement, setting forth the manufacturing, sales and other disposition of Licensed Products sold or otherwise disposed of in sufficient detail to enable royalties and compensation payable to the other Party (the **"Royalty Receiving Party"**) hereunder to be determined. Each Royalty Paying Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the Royalty Receiving Party to verify reports provided for in Sections 11.1, 11.2, or 11.3. Unless the Royalty Receiving Party obtains the prior written consent of the Royalty Paying Party, such accounting firms must be selected from among the four largest global accounting firms. Such audit shall not be performed more frequently that **[*]** per calendar year nor more frequently than **[*]** with respect to records covering any specific period of time. Such examination is to be made at the expense of the Royalty Receiving Party, except in the event that the results of the audit reveal a discrepancy in favor of the Royalty Paying Party of **[*]** or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Royalty Paying Party.

(b) Expense Records. Each Party (the **"Expense Incurring Party"**) agrees to keep full, clear and accurate records for a period of at least **[*]** after the relevant report is made pursuant to Section 4.6(c) or 6.3(b) setting forth its Development Expenses or Operating Expenses, as applicable, incurred in sufficient detail to enable royalties and compensation payable to the other Party (the **"Expense Reimbursing Party"**) hereunder to be determined. Each Expense Incurring Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the Expense Reimbursing Party to verify reports made pursuant to Section 4.6(c) or 6.3(b), as applicable. Unless the Expense Reimbursing Party obtains the prior written consent of the Expense Incurring Party, such accounting firms must be selected from among the four largest global accounting firms. Such audit shall not be performed more frequently that **[*]** per calendar year nor more frequently than **[*]** with respect to records covering any specific period of time. Such examination is to be made at the expense of the Expense Reimbursing Party, except in the event that the results of the audit reveal a discrepancy in favor

of the Expense Incurring Party of **[*]** or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Expense Incurring Party.

11.6 Methods of Payments. All payments due to either PDL or Roche under this Agreement shall be paid in Dollars by wire transfer to a bank in the U.S. designated in writing by the Party to which the payment is due.

11.7 Taxes. If provision is made in law or regulation of any country of the Territory for withholding of taxes of any type, levies or other charges with respect to the any amounts payable hereunder to a Party or its Affiliates, the other Party or its Affiliates (**"Withholding Party"**) shall promptly pay such tax, levy or charge for and on behalf of the Party to the proper governmental authority, and shall promptly furnish the Party with receipt of such payment. The Withholding Party shall have the right to deduct any such tax, levy or charge actually paid from payment due the Party or be promptly reimbursed by the Party if no further payments are due the Party. Each Withholding Party agrees to assist the other Party in claiming exemption from such

deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

11.8 Currency. All payments under this Agreement shall be in Dollars.

11.9 Late Payments. Any amount owed by one Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the **[*]** as reported by Bloomberg (or a successor or similar organization).

ARTICLE 12

PATENTS AND KNOW-HOW

12.1 PDL Technology. Ownership of the PDL Inventions, PDL Know-How and PDL Patents shall remain vested at all times in PDL.

12.2 Joint Inventions and Joint Roche-PDL Patents. Subject to Section 12.6(e), ownership of Joint Inventions and Joint Roche-PDL Patents shall be vested jointly in PDL and Roche. Except where such activities would conflict with an exclusive license granted to a Party in this Agreement or in the Worldwide Daclizumab Agreement, both Parties shall at all times have the co-exclusive right within the Territory to practice, or to make, have made, use, import, offer for sale or sell any Joint Invention under any Joint Roche-PDL Patent, and neither Party shall be obligated to account to the other. As used herein, a right to practice any Joint Roche-PDL Patent for a particular purpose without any obligation to account shall include the right to grant licenses for such purpose without the consent of the other Party. To the extent either Party needs the consent of the other Party to exploit its co-exclusive or exclusive rights with respect to Joint Roche-PDL Patents, including the right to sublicense or enforce

such Joint Roche-PDL Patents, the other Party shall cooperate with the Party making such a request and promptly supply all needed consents, signatures and the like.

12.3 Roche Technology. Except as expressly provided in this Agreement or the Worldwide Daclizumab Agreement, ownership of the Roche Know-How, Roche Patents and Collaboration Inventions shall remain vested at all times in Roche.

12.4 Disclosure of New Inventions. At a regular interval to be agreed by the Parties (but no less than quarterly), the Parties shall disclose to each other any Joint Inventions, Collaboration Inventions, or other inventions that constitute or will constitute new PDL Know-How, Roche Know-How, PDL Patents (if a patent application is filed), or Roche Patents (if a patent application is filed), to extent that any of the foregoing were conceived or reduced to practice since the previous new invention disclosure.

12.5 Prosecution of Sole PDL Patents and Sole Roche Patents.

(a) PDL agrees to prosecute and reasonably maintain all of the patents and applications included within the Sole PDL Patents (except for **[*]**), to the extent it has the rights to do so, consistent with the patent strategy developed by the JPC, and Roche agrees to prosecute and reasonably maintain the Sole Roche Patents, to the extent it has the rights to do so from any co-owner of such Sole Roche Patents, consistent with the patent strategy developed by the JPC. The costs and expenses for such prosecution and maintenance shall be allocated between the Parties as set forth in Section 12.7.

(b) The Party responsible for such patent (**"Responsible Party"**) shall provide the other Party with a reasonable opportunity to comment on all draft filings prior to their submission to the relevant patent authority. On the reasonable request of the Responsible Party, the other Party shall cooperate, in all reasonable ways, in connection with the prosecution of all patent applications included within the Sole PDL Patents or Roche Sole Patents, as the case may be. Should the Responsible Party decide that it is no longer interested in maintaining or prosecuting a Sole PDL Patent

(except for those **[*]**) or Sole Roche Patent, as the case may be, it shall promptly advise the other Party thereof and, at the request of such other Party, PDL and Roche shall negotiate in good faith to determine an appropriate course of action in the interests of both Parties. If any Sole PDL Patents are assigned to Roche, Roche will thereafter prosecute and reasonably maintain such Sole PDL Patents at Roche's own cost to the extent that Roche desires to do so, provided that to the extent such Sole PDL Patent contains claims outside the Asthma Field, PDL and its Affiliates shall have a worldwide immunity from suit thereunder. If Roche's interest in any Sole Roche Patent is assigned to PDL, PDL will thereafter prosecute and reasonably maintain such Sole Roche Patent at PDL's own cost to the extent that PDL desires to do so, provided that to the extent such Sole Roche Patent contains claims outside the Asthma Field, Roche

and its Affiliates shall have a worldwide immunity from suit thereunder. In the event Roche's interest in the Sole Roche Patents is assigned to PDL pursuant to Section 5.4(e) of the Worldwide Daclizumab Agreement, Roche shall have no further rights with respect thereto.

12.6 Prosecution of Joint Inventions.

(a) PDL will have the first right of election to file priority patent applications for Joint Inventions in any country in the Territory. If PDL declines to file such applications then Roche may do so. Such filings and all subsequent prosecution and maintenance shall be consistent with the patent strategy developed by the JPC.

(b) The Party not performing the priority patent filings for Joint Inventions pursuant to this Section 12.6 undertakes without cost to the filing Party to obtain all necessary assignment documents for the filing Party, to render all signatures that shall be necessary for such patent filings and to assist the filing Party in all other reasonable ways that are necessary for the issuance of the patents involved as well as for the maintenance and prosecution of such patents. The Party not performing the patent filings shall on request be authorized by the other Party to have access to the files concerning such patents in any patent offices in the world.

(c) The Party performing the priority patent filings for Joint Inventions pursuant to this Section 12.6 undertakes to perform the corresponding convention filings from case to case, after having discussed the countries for foreign filings with the other Party.

(d) The costs and expenses for prosecution and maintenance of Joint Roche-PDL Patents shall be allocated between the Parties as set forth in Section 12.7.

(e) Should the Responsible Party decide that it is no longer interested in maintaining or prosecuting a Joint Roche-PDL Patent, it shall promptly advise the other Party thereof and the Parties shall discuss whether the Responsible Party shall assign such Joint Roche-PDL Patent to the other Party at no cost to the assignee. If any such patents or patent applications are assigned to Roche, they shall then be deemed to be a Sole Roche Patent and, to the extent such Joint Roche-PDL Patent contains claims outside the Asthma Field, PDL and its Affiliates shall have a worldwide immunity from suit thereunder. If any such patents or patent applications are assigned to PDL, they shall then be deemed to be a Sole PDL Patent and, to the extent such Joint Roche-PDL Patents contain claims outside the Field, Roche and its Affiliates shall have a worldwide immunity from suit thereunder.

12.7 Allocation of Patent Prosecution Expenses. The costs incurred by the Parties with respect to the prosecution and maintenance of PDL Patents and Roche Patents in the U.S. Territory and the European Union, or in connection with the international phase of PCT applications that designate the U.S. and/or European Union countries, shall be included in **[*]** and shall be shared **[*]** by the Parties until the end of the Co-Promotion Term. Thereafter, **[*]** shall be solely responsible for such costs in the **[*]** or in connection with the international phase of PCT applications that designate the **[*]**, and **[*]** shall be solely responsible for such costs in the **[*]** or in connection with the international phase of PCT applications that designate one or more **[*]** countries but not **[*]**. PDL shall bear **[*]** of the costs incurred by the Parties with respect to the post-issuance maintenance of PDL Patents in the ROW Territory (except for the European

Union). Except as set forth in the preceding sentence, Roche shall bear **[*]** of the costs incurred by the Parties with respect to the prosecution and maintenance of PDL Patents and Roche Patents in the ROW Territory (except for the European Union) until the termination of Roche's royalty obligations under Section 10.3. Thereafter, PDL will be solely responsible for such costs with respect to the PDL Patents and Roche shall be solely responsible for such costs with respect to Sole Roche Patents. Notwithstanding anything to the contrary set forth above, PDL will be solely responsible for all costs with respect to the prosecution and maintenance of the **[*]**.

12.8 Enforcement and Defense of Sole Patents.

(a) In the event of any action against a Third Party for infringement of any claim in any issued patent within the Sole PDL Patents or Sole Roche Patents, as the case may be, or the institution by a Third Party of any proceedings for the revocation of any such claim, each Party will notify the other promptly and, following such notification, the Parties shall confer. In the **[*]** Territory, **[*]** shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the **[*]** in the Asthma Field, in its own name and entirely under its own direction and control. The Parties shall share **[*]** all expenses associated with such action or proceeding, provided it is commenced prior to **[*]**. **[*]** shall bear all costs associated with any such action or proceeding commenced after **[*]**. In the **[*]** Territory, **[*]** shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the **[*]** (other than the **[*]**) in the Asthma Field at **[*]**, in its own name and entirely under its own direction and control. **[*]** shall have the right, but not the obligation, to prosecute such actions or to defend such proceedings involving the **[*]** at **[*]**, in its own name and entirely under its own direction and control.

(b) If a Party with the first right hereunder elects not to prosecute any action for infringement or to defend any proceeding for revocation of any claims in any issued patent within the **[*]** (other than the **[*]** and those **[*]** for which **[*]**) in the Asthma Field or **[*]** (other than those **[*]**), as the case may be, within **[*]** of being requested by

the other Party to do so, the other Party may prosecute such action or defend such proceeding at its own expense, in its own name and entirely under its own direction and control, provided however, that the Parties shall **[*]** all expenses associated with actions or proceeding brought in the U.S. Territory prior to **[*]** with respect to **[*]** in the Asthma Field. After **[*]**, **[*]** shall not have any right to bring any action or defend any proceeding in the U.S. Territory with respect to a **[*]**.

(c) In any event, the Party bringing an action (**"Acting Party"**) pursuant to this Section 12.8 shall solicit, and seriously consider in good faith the non-acting Party's input with respect to all material aspects of such action, including without limitation, the development of the litigation strategy and the execution thereof. In furtherance and not in limitation of the foregoing, the Acting Party shall keep the other Party promptly and fully informed of the status of any such action, and the non-acting Party shall have the right to review and comment on the Acting Party's activities related thereto.

(d) Each Party will reasonably assist the Acting Party in any such action or proceeding being prosecuted or defended by the Acting Party, if so requested by the Acting Party or required by law. Without limiting the generality of the foregoing, the non-acting Party agrees to join such action or proceeding if required by law to maintain such action or proceeding. The Acting Party will pay or reimburse the assisting Party for all costs, expenses and liabilities that the assisting Party may incur or suffer in affording assistance to such actions or proceedings. No settlement of any such action or defense that restricts the scope or affects the enforceability of PDL Know-How or Sole PDL Patents may be entered into by either PDL (if it would affect Roche's rights under this Agreement) or Roche without the prior consent of the other Party hereto, **[*]**. No settlement of any such action or defense that restricts the scope or affects the enforceability of Roche Know-How or Sole Roche Patents may be entered into by either PDL or Roche without the prior consent of the other Party hereto (if it would affect the other Party's rights under this Agreement), **[*]**.

(e) If either Party elects to prosecute an action for infringement or to defend any proceedings for revocation of any claims pursuant to this Section 12.8 and subsequently ceases to continue or withdraws from such action or defense, it shall forthwith so notify the other Party in writing and the other Party may substitute itself for the withdrawing Party and the Parties' respective rights and obligations under this Section 12.8 shall be reversed.

(f) Notwithstanding the foregoing, at PDL's request **[*]**, Roche shall assist PDL with respect to enforcement or revocation actions outside the Asthma Field with respect to a Sole PDL Patent claiming the composition of matter of a Licensed Product.

12.9 Enforcement and Defense of Joint Roche-PDL Patents. In the event of any action against a Third Party for infringement of any claim in any issued patent within the Joint Roche-PDL Patents, or the institution by a Third Party of any proceedings for the revocation of any such claim, each Party will notify the other promptly and, following such notification, the Parties shall confer to determine whether either or both Parties shall control the prosecution or defense of such action or proceeding and who shall bear the costs thereof. If both Parties wish to control the prosecution or defense of such action or proceeding and the Parties are unable to reach agreement within **[*]** of the notification referred to above, then **[*]** shall have the exclusive right to bring such action or defend such proceeding, in its own name and entirely under its own direction, and at **[*]** request, **[*]** shall participate in such action or proceeding at **[*]**. No settlement of any action or defense that restricts the scope or affects the enforceability of Joint Roche-PDL Patents may be entered into by either PDL or Roche without the prior consent of the other Party hereto, which consent shall not be unreasonably withheld. In any event, the Acting Party pursuant to this Section 12.9 shall solicit, and seriously consider in good faith the other Party's input with respect to all material aspects of such action, including without limitation, the development of the litigation strategy and the execution thereof. In furtherance and not in limitation of the foregoing, the Acting Party shall keep the other Party promptly and fully informed of the status of any such action, and the

other Party shall have the right to review and comment on the Acting Party's activities related thereto.

12.10 Distribution of Proceeds. In the event either Party exercises the rights conferred in Section 12.8 or 12.9 hereof, and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to reimburse the Parties for all costs and expenses incurred in connection therewith, including reasonable attorneys' fees necessarily involved in the prosecution and/or defense of any suit or proceeding and, if after such reimbursement any funds shall remain from such damages or other sums recovered, said remaining recovery shall be allocated as follows:

(a) With respect to actions or proceedings commenced hereunder in the U.S. Territory prior to the end of the Co-Promotion Term regarding one or more Sole PDL Patents or Sole Roche Patents, the Parties shall **[*]** share such remaining recovery;

(b) With respect to actions or proceedings commenced hereunder in the U.S. Territory after the end of the Co-Promotion Term regarding one or more Sole PDL Patents or Sole Roche Patents, **[*]** shall retain such remaining recovery in its entirety;

(c) With respect to actions or proceedings commenced hereunder in the ROW Territory regarding one or more Sole PDL Patents or Sole Roche Patents, **[*]** shall retain such remaining recovery in its entirety, provided that if **[*]** is the acting Party, then such remaining recovery shall be deemed **[*]** and **[*]** shall pay **[*]** a royalty based thereon in accordance with the terms set forth in Section **[*]**;

(d) With respect to actions or proceedings commenced by PDL hereunder with respect to a Joint Roche-PDL Patent, such remaining recovery shall be divided between the Parties **[*]**; and

(e) With respect to actions or proceedings commenced by Roche hereunder with respect to a Joint Roche-PDL Patent, such remaining recovery shall be divided **[*]** between the Parties.

12.11 Defense of Infringement Actions.

(a) If Roche and/or PDL are named as defendant(s) in a patent infringement suit filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of Licensed Products in the Asthma Field in the ROW Territory, then Roche shall defend such suit at its own cost and shall indemnify and hold PDL harmless against any such patent or other infringement suits, and any claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and cost, that may be incurred by PDL therein or in settlement thereof. Any and all settlements that restrict the scope or enforceability of PDL Know-How or PDL Patents must be approved by PDL, in its sole and absolute discretion, before execution by

Roche. Any and all settlements that restrict the scope or enforceability of Joint Roche-PDL Patents or Sole Roche Patents (other than those Sole Roche Patents co-owned by a Third Party) must be approved by PDL before execution by Roche, such approval not to be unreasonably withheld. PDL shall not be required to approve any settlement that does not include as a condition thereof the granting to PDL of a full and unconditional release of claims.

(b) If Roche and/or PDL are named as defendant(s) in a patent infringement suit filed by a Third Party concerning the methods or products used by or on behalf of PDL during the manufacture of Licensed Products for sale in the Asthma Field in the U.S. Territory, and PDL had not previously disclosed to Roche that it was using such methods or products during such manufacture, then PDL shall defend such suit at its own cost and hold Roche harmless against any such patent or other infringement suits, and any claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and costs, that may be incurred by either Party therein or in settlement thereof. Any and all settlements must be approved by both Parties, such

approval not to be unreasonably withheld. Roche shall not be required to approve any settlement that does not include as a condition thereof the granting to Roche of a full and unconditional release of claims.

(c) If Roche and/or PDL are named as defendant(s) in a patent infringement suit not covered by Section 12.11(b) that is filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of Licensed Products in the Asthma Field in the U.S. Territory prior to the end of the Co-Promotion Term, then the Parties shall share **[*]** all costs associated with such suit including all claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and costs, that may be incurred by either Party therein or in settlement thereof. Any and all settlements must be approved by both Parties, such approval not to be unreasonably withheld. Neither Party shall not be required to approve any settlement that does not include as a condition thereof the granting to such Party of a full and unconditional release of claims.

(d) During the term of this Agreement, each Party shall bring to the attention of the other Party all information regarding potential infringement of Third Party intellectual property rights via the development, manufacture, production, use, importation, offer for sale, or sale of Licensed Products in the Asthma Field in the ROW Territory or the U.S. Territory. The Parties shall discuss such information and decide how to handle such matter.

(e) This Section 12.11 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

12.12 Right to Counsel. Each Party to this Agreement shall always have the right to be represented by counsel of its own selection and its own expense in any suit or other action instituted by the other for infringement, under the terms of this Agreement.

12.13 Conflicts. If the terms set forth in this Article 12 conflict with or are inconsistent with any terms set forth in the Worldwide Daclizumab Agreement, then the terms set forth in this Article 12 shall prevail to the extent necessary to overcome such conflict or inconsistency.

ARTICLE 13

TRADEMARKS

13.1 Selection and Procurement of Trademarks. The JSC shall select a single trademark to be used to market the Licensed Product in the Asthma Field throughout the Territory. If the JSC selects the Zenapax Trademark as the single trademark to be used to market the Licensed Product in the Asthma Field and the Zenapax Trademark has not been previously assigned to PDL pursuant to the Worldwide Daclizumab Agreement, Roche shall be responsible for maintenance of trademark registrations for the Zenapax Trademark in the ROW Territory. Those expenses incurred by Roche with respect to Zenapax Trademark in the U.S. Territory shall be included in Operating Expenses. If the JSC selects a trademark other than the Zenapax Trademark as the single trademark to be used to market the Licensed Product in the Asthma Field or the Zenapax Trademark has been previously assigned to PDL pursuant to the Worldwide Daclizumab Agreement, then the selected trademark shall be deemed a PDL Trademark and shall be owned by PDL. PDL shall be responsible for procurement and maintenance of trademark registrations for the PDL Trademarks in the Territory, except that PDL may cease trademark registration procurement activities for any PDL Trademark in any country in the ROW Territory provided it first offers Roche the opportunity to assume such activities at its own expense. Those expenses incurred by PDL with respect to PDL Trademarks in the U.S. Territory shall be included in Operating Expenses.

13.2 Use of the Trademarks. Roche and its Affiliates and sublicensees shall use the PDL Trademarks only in connection with the development, use, marketing, promotion, detailing, sale, and offer for sale of Licensed Product in the Territory in accordance with the licenses granted in Sections 2.1(a)(iii) and 2.1(b)(ii). It is understood and agreed by PDL that, in the ROW Territory, Roche shall have the right to use the corporate names of Roche and its Affiliates, and associated logos and designs, in conjunction with the PDL Trademarks, and shall identify PDL on all packaging and labeling as the manufacture and co-developer of the Licensed Product. It is also understood and agreed that, during the Co-Promotion Term in the U.S. Territory, the Parties shall have the right to use the corporate names of the Parties and their Affiliates, and all associated logos and designs, in conjunction with the PDL Trademarks.

13.3 PDL House Marks. Roche acknowledges the goodwill and reputation associated with the PDL House Marks and shall use the PDL House Marks in a manner that maintains and promotes such goodwill and reputation. Roche shall take all reasonable precautions and actions to protect the goodwill and reputation that has inured to the PDL House Marks, shall refrain from doing any act that is reasonably likely to impair the reputation of the PDL House Marks, and shall cooperate fully to protect the PDL House Marks.

13.4 Quality Control. Roche's use of the PDL Trademarks and the PDL House Marks must comply with PDL's style and branding guidelines, and Roche shall provide all materials (including without limitation advertising or promotional materials) that incorporate the PDL Trademarks or PDL House Marks to the JDC for prior review and approval.

13.5 Acknowledgement of Ownership Rights. Roche undertakes to conduct its activities in such a way so as not to jeopardize or compromise in any way the PDL Trademarks or rights therein. Roche shall not use the PDL Trademarks or PDL House Marks, as the case may be, as all or part of any corporate name, trade name, trademark, service mark, certification mark, collective membership mark, domain name,

or any other designation confusingly similar to the PDL Trademarks or PDL House Marks in any way that damages the PDL Trademarks or PDL House Marks. If Roche or its Affiliates challenge or, directly or indirectly, assert any right, title or interest in or to the PDL Trademarks, PDL House Marks, or any registrations or applications for registration thereof, or seek to register the PDL Trademarks or PDL House Marks in any country for any goods and services, then PDL shall have the right to give written notice to Roche of such conduct and Roche shall immediately cease such conduct.

13.6 Use of Trademark Designations. The ™ designation may be used in conjunction with each PDL Trademark within the Territory. Once registrations issue, the ® designation may be used in connection with the PDL Trademarks. An appropriate statutory notice of trademark ownership shall be affixed to or imprinted on any material wherever the PDL House Marks or PDL Trademarks are used. PDL's ownership of such marks shall be identified on all materials on which they appear. The exact language for identification of ownership shall be in accordance with branding and implementation guidelines to be agreed on by the Parties.

13.7 Infringement of Trademarks.

(a) Procedure. In the event that either Party becomes aware of (i) actual infringement of a PDL Trademark in the ROW Territory; (ii) a mark or name confusingly similar to a PDL Trademark in the ROW Territory; or (iii) any unfair trade practices, trade dress imitation, passing off, or like offenses, in the ROW Territory that relate to the **[*]** Trademarks, such Party shall promptly so notify the other Party in writing. PDL shall have the right, but not the obligation, at its sole cost and expense, to initiate, prosecute, and control an infringement action or file any other appropriate action or claim related to such infringement of the PDL Trademark against any Third Party. If **[*]** fails to bring any such infringement action within a period of ninety (90) days after delivery of the notice set forth above, then **[*]** shall have the right, but not the obligation, at its sole **[*]**, to initiate, prosecute, and control an infringement action or file any other appropriate action or claim related to such infringement of the PDL Trademark against

any Third Party. In either event, the Party not bringing any such action (i) shall have the right (at its own expense) to participate in such action and to be represented by counsel of its own choice, and (ii) agrees, at the request **[*]** of the Party bringing such action, to be joined as a Party to the suit and to provide reasonable assistance in any such action. The Party controlling such action shall take all reasonable and appropriate steps to protect, defend, and maintain the PDL Trademarks for use by the Parties and shall have the right to control settlement of such action; provided, however, that no settlement shall be entered into without the written consent of the other Party, not to be unreasonably withheld.

(b) Costs. Any damages or monetary award recovered shall be applied first to reimburse the reasonable costs and expenses of the Party bringing such action in connection with such litigation, with the balance being allocated to the Parties **[*]**.

13.8 Third Party Trademark Claims.

(a) Claims Based on Use of the PDL Trademarks. If a claim is brought by a Third Party that the Parties' use of the PDL Trademarks or Zenapax Trademark infringes such Third Party's trademarks, the Party against which (or against whose Affiliate, as the case may be) the action is brought will give prompt written notice to the other Party of such claim. If the JSC or Executive Officers selected such trademark for the Licensed Product by consensus, then (i) **[*]** shall defend any such claim and any resulting suit brought in the ROW Territory **[*]** and shall indemnify **[*]** and its Affiliates against any resulting final judgments and settlements, provided that **[*]** shall not settle any claim or suit in a manner that would adversely affect **[*]** without obtaining **[*]** prior written consent, which shall not be unreasonably withheld, and (ii) **[*]** shall defend any such claim and any resulting suit brought in the U.S. Territory with respect to use of the trademark during the Co-Promotion Term, provided that the costs associated with such defense shall be **[*]** and **[*]** shall not settle any claim or suit in a manner that would adversely affect **[*]** without obtaining **[*]** prior written consent, which

shall not be unreasonably withheld. If the JSC and Executive Officers did not reach consensus regarding the selection of a trademark for use on the License Product and **[*]** selected such trademark pursuant to Section 3.5(b), then **[*]** shall defend such claim and any resulting suit **[*]** and shall indemnify **[*]** and its Affiliates against any resulting final judgments and settlements, provided that **[*]** shall not settle any claim or suit in a manner that would adversely affect **[*]** without obtaining **[*]** prior written consent, which shall not be unreasonably withheld.

(b) Claims Based on Use of the PDL House Marks. If a claim is brought by a Third Party that the use of the PDL House Marks by Roche or its Affiliates in the ROW Territory infringes such Third Party's trademarks, Roche shall give prompt written notice to PDL of such claim. **[*]** shall defend such claim and any resulting suit **[*]** and shall indemnify **[*]** and its Affiliates against any resulting final judgments and settlements, provided that **[*]** shall not settle any claim or suit in a manner that would adversely affect **[*]** without obtaining **[*]** prior written consent, which shall not be unreasonably withheld.

ARTICLE 14

REPRESENTATIONS, WARRANTIES, AND COVENANTS

14.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party:

(a) Such Party is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

(b) The execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

(c) Such Party has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any agreement of such Party with a Third Party; and

(d) To the best of its knowledge, such Party has the right to grant the rights and licenses described in this Agreement.

14.2 Intellectual Property Representations and Warranties.

(a) Roche hereby represents and warrants to PDL that

(i) Roche has received no **[*]** arising out of, and **[*]**, the development, manufacture, use, sale, offer for sale or import of Daclizumab by Roche (collectively, **[*]**"), except for (1) claims of infringement that **[*]** or (2) **[*]** disclosed in Schedule 14.2(a); and

(ii) Except as set forth in Schedule 14.2(a), to Roche's knowledge, neither Roche nor any of its Affiliates has any **[*]** to **[*]** covering the manufacture, use, importation, offer for sale, or sale of Daclizumab.

(b) PDL hereby represents and warrants to Roche that (i) Schedule 14.2(b) sets forth all **[*]** prior to the Effective Date concerning any **[*]** arising out of, and all **[*]** prior to the Effective Date to take a license to any Third Party intellectual property relating to the development, manufacture, use, sale, offer for sale or import of Licensed Products; and (ii) it has previously disclosed to Roche all **[*]** that the **[*]** are aware of as of the Effective Date as **[*]** contemplated to be performed by or on behalf of either Party pursuant to this Agreement.

14.3 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN SECTIONS 14.1 AND 14.2, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS

OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OR DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

14.4 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, EACH PARTY'S PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT FOR DAMAGES ARISING FROM A BREACH OF SECTION 2.3 OR 15.1. THE FOREGOING SHALL NOT LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS HEREUNDER.

ARTICLE 15

CONFIDENTIALITY

15.1 Nondisclosure of Confidential Information. All Information disclosed by one Party to the other Party under this Agreement shall be subject to the nondisclosure and nonuse provisions set forth in Article XIV of the Worldwide Daclizumab Agreement (as amended by this Agreement). The Parties hereby amend Section 14.1(a) of the Worldwide Daclizumab Agreement to permit, in addition to any rights already granted under the Worldwide Daclizumab Agreement, (a) the use by a Party of any trade secrets or proprietary information disclosed to such Party by the other Party (**"Confidential Information"**) for those purposes permitted by this Agreement; and (b) the further disclosure by such Party of such trade secrets or proprietary information disclosed to such Party by the other Party to those of its Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents or

subcontractors as necessary in connection with such Party's performance under this Agreement.

The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to investment bankers, investors, and potential investors, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 15. In addition, a copy of this Agreement may be filed by PDL with the Securities and Exchange Commission. In connection with any such filing, PDL shall endeavor to obtain confidential treatment of economic and trade secret information.

In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information except as permitted hereunder.

15.2 Publicity. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as Exhibit F. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties; provided, however, that any disclosure which is required by law as advised by the disclosing Party's counsel may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure and to the extent practicable shall provide the other Party an opportunity to comment on the proposed disclosure.

15.3 Publications. The Parties shall comply with the terms set forth in Section 14.3 of the Worldwide Daclizumab Agreement with respect to publications of results generated pursuant to this Agreement.

ARTICLE 16

INDEMNIFICATION

16.1 Indemnification by PDL. Unless otherwise provided herein, PDL agrees to indemnify, hold harmless and defend Roche and its directors, officers, employees and agents (the **"Roche Indemnitees"**) from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or losses (including without limitation attorneys' fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) (**"Losses"**) to the extent that such Losses arise out of (a) a breach of a representation or warranty or covenant by PDL under Article 14 or (b) the use, testing, promotion, marketing or sale of a Licensed Product by or on behalf of PDL, its Affiliates or sublicensees (except for Roche), but only to the extent the Losses described in "(b)" result from (i) any violation of applicable law by PDL with respect to co-promotion activity in the Asthma Field in the U.S. Territory under Article 6, or (ii) the negligence or misconduct or failure to act of PDL, its agents or sublicensees in connection with PDL's obligations under this Agreement. Notwithstanding the foregoing, PDL shall not have any obligation to indemnify the Roche Indemnitees with respect to any Losses arising out of the negligence or misconduct or failure to act of Roche, its Affiliates, or sublicensees (except for PDL).

16.2 Indemnification by Roche. Unless otherwise provided herein, Roche shall indemnify, hold harmless and defend PDL and its directors, officers, employees and agents (the **"PDL Indemnitees"**) from and against any and all Losses, to the extent that such Losses arise out of (a) a breach of a representation or warranty by Roche under Article 14 or (b) the distribution, use, testing, promotion, marketing, or sale of a Licensed Product by or on behalf of Roche, its Affiliates or sublicensees (except for PDL), but only to the extent that the Losses described in "(b)" result from (i) any violation of applicable law by Roche with respect to co-promotion activity in the Asthma Field in the U.S. Territory under Article 6, (ii) any ROW Commercialization Activities, or (iii) the negligence or misconduct or failure to act of Roche, its agents or sublicensees in

connection with Roche's obligations under this Agreement. Notwithstanding the foregoing, Roche shall not have any obligation to indemnify the PDL Indemnitees with respect to any Losses arising out of the negligence or misconduct or failure to act of PDL, its Affiliates, or sublicensees (except for Roche).

16.3 Procedure. In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified Party shall promptly notify the other Party ("**Indemnifying Party**") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party, including, as requested by the Indemnifying Party entering into a joint defense agreement. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

16.4 Certain Losses. Any Losses resulting from Third Party suits, claims, or actions in the U.S. with respect to which neither Party owes an indemnification obligation under this Article 16 shall be **[*]**. In addition, notwithstanding anything to the contrary, all Losses arising from latent defects in the Licensed Products shall **[*]** and **[*]** shall have any indemnification obligations with respect thereto.

16.5 Insurance.

(a) PDL, at its own expense, shall maintain product liability insurance in an amount consistent with industry standards for a company of similar standing during the term of this Agreement. PDL shall provide **[*]** prior written notice to any cancellation of its insurance program. PDL shall designate Roche as an additional insured under its applicable insurance policies.

(b) The Parties acknowledge that Roche, as of the Effective Date, self-insures. If during the term of this Agreement Roche **[*]**, Roche shall **[*]** under its **[*]** and shall provide PDL with **[*]** prior written notice of any **[*]**.

16.6 Relationship to Worldwide Daclizumab Agreement. Solely to the extent that either Party has a Loss recoverable under this Article 16, the Parties' rights and obligations under this Article 16 shall supersede any rights or obligations of the Parties granted under Section 17.6 of the Worldwide Daclizumab Agreement.

ARTICLE 17

TERM AND TERMINATION

17.1 Term. The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article 17, will expire on the date on which neither Party has nor will have any additional payment obligations to the other Party under this Agreement. Upon expiration of the Agreement, provided that there has been **[*]** in at least **[*]**, Roche shall have a fully paid-up license with respect to the licenses granted under Section 2.1(b).

17.2 Termination for Breach.

(a) A Party (**"non-breaching Party"**) shall have the right, in addition to any other rights and remedies, to terminate this Agreement in the event the other Party (**"breaching Party"**) is in breach of any of its material obligations under this Agreement, provided that any such termination shall only be effective with respect to the particular Region(s) to which such breach amounted to a material breach, except that a breach of a material obligation related to the Development Plan shall be deemed a breach of the Agreement in its entirety and shall be subject to the terms of Section 17.2(e). The non-breaching Party shall provide written notice to the breaching Party, which notice shall identify the breach and the Region(s) with respect to which the non-

breaching Party intends to have this Agreement terminate. With respect to breaches of any payment provision hereunder, the breaching Party shall have a period of **[*]** after such written notice is provided to cure such breach; provided, however, if there is a dispute as to whether a development event or commercialization event referenced in Sections 9.2 or 10.6, respectively, has occurred (thereby triggering a payment obligation under such sections), Roche shall not be obliged to make such payment until such dispute is resolved in accordance with Article 18. With respect to all other breaches, the breaching Party shall have a period of **[*]** after such written notice is provided to cure such breach. If such breach is not cured within the applicable period set forth above, this Agreement shall terminate immediately with respect to the applicable Region, upon written notice provided by the non-breaching Party of such termination. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach. Termination for a breach occurring in one or more Regions in the ROW Territory shall not affect any rights or obligation hereunder relating to the U.S. Territory, and *vice versa*, except as otherwise provided above.

(b) For clarity and without limiting the generality of the foregoing, any breach of a material obligation relating to co-promotion of Licensed Product under this Agreement shall be treated as a breach with respect to the U.S. Territory and may therefore give rise to a right, pursuant to Section 17.2(a), to terminate this Agreement solely as to the U.S. Territory.

(c) Consequences of Termination for Roche's Breach.

(i) If Roche breaches the Agreement with respect to a Region in the ROW Territory and PDL terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to such Region, then the following shall apply:

(1) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and

drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related the Licensed Products in the affected Region. The costs of such transfers shall be borne **[*]**;

(2) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under the Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the affected Region;

(3) All licenses granted to Roche under Section 2.1(b) shall terminate with respect to the affected Region; and

(4) The Parties' respective co-development and co-promotion rights and obligations in the U.S. Territory, and the Parties' rights and obligations in any other Region in the ROW Territory shall not be affected by any termination of this Agreement with respect to a Region in the ROW Territory.

(ii) If Roche breaches the Agreement with respect to the U.S. Territory and PDL terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to the U.S. Territory, then the following shall apply:

(1) The Co-Promotion Term, if started, shall end and, if not yet started, shall not commence;

(2) All licenses granted to PDL in Sections 2.2(a), 2.2(b) and 2.2(c) shall become exclusive, perpetual, irrevocable, and fully paid;

(3) All licenses granted to Roche under Section 2.1(a) shall terminate, and Roche shall cease to have any right or obligation to Develop or co-promote Licensed Products in the Asthma Field in the U.S. Territory or to participate in any other commercialization- or development-related activities (including sharing of

Operating Expenses) with respect to Licensed Products in the Asthma Field in the U.S. Territory; and

(4) The Parties' respective rights and obligations with respect to the ROW Territory (and all Regions therein) shall not be affected by any termination of this Agreement with respect to the U.S. Territory.

(iii) Notwithstanding the foregoing Sections 17.2(c)(i) and (ii), in the event that Roche breaches the Agreement with respect to the **[*]** then PDL shall have the right to terminate this Agreement in its entirety and such termination shall have the consequences set forth in Section 17.2(e)(ii).

(d) Consequences of PDL's Breach.

(i) If PDL breaches the Agreement with respect to a Region in the ROW Territory and Roche terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to such Region, then the following shall apply:

(1) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related the Licensed Products in the affected Region. The costs of such transfers shall be borne **[*]**;

(2) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under the Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the affected Region;

(3) All licenses granted to Roche under Section 2.1(b) shall terminate with respect to such affected Region; and

(4) The Parties' respective co-development and co-promotion rights and obligations in the U.S. Territory, and the Parties' rights and obligations in any other Region in the ROW Territory shall not be affected by any termination of this Agreement with respect to a Region in the ROW Territory.

(ii) If PDL breaches the Agreement with respect to a Region in the ROW Territory and Roche has the right to terminate the Agreement in such Region as a result, Roche may elect the following as an alternative remedy to termination:

(1) The Parties' respective rights and obligations with respect to the ROW Territory shall remain unchanged, except that Roche shall be relieved of any diligence obligations with respect to the affected Region for so long as PDL's breach in such affected Region prevents Roche from satisfying such diligence obligations; and

(2) The Parties' respective co-development and co-promotion rights and obligations in the U.S. Territory, and the Parties' rights and obligations in all other Regions in the ROW Territory shall not be affected.

(iii) If PDL breaches the Agreement with respect to the U.S. Territory and Roche terminates the Agreement, pursuant to the procedure outlined in Section 17.2(a), with respect to the U.S. Territory, then the following shall apply:

(1) The Co-Promotion Term shall end;

(2) All licenses granted PDL in Sections 2.2(a) and 2.2(c) shall be suspended until **[*]**;

(3) PDL shall grant to Roche, under the PDL Technology, an exclusive license to use, import, offer for sale and sell Licensed Products in the Asthma Field in the U.S. Territory until **[*]**, provided that if PDL or its Third Party

licensee has filed for regulatory approval in an indication outside of the Asthma Field in the U.S. Territory for Licensed Product having the same formulation and mode of administration as Licensed Product being developed or commercialized for the Asthma Field, then the Parties shall discuss in good faith the feasibility of two parties simultaneously booking sales of Licensed Product;

(4) PDL shall cease to have any right or obligation to Develop or co-promote Licensed Products in the Asthma Field in the U.S. Territory or to actively participate in any other commercialization- or development-related activities with respect to Licensed Products in the Asthma Field in the U.S. Territory until **[*]**, provided that PDL shall retain the right of access to information, meetings and planning reasonably required to ensure effective transition, manufacturing support and return to PDL following **[*]**;

(5) the Parties shall share **[*]** Operating Expenses, Roche's Sales Force Expenses and Gross Margin until **[*]**, provided that any payments **[*]** may be offset by the amount of **[*]**, as set forth in a final non-appealable judgment or award granted in accordance with the dispute resolution procedures of Article 18;

(6) On **[*]**, the licenses to Roche set forth in Sections 2.1(a), 2.1(b) and 17.2(d)(iii)(3) shall terminate, the licenses set forth in Sections 2.2(a) and 2.2(c) shall come back into force and become exclusive, and PDL shall have sole responsibility and decision-making authority for the Detailing, marketing, Promotion, sale and distribution of Licensed Product in the Asthma Field in the U.S. Territory. Except as explicitly provided in Section 10.2, PDL shall owe Roche no consideration in respect to sales of Licensed Product in the Asthma Field in the U.S. Territory after **[*]**, except for the **[*]** provided for hereinabove. In particular, PDL shall not have any obligation to make the payments specified in Section 7.2(c) of the Worldwide Daclizumab Agreement on account of any sales of Licensed Product for use in the Asthma Field in the U.S. Territory after such anniversary; and

(7) The Parties' respective rights and obligations with respect to the ROW Territory (including all Regions therein) shall not be affected by any termination of this Agreement with respect to the U.S. Territory.

(e) Consequences of Material Breach of Development Plan. Notwithstanding the applicability of Sections 17.2(c) or 17.2(d), if a Party breaches a material obligation related to the Development Plan, the non-breaching Party shall have the following alternatives;

(i) Continue the Agreement in effect and pursue any and all remedies available in law or at equity, including the right to seek specific performance of the Parties' respective performance and payment obligations under the Development Plan as well as the right to seek appropriate damages; or

(ii) Terminate the Agreement in its entirety, pursuant to the procedure outlined in Section 17.2(a), in which case the following shall apply:

(1) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related the Licensed Products in the Territory. The costs of such transfers shall be borne **[*]**;

(2) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the Territory; and

(3) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate and Roche shall cease to have any rights with respect to the Licensed Products in the Asthma Field in the Territory.

17.3 Termination for Material Delay. If the JSC adopts a revised Development Plan that sets forth an anticipated commercial launch date for the Licensed Product in the Asthma Field in the U.S. Territory that is **[*]** the anticipated commercial launch date set forth in the Development Plan attached to this Agreement on the Effective Date as Exhibit D, then **[*]** shall have the right to terminate this Agreement with respect to both the ROW Territory and the U.S. Territory by providing written notice of such intent to PDL **[*]**. Such termination would become effective **[*]** after PDL's receipt of such notice, and would have the following effect:

(a) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related the Licensed Products in the Territory. The costs of such transfers shall be borne **[*]**;

(b) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the Territory;

(c) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate and Roche shall cease to have any rights with respect to the Licensed Products in the Asthma Field in the Territory; and

(d) During an additional **[*]** period following the effective date of such termination, Roche shall continue to pay its share any non-cancelable Development Expenses and any other non-cancelable costs that are required to be shared under this Agreement, in each case solely with respect to the ROW Territory and subject to PDL's obligation to use reasonable efforts to mitigate such non-cancelable expenses and costs. In addition, Roche shall provide, **[*]** transition services to ensure effective

transition to PDL or a Third Party designated by PDL for a period not to exceed **[*]** following the effective date of such termination, all on terms to be agreed upon by the Parties.

17.4 Termination at Will. Commencing on **[*]**, Roche shall have the right to terminate this Agreement without cause as follows:

(a) During Development. Prior to the receipt of Regulatory Approval in the U.S. Territory or the European Union, such termination shall pertain to both the ROW Territory and the U.S. Territory and such termination shall become effective **[*]** after PDL's receipt of Roche's written termination notice. During the period between Roche's termination notice and the effective date of such termination (the **"Termination Notice Period"**), the Parties shall continue to perform all of their obligations under this Agreement, including sharing Development Expenses and other costs required to be shared under this Agreement; provided, however, that no payments shall become due or payable for any development or commercialization events first achieved during the Termination Notice Period. Termination of this Agreement pursuant to this Section 17.4(a) shall have the following effects:

(i) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related the Licensed Products in the Territory. The costs of such transfers shall be borne **[*]**;

(ii) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the Territory;

(iii) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate and Roche shall cease to have any rights with respect to the Licensed Products in the Asthma Field in the Territory; and

(iv) During an additional **[*]** period following the effective date of such termination, Roche shall continue to pay its share any non-cancelable Development Expenses and any other non-cancelable costs that are required to be shared under this Agreement, in each case solely with respect to the ROW Territory and subject to PDL's obligation to use reasonable efforts to mitigate such non-cancelable expenses and costs. In addition, Roche shall provide**[*]** transition services to ensure effective transition to PDL or a Third Party designated by PDL for a period not to exceed **[*]** following the effective date of such termination, all on terms to be agreed upon by the Parties.

(b) After Regulatory Approval. After the receipt of Regulatory Approval in the U.S. Territory or the European Union, such termination shall be on a Region-by-Region basis in the ROW Territory and shall become effective **[*]** after PDL's receipt of Roche's written termination notice. During the period between Roche's termination notice and the effective date of such termination (the **"Termination Notice Period"**), the Parties shall continue to perform all of their obligations under this Agreement, including sharing costs required to be shared under this Agreement; provided, however, that no payments shall become due or payable for any development or commercialization events first achieved during the Termination Notice Period that apply solely to terminated Regions. Termination of this Agreement pursuant to this Section 17.4(b) shall have the following effects:

(i) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each

case to the extent in Roche's control and to the extent related the Licensed Products in the terminated countries. The costs of such transfers shall be borne **[*]**;

(ii) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the terminated countries;

(iii) All licenses granted to Roche under Section 2.1(b) (and Section 2.1(a) if the U.S. Territory is terminated) shall terminate with respect to the terminated Region; and

(iv) The Parties' respective co-promotion rights and obligations in the U.S. Territory shall not be affected by any termination of this Agreement pursuant to this Section 17.4(b) with respect to only to Regions that are part of the ROW Territory.

17.5 Termination of Co-Promotion Term by Roche. In the event that, any anytime after **[*]** but before **[*]**, **[*]** falls below **[*]**, Roche shall have the right, within **[*]** after the end of such **[*]**, to provide written notice to PDL of Roche's intent to terminate the Co-Promotion Term, which termination shall be effective at the end of such **[*]** period. In the event that Roche terminates the Co-Promotion Term pursuant to this Section 17.5, then the following shall apply:

(a) All licenses granted to Roche under Section 2.1(a) shall terminate, and Roche shall cease to have any right or obligation to co-promote Licensed Products in the Asthma Field in the U.S. Territory or to participate in any other commercialization- or development-related activities (including sharing of Operating Expenses) with respect to Licensed Products in the Asthma Field in the U.S. Territory;

(b) Until **[*]**, PDL shall pay royalties to Roche at the rate of **[*]** of PDL Net Sales. PDL will not have any obligation to pay royalties to Roche pursuant to Section 10.2. The Parties acknowledge and agree that the royalty payment set forth in

this Section 17.5(b) is in lieu of, rather than in addition to, any payments that would otherwise have been due to Roche pursuant to Section 7.2(c) of the Worldwide Daclizumab Agreement on account of the PDL Net Sales described in this Section 17.5(b); and

(c) The Parties' respective rights and obligations with respect to the ROW Territory shall not be affected by any termination of the Co-Promotion Term pursuant to this Section 17.5.

17.6 Change of Control Termination. In the event of a Change of Control of a Party (the **"Acquired Party"**) in which the Acquired Party is acquired by or becomes an Affiliate of a Major Pharmaceutical Company (the **"Acquiror"**), the other Party (the **"Non-Acquired Party"**) shall have the following rights:

(a) if the Acquiror does not have a product that has received regulatory approval for **[*]** in the U.S. or the European Union, or the Acquired Party and the Acquiror have agreed to divest any such product, then the Non-Acquired Party shall have the right to request in writing to and thereafter discuss face-to-face with the Executive Officer of the Acquired Party the future plans of the Acquired Party for the development and commercialization of Licensed Product in the Asthma Field (**"Status Request"**). Such right shall commence on the date of a public announcement (the **"Announcement Date"**) by the Acquired Party of its intention to undergo such a Change of Control (**"Transaction"**) and expire **[*]** after the close of the Transaction.

If, following a Status Request, the Non-Acquired Party believes in good faith the Acquired Party is either (i) failing to progress the development and/or commercialization of the Licensed Product in the Asthma Field in either the U.S. or European Union because of the Transaction or (ii) not expeditiously proceeding with the divestiture, then the Non-Acquired Party may give the Acquired Party written notice of such alleged failure, identifying the issues and specific reasons for such allegation. The Acquired Party shall have **[*]** to provide the Non-Acquired Party a written response specifying details of (1) why the Transaction has not negatively impacted the development and/or

commercialization of the Licensed Product in the Asthma Field or (2) how it is expeditiously proceeding with the divestiture.

If the Acquired Party fails to timely provide such written response, or has failed within the **[*]** period to remedy such allegations, then the Non-Acquired Party shall have the right to terminate this Agreement in its entirety in accordance with Section 17.6(c).

(b) If the Acquiror has a product that has received regulatory approval for **[*]** in the U.S. or the European Union that will not be divested, the Non-Acquired Party may, upon prior written notice delivered within **[*]** following the Announcement Date, either (i) elect to proceed with the Agreement under the terms of Section 17.6(a), or (ii) terminate this Agreement effective **[*]** after the consummation of the closing of the Transaction. If no election is made under this Section 17.6(b), then the Non-Acquired Party shall be deemed to have elected to proceed with the Agreement under the terms of Section 17.6(a).

(c) In the event of any termination of this Agreement pursuant to this Section 17.6, then the following shall apply:

(i) Roche shall, at PDL's written request, promptly (and in any event within **[*]** after Roche's receipt of such request) assign and transfer to PDL, all of Roche's right, title, and interest in and to all regulatory filings (such as INDs and drug master files), Regulatory Approvals, clinical trial agreements (to the extent assignable and not cancelled), and data, including clinical data, materials, and information, in each case to the extent in Roche's control and to the extent related the Licensed Products in the Territory. The costs of such transfers shall be borne **[*]**

(ii) Roche shall grant to PDL an exclusive, perpetual, irrevocable, fully paid license, under Roche Technology, Collaboration Inventions and patents claiming Collaboration Inventions, to make, have made, use, offer for sale, sell and import Licensed Products in the Asthma Field in the Territory; and

(iii) All licenses granted to Roche under Sections 2.1(a) and 2.1(b) shall terminate and Roche shall cease to have any rights with respect to the Licensed Products in the Asthma Field in the Territory.

17.7 Survival; Accrued Rights. The rights and obligations of the Parties under the following provisions of this Agreement shall survive expiration or any termination of this Agreement: Sections 2.2, 7.7, 8.7, 11.5, 11.9, 12.1, 12.2, 12.3, 12.6, 12.9, 12.10 (solely with respect to Joint Roche-PDL Patents), 12.13, 14.4, 15.1, 15.3, 16.1, 16.2, 16.3, 16.6, 17.1, 17.2(c), 17.2(d)(i), 17.2(d)(iii), 17.2(e)(ii), 17.3, 17.4, 17.6(c), 17.7, and 19.4 and Article 18. In any event, expiration or termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

ARTICLE 18

DISPUTE RESOLUTIONS; GOVERNING LAW

18.1 Disputes. Unless otherwise set forth in this Agreement, in the event of any dispute arising under this Agreement between the Parties (including without limitation any dispute under Article 17), the Parties shall refer such dispute to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute.

18.2 Arbitration. If the Parties are unable resolve a given dispute pursuant to Section 18.1 within sixty (60) days of referring such dispute to the Executive Officers, either Party may have the given dispute settled by binding arbitration in the manner described below:

(a) Arbitration Request. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods as to which Party must cure a breach of this Agreement becomes suspended as to the subject matter of the dispute.

(b) Additional Issues. Within ten (10) business days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

(c) No Arbitration of Patent Issues. Unless otherwise agreed by the Parties, disputes relating to patents shall not be subject to arbitration, and shall be submitted to a court of competent jurisdiction.

(d) Arbitration Procedure. Except as expressly provided herein, the sole mechanism for resolution of any claim, dispute or controversy arising out of or in connection with or relating to this Agreement or the breach or alleged breach thereof shall be arbitration by the American Arbitration Association (**"AAA"**) in **[*]**, under the commercial rules then in effect for the AAA except as provided herein. All proceedings shall be held in English and a transcribed record prepared in English. The Parties shall choose, by mutual agreement, one arbitrator within thirty (30) days of receipt of notice of the intent to arbitrate. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the AAA shall make such appointment within thirty (30) days of such failure. The award rendered by the arbitrator shall include costs of arbitration, reasonable attorneys' fees and reasonable costs for expert and other witnesses, and judgment on such award may be entered in any court having jurisdiction thereof. The Parties shall be entitled to discovery as provided in Sections 1283.05 and 1283.1 of the Code of Civil Procedure of the State of California, whether or not the

California Arbitration Act is deemed to apply to said arbitration. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or

any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, proprietary information, trade secrets, know-how or any other proprietary right. If the issues in dispute involve scientific or technical matters, any arbitrator chosen hereunder shall have educational training and/or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

18.3 Choice of Law. The validity, performance, construction, and effect of this Agreement shall be governed by the laws of the **[*]**, without regard to conflicts of law principles that would provide for application of the law of a jurisdiction outside **[*]** and excluding the United Nations Convention on Contracts for the International Sales of Goods.

ARTICLE 19

MISCELLANEOUS

19.1 Assignment. Either Party may assign this Agreement and the licenses herein granted (a) to any Affiliate of such Party without the prior written consent of the other Party, provided that such Party remains fully liable for the performance of such Party's obligations hereunder by such Affiliate, or (b) without the prior written consent of the other Party, to any Third Party purchaser of all or substantially all of the business unit to which this Agreement relates, which in the case of PDL, shall mean PDL's therapeutic antibody business, and in the case of Roche, shall mean Roche's therapeutic antibody business. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment in violation of this Section 19.1 shall be null and void. This Agreement shall be binding on and shall inure to the benefit of the permitted successors and assigns of the Parties hereto.

19.2 Force Majeure. If either Party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, strike or labor differences, governmental enactment, rule or regulation, or any other cause beyond such Party's control, such Party shall not be liable to the other therefor; and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. The Party invoking such force majeure rights of this Section 19.2 must notify the other Party by courier or overnight dispatch (e.g., Federal Express) within a period of fifteen (15) days of both the first and last day of the force majeure unless the force majeure renders such notification impossible in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds six (6) months, both Parties shall consult together to find an appropriate solution.

19.3 Entire Agreement. This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter herein and, effective as of the Effective Date, supersedes all previous agreements, whether written or oral. Notwithstanding the foregoing, the terms of the Worldwide Daclizumab Agreement shall remain in force and effect (including but not limited to Section 19.3 thereof), except to the extent this Agreement indicates otherwise by specific reference in Sections 6.2(e), 7.7, 10.1, 10.2(b), 10.3(c), 10.5, 15.1, 16.6, 17.2(d)(iii)(6), and 17.5(b) and Article 12 herein. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both Parties.

19.4 Severability. If a Party receives notification of any investigation, inquiry or proceeding regarding the legality, validity or enforceability of any provision under this Agreement, the Parties shall promptly meet to discuss the provision in question and discuss in good faith the appropriate actions, if any, to be taken in response to such notification. If any provision of this Agreement is declared illegal, invalid or unenforceable by an arbitrator pursuant to Article 18 or by a court of last resort or by

any court or other governmental body from the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement, in all other respects and all other jurisdictions, will remain in force; provided, however, that the Parties shall negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing such amendment, either Party may submit the matter to arbitration for resolution pursuant to Article 18.

19.5 Notices. Any notice or report required or permitted to be given under this Agreement shall be in writing and shall be mailed by certified or registered mail, or telexed or telecopied and confirmed by mailing, as follows and shall be effective five (5) days after such mailing:

If to PDL:
Protein Design Labs, Inc.
34801 Campus Drive
Fremont, California 94555
U.S.A.
Attention: Chief Executive Officer

and
Protein Design Labs, Inc.
34801 Campus Drive
Fremont, California 94555
U.S.A.
Attention: General Counsel

If to Roche: Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110
Attention: Corporate Secretary

and F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
CH-4002 Basel, Switzerland
Attention: Law Department

19.6 Further Assurances. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and shall (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

19.7 Agency. Neither Party is, nor will be deemed to be, an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

19.8 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Roche or PDL are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, will be promptly delivered to them (a) upon any such commencement of a bankruptcy proceeding upon their written

request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

19.9 No Waiver. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other Party, shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.

19.10 No Strict Construction. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party.

19.11 Headings. The captions used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits, or limitations.

19.12 Counterparts. This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Co-Development and Commercialization Agreement through their duly authorized representatives to be effective as of the Effective Date.

PROTEIN DESIGN LABS, INC.

By: _____

Title: Chief Executive Officer

Date: _____

HOFFMANN-LA ROCHE INC.

By: _____

Title: _____

Date: _____

F. HOFFMANN-LA ROCHE LTD

By: _____

Title: _____

Date: _____

By: _____

Title: _____

Date: _____

SIGNATURE PAGE

EXHIBIT A

FINANCIAL APPENDIX

This Financial Appendix is a supplement to the definitions and procedures provided in Articles 1 and 11 and Sections 4.6 and 6.3 of this Agreement. References to Articles and Sections are references to the articles and sections of the Agreement. This Appendix sets forth the principles for capturing, reporting and consolidating Operating Expenses, Development Expenses, royalties and gross margin profit sharing. Further, it describes the accounting (i.e. the frequency of reporting, currency, taxes, methods of determining payments between the Parties, auditing of accounts, etc.) and the definitions of Sales Force Expenses, Development Expenses and Operating Expenses.

REPORTING AND CONSOLIDATION

During the applicable period in which such revised budgets are required under the Agreement, preparation of revised annual budgets associated with the Development Plan or the Commercialization Plan (as the case may be) will be initiated in each **[*]** during such period and a preliminary budget should be presented for review by the JSC before end of each **[*]** during such period. The completed annual budget should be endorsed by the JSC between the Parties by the end of each **[*]** during such period. Reporting by each Party will be performed as follows (with copies provided to the JSC and to the other Party):

Reporting Event (calendar basis)	Frequency	Submission Deadline
[*] actuals	end of quarter	**[*]** after end of quarter
[*]	end of quarter	**[*]** after end of quarter
Accruals	end of quarter	**[*]** of last month of the quarter
Preliminary annual budget	annually	**[*]**
Final annual budget	annually	**[*]**
Forecasts (rolling **[*]**), except **[*]**	quarterly	end of **[*]** of the quarter

Responsibility for approving the annual budgets associated with the Development Plan and the Commercialization Plan will rest with the JSC.

The JFC shall be responsible for the preparation of consolidated reporting (actuals, budgets and forecasts) for the Operating Expenses and Development Expenses as well as determination of the cash settlement. The JFC shall provide the JSC (and the Party not preparing the consolidated reporting on behalf of the JFC) within forty-five working days after the submission date shown above, a statement showing the consolidated results, forecasts and cash settlements required in a format agreed to by the Parties.

The JFC will be responsible for monitoring and agreeing upon appropriate controls to ensure reasonable and consistent calculation and allocation of Sales Force Expenses, Operating Expenses and Development Expenses under the Agreement. More specifically, the JFC shall review the projected versus actual FTE's per quarter and the process by which third parties are retained to provide services in the performance by the Parties under the Agreement. In any event, the JFC shall review use of FTE resources on a quarterly basis. The Parties shall also use commercially reasonable efforts to provide access to available discounts and discount programs available from existing vendors for the benefit of the Parties under the Agreement.

Reports of actual results compared to budget will be made by the JFC. The Parties will work together to keep actual spending within the approved budget. The Parties shall discuss in good faith the adoption of additional control measures to address deviations from the approved budget on an aggregate annual basis above **[*]** In any event, if a Party contemplates that an expenditure will increase the annual budget in excess of **[*]**, the Parties shall review the expenditure with the JFC prior to commitment to that expenditure. The JFC will meet as appropriate to review and approve the reporting events (actuals, accruals, budgets and forecasts).

Each Party will use its applicable project cost system with the goal of tracking and reporting costs on a project/product indication/work package basis consistent with its other projects/products in development.

ACCOUNTING

1. Audits. Each Party (the **"Audited Party"**) agrees to keep full, clear and accurate records for a period of at least three (3) years after the relevant report is made pursuant to Section 4.6(c), 6.3(b) or 11 setting forth its Development Expenses, Operating Expenses, Sales Force Expenses or Net Sales, as applicable, incurred in sufficient detail to enable royalties and compensation payable to the other Party (the **"Auditing Party"**) hereunder to be determined. Each Audited Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the Auditing Party to verify reports made pursuant to Section 4.6(c) or 6.3(b), as applicable. Unless the Auditing Party obtains the prior written consent of the Audited Party, such accounting firms must be selected from among the four largest global accounting firms. Such audit shall not be performed more frequently that **[*]** per

calendar year nor more frequently than **[*]** with respect to records covering any specific period of time. Such examination is to be made at the expense of the Auditing Party, except in the event that the results of the audit reveal a discrepancy in favor of the Audited Party of **[*]** or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Audited Party**.**

2. Methods of Payments. All payments due to either PDL or Roche under this Agreement shall be paid in Dollars by wire transfer to a bank in the U.S. designated in writing by the Party to which the payment is due**.**

3. Taxes. If provision is made in law or regulation of any country of the Territory for withholding of taxes of any type, levies or other charges with respect to any amounts payable hereunder to a Party, the other Party (**"Withholding Party"**) shall promptly pay such tax, levy or charge for and on behalf of the Party to the proper governmental authority, and shall promptly furnish the Party with receipt of such payment. The

Withholding Party shall have the right to deduct any such tax, levy or charge actually paid from payment due the Party or be promptly reimbursed by the Party if no further payments are due the Party. Each Withholding Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted**.**

4. Currency. All payments under this Agreement shall be in Dollars. Whenever payments require conversion from a foreign currency, then this shall be converted using the average daily exchange rate for the period to be reported based on Roche Swiss Franc Sales Statistics, which shall be based on exchange rate information obtained from the Reuters system**.**

5. Late Payments. Any amount owed by one Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the **[*]** as reported by Datastream (or a successor or similar organization)**.**

6. General. As a general matter, the Parties do not intend that expenses paid for or credited under this Agreement will be charged or credited more than once.

DEFINITIONS

A. SALES FORCE EXPENSES

Sales Force Expenses shall mean costs directly associated with the efforts of field sales representatives with respect to Licensed Products, including costs associated with field sales forces, field sales offices, and home offices staffs directly involved in the management of and the performance of the selling functions.

B. DEVELOPMENT EXPENSES

Development Expenses shall mean the expenses incurred by a Party or for its

account that are consistent with the Development Plan and specifically are attributable to the Development of a Licensed Product. Development Expenses shall include amounts paid by a Party to Third Parties involved in the Development of Licensed Products, and all internal costs incurred by a Party in connection with the Development of Licensed Products. Notwithstanding anything to the contrary herein, Development Expenses shall not include any Incremental Development Expenses. Development Expenses for manufacturing of clinical supplies shall be as set forth in Article 8.

Development Expenses shall include but are not limited to the cost of the development of research plans and programs, screening, lead optimization, in vitro and in vivo testing, studies on the toxicological, pharmacokinetic, metabolic or clinical aspects of such Product conducted internally or by individual investigators, or consultants necessary for the purpose of obtaining and/or maintaining approval of such Product by a government organization in a country, and costs for preparing, submitting, reviewing or developing data or information for the purpose of a submission to a governmental authority to obtain and/or maintain approval of Product in a country as well as costs of process development and scale-up costs and recovery (including plant costs). Development Expenses shall further include costs of Phase IV Trials and Post-Launch Product R&D Expenses. Development Expenses shall not include patent costs, pre-Registration marketing costs (e.g. trademark costs, advertising agency selection costs, pre-marketing studies), post-Registration clinical studies which are not enabling for Registration of the Product and post-Registration marketing studies.

Development Expenses constitute of two main accounting elements, variable costs and fixed costs.

Variable costs are external costs invoiced from third parties.

Fixed costs include the amounts expended for personnel, relocation, travel, entertainment and training incurred by the functions directly operating the program. The work scope of these functions include activities within the areas of development operations, clinical quality insurance, medical science, genetics integrated medicine,

drug regulatory and technical development. To these primary fixed costs should be added the secondary fixed costs which are attributable to a Party's costs for IT software and hardware, IT external costs, depreciation, occupancy costs, corporate bonus (to the extent not charged directly), and its payroll, information systems, human relations or purchasing functions. These secondary fixed costs are allocated to company departments based on space occupied or headcount or other activity-based method. The secondary fixed costs further includes costs attributable to general corporate activities for executive

management, investor relations, business development, legal affairs and finance. In determining all these fixed costs, the Parties have agreed on an FTE-rate that will be charged for the resources allocated to the programs from the functions directly operating the programs on a fractional FTE-basis. The Parties have agreed on a FTE rate which will be used for calculating FTE's in the performance of Development activities under the Agreement. The Parties contemplate that this rate captures total actual personnel and fixed costs attributable to the performance of the Joint Development Plan under this Agreement.

All FTE expenditures shall be included in Development Expenses based on a rate of **[*]** per FTE. Each **[*]** beginning **[*]**, the FTE rate will be **[*]** compared to previous calendar year.

Time-recording will be used by all people within these functions to record actual time spent on the activities under the programs. For clarity, FTE time recording should be made on a fractional basis. Each Party will also use its applicable project cost system with the purpose of tracking and reporting costs on a project/product indication/work package level.

C. POST-LAUNCH PRODUCT R&D EXPENSES

Post-Launch Product R&D Expenses shall include certain research and development costs incurred by a Party in relation to a Licensed Product after the first commercial launch and shall exclude administrative expenses and costs that are

included within Costs of Goods Sold. Such post-launch research and development costs shall include, to the extent relating to a Licensed Product:

- Phase IV Trials.
- Ongoing medical affairs (PDL) and the counterpart for Roche.
- Preclinical research.
- Contract R&D costs performed by others for a particular project that have no alternative future uses in other R&D projects or otherwise.
- Fees and expenses of outside counsel in respect of regulatory affairs unrelated to obtaining Regulatory Approval.

D. OPERATING EXPENSES

Operating Expenses means those expenses incurred by a Party which are generally consistent with the Commercialization Plan (and associated budget) and are specifically attributable to Licensed Products in the U.S. Territory, and shall consist of (i) Marketing Expenses, (ii) Distribution Expenses, (iii) Third Party License Expenses, (iv) Allocated Administration Expenses, and (v) Patent and Legal Expenses. Operating Expenses shall exclude Development Expenses and Sales Force Expenses. Notwithstanding the foregoing, Patent and Legal Expenses need not be consistent with the Commercialization Plan (and associated budget) as long as they have been approved by the JSC.

1. MARKETING EXPENSES

Marketing Expenses means the costs incurred by a Party, excluding Allocated Administration Expenses and Sales Force Expenses, which are generally consistent with the Commercialization Plan (and associated budget) and are specifically attributable to the sale, promotion, and/or marketing of a Licensed Product in the U.S. Territory. Marketing Expenses shall be the sum of Marketing Management, Market and

Consumer Research, Advertising, Trade Promotion, Consumer Promotion, and Education Expenses (each of which is specified below), and the cost of performing Non-Registrational Trials (as defined in Section 1.44).

1.1 ***"Marketing Management"*** shall include product management and sales promotion management compensation and departmental expenses. This shall include costs associated with developing overall sales and marketing strategies and planning for Licensed Products. In addition, payments to Third Parties in connection with trademark selection, filing, prosecution and enforcement shall be included in this category.

1.2 ***"Market and Consumer Research"*** shall include compensation and departmental expenses for market and consumer research personnel and payments to Third Parties related to conducting and monitoring professional and consumer appraisals of existing, new or proposed Licensed Products such as market share services (e.g., IMS data), special research testing, and focus groups. Costs incurred pursuant to Section 7.6 shall not be included in Market and Consumer Research, but shall be shared in accordance with the terms set forth in Section 7.6.

1.3 ***"Advertising"*** shall include all media costs associated with Licensed Product advertising as follows: production expense/artwork including set up; design and art work for an advertisement; the cost of securing print space, air time, etc. in newspapers, magazines, trade journals, television, radio, billboards, etc.

1.4 ***"Trade Promotion"*** shall include the allowances given to retailers, brokers, distributors, hospital buying groups, etc. for purchasing, promoting, and distribution of Licensed Products. This shall include purchasing, advertising, new distribution, and display allowances as well as free goods, wholesale allowances and reasonable field sales samples. To the extent multiple products are involved and some of such products are not Licensed Products, then such allowances shall be allocated on a *pro rata* basis based upon net sales of each respective product by such operating unit during the most recent quarter.

1.5 ***"Consumer Promotion"*** shall include the expenses associated with programs to promote Licensed Products directly to the end user. This category shall include expenses associated with promoting products directly to the professional community such as professional samples, professional literature, promotional material costs, patient aids and detailing aids. To the extent multiple products are involved and some of such products are not Licensed Products, then such allowances shall be allocated on a *pro rata* basis based upon net sales of each respective product by such operating unit during the most recent quarter.

1.6 ***"Education"*** shall include expenses associated with professional education with respect to Licensed Products through any means not covered above, including articles appearing in journals, newspapers, magazines or other media; seminars, scientific exhibits, and conventions; and symposia, advisory boards and opinion leader development activities.

2. DISTRIBUTION EXPENSES

Distribution Expenses shall be the sum of Stock and Shipping expenses and Transportation expenses, each as specified below.

2.1 ***"Stock and Shipping"*** shall include the portion of distribution costs for the warehousing of Licensed Product finished goods from the point of completion of production to the time the goods are turned over to a carrier for delivery as follows: order filling/assembly functions; reasonable order billing and customer service functions; reasonable portion of company owned/leased facilities relating to warehousing of finished products; storage of products at public warehouses.

2.2 ***"Transportation"*** shall include the portion of distribution costs relating to moving Licensed Product goods from a warehouse to the customer as follows: outbound transportation costs; costs of moving goods from a manufacturing point to a warehouse at another location from which it is ultimately to be distributed to a customer;

the costs of the traffic department where there is a separate department that has responsibility for administration of freight costs.

3. THIRD PARTY LICENSE EXPENSES

Third Party License Expenses means all payments by a Party under Third Party Licenses that are allocable to the use, development, sale, manufacture, or import of Licensed Product in the U.S. Territory, including without limitation all payments by a Party under Third Party Licenses (a) calculated based on sales of Licensed Product in the U.S. Territory; (b) made on account of achievement of particular events relating to development or commercialization of Licensed Product in the U.S. Territory; and (c) as consideration for a grant of a license or other rights in the U.S. Territory.

4. ALLOCATED ADMINISTRATION EXPENSES

Allocated Administration Expenses means the administration expenses incurred by a Party or any of its operating units that are actually directly engaged in the commercialization of Licensed Products in the U.S. Territory pursuant to the Commercialization Plan, to be calculated in the manner set forth below. In view of the manner in which Allocated Administration Expenses are calculated, administration expenses shall be excluded from the definition of each of the other elements which make up Operating Expenses.

The costs recoverable as Allocated Administration Expenses are the costs of finance, management information services, human resources, legal, and employees engaged in general management functions for the operating units in question. Cost categories included within Allocated Administration Expenses shall not be included in any other cost recoverable under this Agreement.

Recoverable administration expenses shall include the direct costs of employees performing such functions, the costs of supporting such individuals in the performance of their job (e.g., occupancy costs, travel, computers, and telephones), and outside services (e.g., consulting and audit services). Such costs shall be calculated in

accordance with the customary accounting methodology of the Party incurring such expenses, consistently applied throughout such organization. Such costs shall be allocated based on a percentage determined by sales of Licensed Product supported by such operating unit(s) divided by the total product sales supported by such operating unit(s) during the relevant quarter. Total Allocated Administrative Expenses of a Party shall not exceed **[*]** of the Operating Expenses incurred by such Party (less Allocated Administrative Expense), on an annualized basis.

5. PATENT AND LEGAL EXPENSES

Patent and Legal Expenses means (a) the fees and expenses of outside counsel and payments to Third Parties incurred after the Effective Date in connection with the preparation, filing, prosecution and maintenance of PDL Trademarks and those patent fees and expense set forth in Section 12.7, (b) all expenses associated with Third Party claims in the U.S. Territory for which neither Party has an indemnification obligation pursuant to Article 16, and (c) all expenses associated with latent defects in the Licensed Product in the U.S. Territory for which neither Party has an indemnification obligation pursuant to Article 16. For clarity, no internal legal costs shall be included in Patent and Legal Expenses.

EXHIBIT B

GMP AUDIT

Following the Effective Date, the Parties shall form an advisory group, consisting of qualification experts from both PDL and Roche. This group will advise PDL on the qualification and validation activities (including a discussion of the PDL process evaluation and process validation plan for Daclizumab) required to license PDL's manufacturing facility. They will also coordinate an initial, informal audit by Roche of the PDL manufacturing facility project. This audit should be performed following mechanical completion **[*]**, and include a review of the Impact Assessment, the System Boundary Drawings, the Commissioning Documents, and sample IQ, OQ, and PQ Documents; which is consistent with the ISPE Baseline Guide for Commissioning and Qualification Activities (the qualification approach currently being applied by PDL). This initial audit is advisory only, and as such, will not trigger any development event payment.

Roche will perform a formal GMP Audit after the completion of PQ by PDL. This audit will include a review of PDL's PQ Plans and Reports, and their overall Quality Management System, using the standards set forth in ICH Q7A and the US and EMEA Regulations. For clarity, PQ, Process Qualification, is the documented verification that premises and equipment perform effectively, reliably, and meeting predetermined acceptance criteria. The PQ of process support and utility systems involves the operation, sampling, and monitoring of the system under specified conditions over a relevant period of time. Therefore, PQ is mandatory for the critical process support and utility systems, as determined in the PDL Impact Assessment.

PDL should keep Roche directly informed as to their progress toward completion of the PQ, informing Roche of any significant issues that arise. When nearing the completion of PQ, PDL should supply Roche with advance copies of their PQ procedures, plans, and other related documents, and determine, with Roche, an appropriate timeline for the GMP Audit, which allows both parties to prepare properly.

The GMP Audit will be successful if (a) the PQ Plans, PQ Reports, and Quality Management System are in compliance with cGMP guidelines and (b) there are no observations which (i) will lead to a significant delay of Phase III clinical development or the anticipated launch of the product, (ii) present a significant risk of non-acceptance of the site by regulatory authorities for clinical and/or commercial supplies, or (iii) may place clinical material or commercial supplies "at risk".

Following the completion of a **[*]**, but prior to **[*]**, the payment described in 9.2(c) will be due.

EXHIBIT C

THIRD PARTY LICENSES

7. [*]

To the extent that one or more additional agreements entered into by a Party prior to the Effective Date are necessary for the use, manufacture, sale, offering for sale, or importation of Licensed Products in the Asthma Field in the Territory (or to the extent that one or more of the agreements listed on this Exhibit C as of the Effective Date are not necessary therefor), the Parties agree to discuss in good faith the amendment of this Exhibit C to include (or to remove, as appropriate) any such agreements that a Party may reasonably suggest to the other Party in writing during the thirty (30) days immediately following the Effective Date.

EXHIBIT D

DEVELOPMENT PLAN

The attached Development Plan currently identifies the timeline and budget agreed upon by the Parties effective as of **[*]**. The budget does not include **[*]**, which the Parties have agreed will be reviewed by the JDC for inclusion or exclusion as part of the Development Plan. The Development Plan consists of the following documents:

1. Development Plan Summary
2. Development Plan Gantt Chart
3. Clinical Model Roche Rate
4. Daclizumab IPP
5. Detailed Activity breakdown
6. Development Timeline Allocation of Responsibilities
7. Clinical Development Information

The Parties acknowledge that the Phase III clinical studies in the Development Plan will not be initiated without available clinical supply manufactured in the facility expected to produce the commercial supply.

The Parties currently agree that the available safety database at BLA filing shall contain **[*]** (currently contemplated to be approximately **[*]**. If the Parties identify that, due to factors such as drop-out rate, changes in the Development Plan, or other factors, the number of treated patients in the safety database at

filing will be less than **[*]**, then the JDC will propose amendments to the Development Plan to ensure that the safety database contains **[*]**.

[*]

EXHIBIT E

[*] TESTING PLAN

Roche and PDL recognize that the ideal assessment of Daclizumab **[*]** would accurately determine clinically relevant **[*]** responses to Daclizumab for the proposed asthma indication within this particular patient population. Clinically relevant responses reflect issues related to **[*]**.

The **[*]** plan should be discussed on a regular basis with regulatory authorities especially at the end of phase II meeting.

I. Assay outline:

Samples from clinical study subjects in the asthma development program will be tested for **[*]** The primary **[*]** assessment methods will comprise:

[*]

II. [*] definition:

For the purposes of identifying **[*]** response, a **[*]** is defined as one of the following:

[*]

III. [*] and Patient testing:

Throughout the development of the compound, **[*]** will be done.

[*]

IV. Deliverables:

End of Phase 1:

[*]

Interim analysis of **[*]**

[*]

The JDC will assess the possibility and desirability of developing **[*]** for testing **[*]**.

[*]

V. Development Events:

For the purposes of this Agreement, the rate of **[*]** as determined by step 3 **[*]** will be used for certain development payments and project decisions.

Phase 1 Development Event:

(1) Not more than **[*]** and (2) an acceptable **[*]**

Phase 2 Development Event:

Not more than **[*]**

EXHIBIT F

PRESS RELEASE

Media Release

Basel, Switzerland and Fremont, CA 16 September, 2004

Roche and Protein Design Labs to jointly develop Zenapax for Asthma

Roche and Protein Design Labs (PDL) (NASDAQ: PDLI) today announced a worldwide agreement to co-develop and commercialize Zenapax® (Daclizumab) for asthma and related respiratory diseases, based on recent positive phase II data in patients with moderate to severe asthma.

Mark McDade, Chief Executive Officer, PDL, said, "The continued development of daclizumab in asthma is among PDL's highest clinical development priorities. With Roche as our ongoing partner in this indication, we believe daclizumab will obtain the resources needed to develop the full potential of this humanized antibody in asthma."

"This new agreement will strengthen our pipeline in asthma, where we are currently in phase II development of a novel oral treatment," said William Burns, Head of Roche's Pharmaceuticals Division. "We believe that daclizumab will offer patients a significant improvement over today's current therapy. Our long-standing relationship with PDL continues to grow as we develop daclizumab further."

Under terms of the agreement, PDL will receive a $17.5 million upfront payment as well as up to $187.5 million in development and commercialization milestones for successful further development of

daclizumab. Roche and PDL will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the US. Outside the US, PDL will receive royalties on net sales of the product in asthma.

About the Roche - PDL partnership
In 1989, Roche acquired the worldwide rights to daclizumab, a product that has since gained an important position within Roche's transplantation portfolio. In October 2003, Roche resold to PDL all rights to daclizumab, except in transplantation, until 2007 when PDL will have the option to re-acquire the transplantation rights as well. In 2004, PDL approached Roche with compelling phase II data for daclizumab in asthma, leading to today's announcement for the continued co-development of daclizumab in respiratory disorders by Roche and PDL.

About Asthma
Asthma is among the most common chronic medical conditions in the United States and worldwide, affecting more than 20 million people in the United States, according to the American Lung Association (ALA) and the American Academy of Allergy, Asthma & Immunology (AAAAI). According to a recent report on the global burden of asthma published by the NIH, WHO and the Global Initiative for Asthma, asthma is one of the most common chronic diseases in the world and it is estimated that around 300 million people in the world currently have asthma. The rate of asthma continues to increase and it is estimated that there may be an additional 100 million persons suffering from asthma by 2025. Asthma accounts for 1 in every 250 deaths worldwide.

About Protein Design Labs
In October 2003, PDL acquired all rights to Zenapax®, excluding transplantation indications but with the option to gain such indication rights by 2007. PDL retains this right in accordance with the terms of the October 2003 agreement.
Protein Design Labs is a leader in the development of humanized antibodies to prevent or treat various disease conditions. PDL currently has antibodies under development for autoimmune and inflammatory

conditions, asthma and cancer. PDL holds fundamental patents for its antibody humanization technology. Further information on PDL is available at www.pdl.com.

About Roche
Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is number one in the global diagnostics market, a leading supplier of pharmaceuticals for cancer and transplantation and a market leader in virology. In 2003 prescription drug sales by the Pharmaceuticals Division totalled 19.8 billion Swiss francs, while the Diagnostics Division posted sales of 7.4 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has alliances and R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

Webcast scheduled for 8:30 a.m. Eastern time on September XXX.
PDL will host a webcast beginning at 8:30 a.m. Eastern time on September XX, 2004, to discuss the joint development and commercialization agreement.

The live webcast will be available through the PDL website: www.pdl.com. Please connect to this website at least 15 minutes prior to the live webcast to allow time for any software download that may be needed to hear the webcast. A replay will be available at www.pdl.com starting approximately one hour after completion of the webcast.

An audio replay will also be available by telephone from approximately 10:30 a.m. Eastern time on September XX, 2004 through 10:30 a.m. Eastern time on September XX, 2004. To access the replay, dial 800-633-8284 from inside the United States and 402-977-9140 from outside the United States; enter conference ID number 21207310.

Conditions

The foregoing contains forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those in the forward-looking statements. Factors that may cause such differences are discussed in PDL's Annual Report on Form 10-K for the year ended December 31, 2003, in its Quarterly Report on Form 10-Q for the three months ended June 30, 2004, and in other filings made with the Securities and Exchange Commission. In particular, results obtained in the Phase II study may not be predictive of results to be obtained in the additional evaluations that would be necessary to demonstrate the antibody to be safe and effective in the treatment of asthma, nor can there be assurance that PDL will initiate subsequent clinical trials in asthma.

Protein Design Labs and Humanizing Science are registered U.S. trademarks and the PDL logo is considered a trademark of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche

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ENDS

EXHIBIT G

REGIONS

1) United States of America

2) Canada

3) Japan

4) Western Europe
- The 15 pre May 1, 2004 EU member states
- Switzerland
- Turkey
- Norway
- Iceland

5) Central and Eastern Europe
- Albania
- Belarus
- Bosnia-Herzegovina
- Bulgaria
- Croatia
- Czech Republic
- Estonia
- Hungary
- Latvia
- Lithuania
- Macedonia
- Moldavia
- Poland

Romania
Russia
Serbia & Montenegro
Slovakia
Slovenia
Ukraine

6) Latin America

34 countries from Mexico to Argentina including:
Argentina
Brazil
Chile

Colombia
Costa Rica
Ecuador
Mexico
Peru
Uruguay
Venezuela

7) Asia/Pacific

Bangladesh
Cambodia
China (including Hong Kong)
India
Indonesia
Korea
Malaysia
Pakistan
Philippines
Singapore
Sri Lanka
Taiwan
Thailand
Vietnam
Australia
New Zealand

8) Pharma International

All countries not listed above

SCHEDULE 14.2(A)

[*]

SCHEDULE 14.2(B)

[*]

EXHIBIT 31.1

CERTIFICATIONS

I, Mark McDade, certify that:

1. I have reviewed this quarterly report on Form 10Q of Protein Design Labs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2004

/s/ Mark McDade

Mark McDade
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Glen Sato, certify that:

1. I have reviewed this quarterly report on Form 10Q of Protein Design Labs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2004

/s/ Glen Sato
Glen Sato
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATIONS

Mark McDade, Chief Executive Officer and Glen Sato, Chief Financial Officer of Protein Design Labs, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

(1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

A signed original of this written statement required by Section 906 has been provided to the Securities and Exchange Commission or its staff upon request.

Dated: November 3, 2004

By:

/s/ Mark McDade
Mark McDade
Chief Executive Officer

/s/ Glen Sato
Glen Sato
Chief Financial Officer