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, 2005

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 the Exchange Act). Yes ☒ No o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

As of October 31, 2005 there were 112,836,807 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,	
	2005	2004	2005	2004
Revenues:				
Product Sales	$ 43,144	$ —	$ 79,437	$ —
Royalties	26,003	17,131	96,695	63,872
License and other	7,536	2,653	17,127	9,323
Total revenues	76,683	19,784	193,259	73,195
Costs and expenses:				
Cost of product sales	22,209	—	43,481	—
Research and development	49,480	27,326	125,080	92,364
Selling, general and administrative	26,795	7,664	54,267	23,182
Asset impairment charge	15,225	—	15,225	—
Acquired in-process research and development	—	—	79,417	—
Total costs and expenses	113,709	34,990	317,470	115,546
Operating loss	(37,026)	(15,206)	(124,211)	(42,351)
Interest and other income, net	2,027	2,822	6,835	7,689
Interest expense	(2,671)	(1,193)	(7,522)	(3,929)
Loss before income taxes	(37,670)	(13,577)	(124,898)	(38,591)
Provision for income taxes	1,680	12	1,767	68
Net loss	$ (39,350)	$ (13,589)	$ (126,665)	$ (38,659)
Net loss per basic and diluted share	$ (0.37)	$ (0.14)	$ (1.24)	$ (0.41)
Shares used in computation of net loss per basic and diluted share:	105,272	95,196	101,910	94,771

See accompanying notes.

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

	September 30, 2005	December 31, 2004
ASSETS		

Current assets:		
Cash and cash equivalents	$ 181,766	$ 91,395
Marketable securities, including $6.8 million and $6.9 million of restricted investments at September 30, 2005 and December 31, 2004, respectively	150,912	298,969
Accounts receivable, net of allowances of $6.4 million	17,906	—
Inventories	18,688	—
Deferred tax assets	10,100	—
Prepaid expenses and other current assets	10,677	9,750
Total current assets	390,049	400,114
Land, property and equipment, net	261,698	238,077
Goodwill	57,520	—
Other intangible assets, net	424,104	31,309
Restricted investments	—	6,716
Other assets	13,606	7,516
Convertible note receivable	30,000	30,000
Total assets	**$ 1,176,977**	**$ 713,732**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,000	$ 4,921
Accrued compensation	14,801	6,977
Accrued clinical trial costs	4,021	1,324
Accrued interest	1,485	2,593
Royalties payable	2,830	—
Income taxes payable	3,020	—
Other accrued liabilities	23,089	9,327
Deferred revenue	56,675	17,389
Current portion of long-term obligations	697	923
Total current liabilities	117,618	43,454
Convertible subordinated notes	499,998	249,998
Notes payable	—	7,469
Other long-term debt	7,387	301
Total liabilities	625,003	301,222
Commitments		
Stockholders' equity:		
Common stock, par value $0.01 per share, 250,000 shares authorized; 112,646 and 95,857 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	1,125	959
Additional paid-in capital	955,319	686,302
Deferred stock-based compensation	(2,122)	—
Accumulated deficit	(400,197)	(273,532)
Accumulated other comprehensive loss	(2,151)	(1,219)
Total stockholders' equity	551,974	412,510
Total liabilities and stockholders' equity	**$ 1,176,977**	**$ 713,732**

See accompanying notes.

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

	Nine Months Ended September 30, 2005	2004
Cash flows from operating activities:		
Net loss	$ (126,665)	$ (38,659)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Asset impairment charge	15,225	—
Acquired in-process research and development	79,417	—
Adjustment to goodwill related to ESP Pharma acquisition	9,839	—
Depreciation and amortization	11,214	8,613
Amortization of convertible notes offering costs	1,620	905
Stock-based compensation expense	510	878
Amortization of intangible assets	26,506	1,839
Stock option income tax benefit	300	—
Loss on disposal of fixed assets	—	515
Non-cash license and other revenue	—	(4,000)
Non-cash in-licensing research and development expenses	—	3,000
Changes in assets and liabilities:		
Inventories	48	—
Accounts receivable, net	(26,231)	—
Interest receivable	(157)	(844)
Deferred tax assets	(10,100)	

Prepaid expenses and other current assets	977	5,982
Other assets	459	(657)
Accounts payable	4,243	868
Accrued liabilities	2,727	(7,079)
Deferred revenue	39,286	17,099
Total adjustments	155,883	27,119
Net cash provided by (used in) operating activities	29,218	(11,540)
Cash flows from investing activities:		
Purchases of marketable securities	—	(312,228)
Maturities of marketable securities	147,060	172,849
Maturities of restricted investments	6,876	7,313
Cash paid for ESP Pharma acquisition	(325,000)	—
Cash obtained from ESP Pharma	2,442	—
Cash paid for Retavase acquisition	(110,000)	—
Purchases of property and equipment	(32,564)	(80,693)
Net cash used in investing activities	(311,186)	(212,759)
Cash flows from financing activities:		
Proceeds from issuance of capital stock	131,117	14,453
Proceeds from issuance of convertible notes	241,831	—
Payments on other long-term obligations	(609)	(1,022)
Net cash provided by financing activities	372,339	13,431
Net increase (decrease) in cash and cash equivalents	90,371	(210,868)
Cash and cash equivalents at beginning of period	91,395	341,768
Cash and cash equivalents at end of period	$ 181,766	$ 130,900

See accompanying notes.

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
September 30, 2005
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. (we, us, our, PDL or the Company) is a biopharmaceutical company focused on the research, development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several biopharmaceutical products in the United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products.

On June 8, 2005, our stockholders approved a change in the name of the Company to PDL BioPharma, Inc. We anticipate that this name change will become effective in January 2006.

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 for quarterly reporting.

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, 2004. The Consolidated Condensed Balance Sheet as of December 31, 2004 is derived from our audited consolidated financial statements as of that date.

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, Inc. (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 since we generally recognize royalty revenue in the quarter subsequent to sales by our licensees (see Royalties section below). In addition, as a result of the closing of our acquisition of ESP Pharma Holding Company, Inc. (ESP Pharma) on March 23, 2005, the results of operations of ESP Pharma from March 24, 2005 are included in our consolidated condensed financial statements (see Note 6).

Principles of Consolidation

The consolidated condensed financial statements include the accounts of the Company and its wholly owned subsidiaries after elimination of inter-company accounts and transactions.

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.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in, first-out method. If the inventory costs exceed the market value, reserves are recorded currently for the difference between the cost and the market value. These reserves are determined based on management's estimates. Inventories consist of finished goods, work-in-process and raw materials (including active pharmaceutical ingredients). As a result of the ESP Pharma and *Retavase*®

acquisitions (see Notes 6 and 7), we acquired and recorded inventories at then fair market value, which approximated the original cost of the inventory purchased from third-party manufacturers.

Revenue Recognition

We currently recognize revenues resulting from product sales, from licensing and use of our technology, from reimbursement of development costs and from services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." Royalty, licensing and other 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 in a revenue arrangement 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, when 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:

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances and accruals are established for estimated discounts, sales returns, doubtful accounts, chargebacks and rebates.

Accounts Receivable, Sales Allowances and Rebate Accruals

Accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, government chargebacks, rebates and sales returns. When we estimate cash discounts, government chargebacks and sales returns we consider contractual terms, historical trends experienced by ESP Pharma and the previous owner of the products, and expectations regarding the utilization rates for these programs. These amounts are recorded as an offset to product sales in the same period the related revenue is recognized. In determining allowances for product returns, chargebacks and rebates, we must make significant judgments and estimates. For example, in determining these amounts, we estimate hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers. Making these determinations involves estimating whether trends in past buying patterns will predict future product sales. Our estimates are based on the historical chargeback data we receive from wholesalers and the applicable customer chargeback rates, returns and rebate thresholds we have from Wyeth and Centocor, Inc. (Centocor) with respect to *Cardene* IV and *Retavase*, respectively. Allowances for chargebacks, returns and rebate accruals require substantial judgment. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made, based on actual results.

Since our acquisition of ESP Pharma, we have adjusted our allowances for product returns, chargebacks and rebates based on more recent experience rates, and we will likely be required to make adjustments to these allowances in the future as we market and promote these products for ourselves. We continually monitor our allowances and make adjustments when we believe actual experience may differ from our estimates.

Accrued rebates include amounts due under Medicaid and other commercial contractual rebates. Rebates are recorded in the same period that the related revenue is recognized resulting in a reduction of product sales revenue and the establishment of either a contra asset or a liability, which are included in sales allowances or other accrued liabilities, respectively. Accrued rebates are recorded based on a percentage of selling price determined from historical experience rates. Medicaid rebate accruals are evaluated based on historical rebate payments by product as a percentage of historical sales, product pricing and current contracts.

Estimates for our allowance for doubtful accounts are determined based on existing contractual obligations, historical payment patterns of our customers, credit quality of our customers and individual customer circumstances and are included in selling, general and administrative expenses.

Royalties

Under most of our patent license agreements, we receive royalty payments based upon our licensees' net sales of products. Generally, under these agreements 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 also receive royalties on a generic product that

we have licensed for sale. 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 licensees, such as product licenses. Under these agreements, our licensees 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. In certain instances, our collaboration agreements involve a combination of upfront fees, milestones and development costs where we are not able to establish fair value of all of the undelivered elements. We recognize these upfront fees, milestones and reimbursements of development costs as the services are performed and out-of-pocket costs are incurred.

Advertising and Promotion

The Company engages in promotional activities, which typically take the form of industry publications, journal ads, exhibits, speaker programs, and other forms of media. In accordance with procedures defined under Statement of Position 93-7, "Reporting on Advertising Costs," advertising and promotion expenditures are expensed as incurred. Total advertising costs incurred during the three and nine months ended September 30, 2005 were $6.2 million and $9.9 million, respectively, and no such costs were incurred in 2004.

Stock-Based Compensation

As of September 30, 2005, 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. Accordingly, we recognize no compensation expense in our consolidated statements of operations with respect to options awarded to our employees with exercise prices greater than or equal to the fair value of the underlying common stock at the date of grant. However, we recognize compensation expense in our consolidated statements of operations with respect to the modification of certain employee stock option awards. During the quarter ended September 30, 2005, we recognized approximately $121,000 in stock-based compensation expense related to the issuance of restricted stock to certain employees, compared to $17,000 recognized in the corresponding quarter of 2004 related to the modification of 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.

(In thousands, except per share data)	Three Months Ended September 30, 2005	Three Months Ended September 30, 2004	Nine Months Ended September 30, 2005	Nine Months Ended September 30, 2004
Net loss, as reported	$ (39,350)	$ (13,589)	$ (126,665)	$ (38,659)
Add: Stock-based employee compensation expense included in reported net loss, net of taxes	121	17	265	409
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards, net of taxes	(5,303)	(4,427)	(14,095)	(13,931)
Pro forma net loss	$ (44,532)	$ (17,999)	$ (140,495)	$ (51,181)
Basic and diluted net loss per share:				
As reported	$ (0.37)	$ (0.14)	$ (1.24)	$ (0.41)
Pro forma	$ (0.42)	$ (0.19)	$ (1.38)	$ (0.54)

For the periods presented in the table above, 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, 2005	Three Months Ended September 30, 2004	Nine Months Ended September 30, 2005	Nine Months Ended September 30, 2004
Expected life, in years	3.5	2.2	3.1	2.4
Risk-free interest rate	3.9%	2.6%	3.7%	2.6%
Volatility	63%	61%	64%	64%
Dividend yield	—	—	—	—

In December 2004, the FASB issued Statement No. 123R "Share Based Payment," (SFAS 123R) which revises SFAS No. 123 and requires all equity-based awards to employees to be recognized in the statement of operations based on their fair values. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are evaluating the requirements of SFAS 123R and we expect that the adoption of SFAS 123R will have a material impact on our consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting SFAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Under the current regulations, as amended in April 2005, we will be required to adopt SFAS 123R on January 1, 2006.

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 $62,000 and $273,000 for the three months ended September 30, 2005 and 2004, respectively, and $245,000 and $442,000 for the nine months ended September 30, 2005 and 2004, 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 only one segment with facilities located primarily within the United States. The majority of our revenues are earned in the United States.

Sales of *Cardene* IV, IV *Busulfex* and *Retavase* accounted for 88% of total product sales in the third quarter of 2005, and 91% of total product sales in the first nine months of 2005. Sales of *Cardene* IV, IV *Busulfex* and *Retavase* accounted for 50% of total revenues in the third quarter of 2005, and 37% of total

revenues in the first nine months of 2005.

Royalty, license and other revenues from Genentech, Inc. (Genentech) in the third quarters of 2005 and 2004 accounted for 29% and 70% of total revenues, respectively, and revenues from Genentech in the first nine months of 2005 and 2004 accounted for 31% and 45% of total revenues, respectively. Royalty, license and other revenues from MedImmune in the third quarters of 2005 and 2004 accounted for 2% and 8% of total revenues, respectively, and revenues from MedImmune in the first nine months of 2005 and 2004 accounted for 15% and 37% of total revenues, respectively. No other revenue from any other source exceeded 10% of total revenues for any periods presented.

Goodwill, Other Intangible Assets and Other Long-Lived Assets

Intangible assets consist of purchased core technology, a reversion right to purchase certain technology from Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd (Roche), product rights obtained through the acquisition of ESP Pharma and licensed research technology. In accordance with FASB Statement No. 142, "Goodwill and Other Intangible Assets" (SFAS 142), we are amortizing our intangible assets with definite lives over their estimated useful lives and review them for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We are amortizing the core technology, product rights and licensed research technology assets on a straight-line basis over their estimated useful lives, 10, 4 to 12, and 5 years, respectively. We will reclassify the reversion right asset into core technology at that time when the rights to the technology revert back to us. Upon reclassifying the reversion right asset to core technology, we will amortize the asset over the remaining term of the patents underlying the acquired technology. Amortization of intangible assets is included primarily in research and development expenses and costs of product sales in the Consolidated Condensed Statement of Operations.

On March 23, 2005, we recorded goodwill in connection with our acquisition of ESP Pharma (see Note 6). In accordance with SFAS 142, we do not amortize goodwill. We will test goodwill for impairment using a two-step process on an annual basis, and between

annual tests under certain circumstances. Factors that are considered important when evaluating whether impairment might exist include a significant adverse change in the business climate, unanticipated competition, loss of key personnel, significant continued under-performance compared to peers, or other factors specific to each asset or reporting unit 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 effect on our consolidated results of operations.

In accordance with FASB Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," we identify and record impairment losses, as circumstances dictate, on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the discounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During the three months ended September 30, 2005, we recorded an impairment charge of $15.2 million related to certain intangible assets we acquired from ESP Pharma (see Note 10).

2. Net Loss Per Share

In accordance with FASB Statement No. 128, "Earnings Per Share," basic net loss per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net loss per share is computed using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted earnings per share result from the assumed release of shares in escrow from the ESP Pharma acquisition and the assumed exercise of stock options, restricted stock and convertible notes, using the treasury stock method. For all periods presented, we incurred a net loss, and as such, we did not include the effect of outstanding stock options, outstanding shares in escrow, outstanding restricted stock, or outstanding convertible notes in the diluted net loss per share calculations, as their effect would be anti-dilutive.

The following table summarizes the number of common equivalent shares excluded from the calculation of diluted net loss per share reported in the statement of operations and excluded from the table presented in the Stock-Based Compensation section in Note 1 above, as their effect would have been anti-dilutive:

	As of September 30,	
(In thousands)	2005	2004
Stock option	14,917	15,359
Common stock in escrow	1,257	—
Restricted stock	4,162	—
Convertible notes	22,968	12,415
Total	43,304	27,774

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2005	2004	2005	2004
Net loss	$ (39,350)	$ (13,589)	$ (126,665)	$ (38,659)
Other comprehensive loss:				
Change in unrealized gains and losses on marketable securities	(475)	980	(932)	(1,287)
Total comprehensive loss	$ (39,825)	$ (12,609)	$ (127,597)	$ (39,946)

4. Inventory

Inventories consisted of the following:

(In thousands)	September 30,	December 31,

	2005	2004
Raw materials	$ 9,655	$ —
Work-in-process	6,216	—
Finished goods	2,817	—
	$ 18,688	$ —

5. Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(In thousands)	September 30, 2005	December 31, 2004
Construction-in-process	$ 815	$ 3,810
Consulting and services	8,186	5,229
Sales rebates	8,313	—
Promotional accrual	3,030	—
Other	2,745	288
	$ 23,089	$ 9,327

6. ESP Pharma Acquisition

In January 2005, we entered into a definitive agreement with ESP Pharma Holding Company, Inc. (ESP Pharma), a privately held, hospital focused pharmaceutical company, under which PDL would acquire ESP Pharma for $300 million in cash and approximately $175 million in PDL common stock, or an aggregate value of approximately $475 million. In February 2005, this agreement was amended to reflect ESP Pharma's agreement to acquire from Centocor, a biopharmaceutical operating company of Johnson & Johnson, rights to manufacture, develop, market and distribute *Retavase*® (reteplase) in the United States and Canada. The amendment increased the purchase price for ESP Pharma by $25 million in cash payable to the ESP Pharma stockholders at the closing of the ESP Pharma acquisition. The acquisition price paid to Centocor for the rights to *Retavase* was $110.5 million. Milestone payments of up to $45 million may be made to Centocor if additional conditions relating to ongoing clinical trials and manufacturing arrangements for *Retavase* are satisfied. As of September 30, 2005, no milestone payments have been achieved.

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma. The aggregate purchase price was approximately $471.3 million, including the cash paid to ESP Pharma stockholders of $325.0 million, the fair value of 9,853,770 shares of PDL's common stock issued to ESP Pharma stockholders totaling approximately $140.9 million, and direct transaction costs of approximately $5.4 million. The value assigned to our common stock issued to ESP Pharma stockholders was based on the average closing market price of our common stock a few days before and after the "measurement date." In accordance with EITF Issue No. 99-12, "Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination," the measurement date was the date on which the number of shares issuable to ESP Pharma became fixed at 9,835,770 (March 4, 2005). The ESP Pharma acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The results of operations of ESP Pharma from March 24, 2005 have been included in our three and nine months ended September 30, 2005 condensed consolidated financial statements.

Of the 9,853,770 shares of PDL common stock issued to ESP Pharma stockholders, 2,523,588 shares were to remain in an escrow account for a period of between six months and one year from the date of the close of the acquisition, pursuant to the terms of the Amended and Restated Agreement and Plan of Merger. At acquisition, we expected to issue substantially all of the shares to the former ESP Pharma stockholders at the end of this contingency period, and as such, we included the value for all shares issued in the purchase price of ESP Pharma in March 2005. However, in September 2005, we delivered a claim against 952 shares held in escrow based on ESP Pharma's breaches of certain representations and warranties under the Amended and Restated Agreement and Plan of Merger; if the agent representing the ESP Pharma stockholders does not respond to this claim within 60 days from the date of the claim, then the 952 shares will be released to us and cancelled. Pursuant to the terms of the Amended and Restated Agreement and Plan of Merger, 1,260,842 shares were released from escrow to the ESP Pharma stockholders on September 23, 2005, leaving 1,261,794 shares remaining in escrow until March 23, 2006 (in addition to the 952 shares held pending the outcome of our claim). Moreover, we estimated based on information to date that we will be able to deliver a claim against some of the remaining shares held in escrow primarily as a result of higher sales returns than originally anticipated at acquisition. As such, the escrow value was reduced by $5.8 million during the third quarter of 2005.

As part of the purchase and included in the $325.0 million paid to ESP Pharma stockholders, ESP Pharma had established a workforce reduction plan and as of the acquisition date, approximately $7.4 million of employee termination costs had been recorded as a severance liability to be paid out over a period of approximately one year. ESP Pharma stockholders were obligated to pay such termination costs from the cash acquisition proceeds of $325.0 million. At September 30, 2005, approximately $0.4 million of these ESP Pharma termination costs remained as a liability.

The net book value of acquired assets and liabilities, which approximated fair value as of March 23, 2005, was as follows (in thousands):

Assets:	
Cash and cash equivalents	$ 2,442
Inventories	4,612
Other current assets	1,904
Fixed assets	808
Total assets	$ 9,766

Liabilities:		
Accounts payable	$	1,836
Accrued compensation		1,803
Accrued royalties		5,432
Accrued sales rebates		4,817
Other current liabilities		10,518
Total liabilities	$	24,406
Net book value of acquired assets and liabilities	$	(14,640)

Based in part upon an independent third-party valuation of the intangible assets acquired, we have allocated the total purchase price on March 23, 2005 as follows (in thousands):

Net liabilities	$	(14,640)
Goodwill		67,359
Intangible assets		339,200
Acquired in-process research and development		79,417
	$	471,336

The $339.2 million value assigned to the intangible assets relates to product rights for the six products sold by ESP Pharma, and this value is amortized over periods between 4 and 12 years, or a weighted-average period of approximately 10 years, the estimated useful lives of these assets. As discussed in Note 10, during the third quarter of 2005, we concluded that the carrying amount of the product rights for the off-patent branded products, representing four of the six products purchased, was impaired as the fair value of these product rights was less than the net carrying value. Accordingly, we recorded an impairment charge of $15.2 million in the third quarter to reduce the carrying value of these product rights to $11.0 million.

The amount of the purchase price originally allocated to goodwill was reduced in the third quarter of 2005 by a $10.1 million federal deferred tax asset related to the carry back of a tax loss for the tax period from January 1, 2005 through March 23, 2005, $0.4 million of prepaid state taxes related to the tax year ended December 31, 2004 and $0.5 million related to carry forward of a tax loss for the tax period from January 1, 2005 through March 23, 2005. It was partially offset by a $1.2 million increase for tax exposure items related to tax years ended December 31, 2002, 2003 and 2004.

As part of the allocation of the purchase price, $79.4 million was allocated to acquired in-process research and development related to ESP Pharma's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date. A summary of these programs follows:

Program	Description	Status of Development	Value (in thousands)
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for hepatorenal syndrome (HRS)	Our third-party licensor, Orphan Therapeutics, LLC (Orphan Therapeutics holds the IND and is conducting a Phase III trial in patients with type I HRS in the United States)	$ 23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	Our third-party licensor, CardioPep Pharma GmbH (CardioPep, has conducted SIRIUS II, a double-blind, placebo-controlled Phase II study)	55,652
			$ 79,417

The nature of the remaining efforts for completion of ESP Pharma's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist which could prevent completion of development, including the uncertainty and timing of patient enrollment and uncertainties related to the results

of the clinical trials, and obtaining FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that these potential products will be approved in the United States or the European Union or whether marketing approvals will have significant limitations on their use. The acquired products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals and the fact that the cost of sales to produce these products in a commercial setting has not been determined. As a result, we may make a strategic decision to discontinue development of a given product if we do not believe successful commercialization is possible. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 14%. This discount rate is a significant assumption and is based on our estimated weighted-average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets. In determining the value of the in-process research and development, the assumed commercialization dates for these potential products begins in 2007.

Pro Forma Results

The unaudited pro forma results of operations for the three and nine months ended September 30, 2005 and 2004 are set forth below. This presentation assumes that the ESP Pharma acquisition had been consummated as of the beginning of each period presented. The net loss includes, on a pre-tax basis, $79.4 million for the write-off of acquired in-process research and development costs, $15.2 million for the impairment of off-patent branded product rights and

$11.9 million and $33.0 million for the amortization of intangible assets for the three and nine months ended September 30, 2005, respectively, and $8.9 million and $26.9 million for the three and nine months ended September 30, 2004, respectively.

(In thousands, except per share amounts)	Three Months Ended September 30, 2005	Three Months Ended September 30, 2004	Nine Months Ended September 30, 2005	Nine Months Ended September 30, 2004
Revenue	$ 76,683	$ 38,368	$ 213,547	$ 140,811
Net loss	(39,350)	(22,566)	(141,643)	(133,964)
Basic and diluted net loss per share	$ (0.37)	$ (0.22)	$ (1.39)	$ (1.23)

The unaudited pro forma information is not necessarily indicative of the results that actually would have occurred had the above-noted acquisition been consummated on January 1, 2004 or 2005, or of results that may occur in the future.

7. *Retavase*® Acquisition

On March 23, 2005, ESP Pharma completed its acquisition of rights to manufacture, develop, market and distribute *Retavase* in the United States and Canada. The aggregate purchase price was approximately $110.5 million, the cash paid to Centocor. As we did not acquire any employees, and therefore the acquisition lacked the necessary inputs, processes and outputs to constitute a business, we have accounted for the *Retavase* acquisition as an acquisition of assets rather than as a business combination in accordance with EITF Issue No. 98-3, "Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business." There were no *Retavase* product sales included in our results of operations during the first quarter of 2005, as the re-launch of the product occurred during April 2005.

The following table summarizes the purchase price allocation of the *Retavase* assets on March 23, 2005 (in thousands):

Tangible assets	$ 16,500
Intangible assets	93,500
Transaction costs	500
	$ 110,500

The $93.5 million value assigned to the intangible assets is amortized over periods between 3 and 8 years, or a weighted-average period of 7.9 years, the estimated useful lives of these assets.

8. Convertible Debt

In February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million (the 2005 Notes). The 2005 Notes are convertible into our common stock at a conversion price of $23.69 per share, subject to adjustment in certain events. Interest on the 2005 Notes is payable semiannually in arrears on February 15 and August 15 of each year. The 2005 Notes are unsecured and senior in right to all our existing and future indebtedness which is subordinated by its terms and may be redeemed at our option, in whole or in part, beginning on February 19, 2010 at par value.

9. Collaborative and Licensing Agreements

On August 2, 2005 we entered into a collaboration with Biogen Idec, Inc. (Biogen Idec) for the joint development, manufacture and commercialization of three Phase II antibody products. The agreement provides for shared development and commercialization of daclizumab in multiple sclerosis and indications other than transplant and respiratory diseases, and for shared development and commercialization of M200 (volociximab) and *HuZAF*™ (fontolizumab) in all indications.

The collaboration and purchase agreements became effective on September 12, 2005. PDL received an upfront cash license fee payment of $40.0 million, and Biogen Idec purchased approximately 4.1 million shares of our common stock at $24.637 per share, which represents the then fair market value of the stock, for approximately $100.0 million in cash. These shares are subject to a lock-up period, half for six months and the remainder one year from the closing date. Biogen Idec also agreed to a standstill period of one year during which it is restricted from acquiring or soliciting other parties to acquire PDL's voting securities.

We and Biogen Idec will share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies will jointly oversee development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. PDL will be eligible to receive development and commercialization milestones based on the further successful development of these molecules. Each party will have co-promotion rights in the United States and Europe. Outside the United States and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to PDL on sales of collaboration products.

We determined that all elements under the collaboration agreement should be accounted for as a single unit of accounting under EITF 00-21, *Multiple Element Arrangements*. As such, we have continuing obligations under the collaboration agreement, and as significant development risk remains, we recorded the $40.0 million upfront cash license fee as deferred revenue and recognize this amount over development periods of the various molecules ranging from 5 to 9 years. During the three months ended September 30, 2005, we recognized $0.9 million related to the amortization of the upfront license fee and $3.9 million for reimbursement of certain research and development expenses.

10. Asset Impairment Charge

In March 2005, we acquired both branded and off-patent branded products through the acquisition of ESP Pharma. In June 2005, we engaged a financial advisor to market our off-patent branded products for sale. During the third quarter of 2005, we received inquiries from multiple potential buyers to acquire the off-patent branded products and the related inventory. Based on the indications of interests that we have received, we concluded that the net carrying value of these product rights and related inventory was impaired at September 30, 2005 and recorded an impairment charge of $15.2 million to reduce the net carrying value of these product rights to $11.0 million. As of September 30, 2005, we also classified these product rights and the related inventory as held for

sale and ceased the amortization of these product rights. In addition, we reserved $1.0 million of this off-patent inventory on hand as of September 30, 2005 based on its expected realizable amount. We anticipate that a sale of these products will be completed in the fourth quarter of 2005.

11. Restructuring 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 facility. As a result of the restructuring plan, we incurred a charge of approximately $305,000, including an adjustment in the fourth quarter of 2004 related to the extension of a sublease of the facilities, included in research and development expenses in the Consolidated Condensed Statement of Operations, $288,000 of which was expenses in the nine months ended September 30, 2004. The restructuring charge included approximately $164,000 of severance-related amounts, $97,000 of which was included in the nine months ended September 30, 2004; $119,000 of committed costs for our New Jersey leased facility (net with expected

proceeds from a short-term sublease entered into in October 2004), $169,000 of which was included in the nine months ended September 30, 2004, 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 expired in October 2005, partially offset by expected proceeds from a short-term sublease entered into in October 2004. The actual future cash requirements were adjusted downward from the accrual at June 30, 2004 due to subleasing the facility. The balance of the severance costs was paid during the third quarter of 2004, and the balance of the facility-related costs was paid during the third quarter of 2005.

12. Income Taxes

We recorded a tax provision of approximately $1.7 million and $12,000 for the three months ended September 30, 2005 and 2004, respectively. We recorded a tax provision of approximately $1.8 million and $68,000 for the nine months ended September 30, 2005 and 2004, respectively. Taxes during the three and nine months ended September 30, 2005 are primarily related to state income taxes on income earned by ESP Pharma, federal alternative minimum taxes on the consolidated income, and foreign taxes on income earned by our foreign operations. Taxes during the three and nine months ended September 30, 2004 are primarily related to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee. We recorded a $10.1 million federal deferred tax asset related to the carry back of ESP Pharma's tax loss for the period from January 1, 2005 through March 23, 2005, the date of the ESP Pharma acquisition. This $10.1 million deferred tax asset was recorded as a reduction of the goodwill from the ESP Pharma acquisition (see Note 6).

13. Related-Party Transaction

On September 15, 2005, we entered into a transition agreement (the Transition Agreement) with Glen Sato, our Senior Vice President and Chief Financial Officer (CFO), pursuant to which Mr. Sato resigns as our CFO and all other positions as an officer of PDL, including principal financial officer, effective as of the date we file our Form 10-Q for the quarter ended September 30, 2005 (the Termination Date). Under the terms of the Transition Agreement, Mr. Sato will remain a non-officer employee after the Termination Date, reporting to our Chief Accounting Officer, until and including January 1, 2006. Effective as of the Termination Date, George Jue, PDL's Vice President, Finance and Chief Accounting Officer, will oversee our financial organization until a new CFO is hired. Mr. Sato and we also agree to enter into a consulting agreement for the period January 2, 2006 through and including March 1, 2006.

14. Subsequent Event

On October 28, 2005, we executed an Amended and Restated Co-Development and Commercialization Agreement and a Second Amended and Restated Worldwide Agreement (collectively, the Agreements) with Roche. The Agreements amended the Amended and Restated Worldwide Agreement dated October 1, 2003 and the Co-Development and Commercialization Agreement dated September 14, 2004 between Roche and PDL (the Prior Agreements).

The Agreements expand the existing relationship between us and Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer term maintenance therapy (transplant maintenance). The Agreements provide that we will receive a $10 million upfront payment and may receive up to $145 million in development and commercialization milestone payments if the development of daclizumab in transplant maintenance is successful. We will share global development costs equally with Roche. We will have the option to co-promote daclizumab for transplant maintenance in the United States and will share in the profits in the United States, and we will receive royalties on net sales of the product in transplant maintenance outside the United States.

The Agreements also provide that we will not exercise the option, under the Prior Agreements, to promote Zenapax for prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2006. The Agreements also amended the royalty obligations of Roche with respect to future sales of Zenapax in the existing transplant indication by including a revenue threshold below which royalties are not due.

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 biopharmaceutical company focused on the research, development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several biopharmaceutical products in the United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products. On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma Holding Company, Inc. (ESP Pharma), a privately held, hospital-focused pharmaceutical company. The aggregate purchase price was approximately $471.3 million, including the cash paid to ESP Pharma stockholders of $325.0 million, the fair value of 9,853,770 shares of PDL's common stock issued to ESP Pharma stockholders totaling approximately $140.9 million, and direct transaction costs of approximately $5.4 million. The ESP Pharma acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The results of operations of ESP Pharma from March 24, 2005 have been included in our first quarter consolidated condensed financial statements.

Also on March 23, 2005, ESP Pharma completed its acquisition of rights to manufacture, develop, market and distribute *Retavase*® in the United States and Canada. The aggregate purchase price was approximately $110.5 million, including the cash paid to Centocor of $110.0 million and direct transaction costs of approximately $0.5 million.

In order to partially fund the acquisition of ESP Pharma, in February 2005, we issued 2.00% Convertible Senior Notes due February 14, 2012 with a principal amount of $250.0 million (the 2005 Notes). The 2005 Notes are convertible into our common stock at a conversion price of $23.69 per share, subject to adjustment in certain events. Interest on the 2005 Notes is payable semiannually in arrears on February 15 and August 15 of each year. The 2005 Notes are unsecured and subordinated to all our existing and future indebtedness and may be redeemed at our option, in whole or in part, beginning on February 19, 2010 at par value.

Significant Risks

In general, we have a history of operating losses and may not achieve sustained profitability. As of September 30, 2005, we had an accumulated deficit of approximately $400.2 million. Our expenses will continue to increase over the next several years because of the extensive resource commitments required to identify and develop antibody candidates to achieve regulatory approval, to market and sell products and to develop potential products. Also, over the next several years we expect to incur substantial additional expenses as we continue to invest in research and improve and expand our development and manufacturing capabilities.

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.

The integration of the product rights, technologies, operations and personnel of PDL and ESP Pharma is a complex, time consuming and expensive process and has and will require significant attention from management and other personnel, which may distract their attention from the day-to-day business of the combined company. The diversion of management's attention and any difficulties associated with integrating ESP Pharma into PDL could have a material adverse effect on the operating results of the combined company after the merger and the value of PDL shares, and could result in the combined company not achieving the anticipated benefits of the merger. While we have achieved a significant level of integration, it is not certain that we will achieve all aspects of integration successfully or that all of the anticipated benefits will be realized. Failure to do so could have a material adverse effect on the business and operating results of the combined company.

In order to reach our goal to be cash flow positive on a quarterly basis beginning in the fourth quarter of 2005, we will have to continue to increase sales from historical levels for *Cardene* IV, *Retavase* and IV *Busulfex*. Accordingly, we will need to continue to effectively transition existing relationships with distributors, third-party vendors, manufacturers and customers of ESP Pharma. Although we have retained most of the hospital focused sales force and related sales infrastructure, we have never sold, marketed or distributed products, and we may not be able to successfully integrate and further grow such capabilities from ESP Pharma necessary to continue to successfully promote the ESP Pharma products. In addition, the markets for *Cardene* IV and *Retavase* are highly competitive, and we will be marketing against pharmaceutical, biopharmaceutical and specialty pharmaceutical companies with substantially greater revenues and experience in marketing products than we have.

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 our proprietary products or maintain desired margins for products sold, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach a sustainable cash flow positive position and profitability are highly uncertain.

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

In addition, as of September 30, 2005 we have approximately $500.0 million in convertible notes outstanding, approximately $250.0 million of which are callable in each of 2008 and 2010. In order to be able to service our debt in the future, we will need to generate positive cash flows from our operations or obtain other financing.

Significant Events and Recent Events

On August 2, 2005 we entered into a collaboration with Biogen Idec for the joint development, manufacture and commercialization of three Phase II antibody products. The agreement provides for shared development and commercialization of daclizumab in multiple sclerosis and indications other than transplant and respiratory diseases, and for shared development and commercialization of M200 (volociximab) and *HuZAF*™ (fontolizumab) in all indications.

The collaboration agreement and purchase agreement became effective on September 12, 2005. PDL received an upfront cash license fee payment of $40.0 million, and Biogen Idec purchased approximately 4.1 million shares of our common stock at $24.637 per share, which represents the then fair market value of the stock, for approximately $100.0 million in cash. These shares are subject to a lock-up period, half for six months and the remainder one year from the closing date. Biogen Idec also agreed to a standstill period of one year during which it is restricted from acquiring or soliciting other parties to acquire PDL's voting securities.

We and Biogen Idec will share equally the costs of all development activities and all operating profits from each collaboration product within the United States and Europe. The companies will jointly oversee development, manufacturing and commercialization plans for collaboration products and intend to divide implementation responsibilities to leverage each company's capabilities and expertise. PDL will be eligible for development and commercialization milestones based on the further successful development of these molecules, if achieved. Each party will have co-promotion rights in the United States and Europe. Outside the United States and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to PDL on sales of collaboration products.

In March 2005, we acquired both branded and off-patent branded products through the acquisition of ESP Pharma. In June 2005, we engaged a financial advisor to market our off-patent branded products for sale. During the third quarter of 2005, we received inquiries from multiple potential buyers to acquire the off-patent branded products and the related inventory. Based on the indications of interests that we have received, we concluded that the net carrying value of these product rights and related inventory was impaired at September 30, 2005 and recorded an impairment charge of $15.2 million to reduce the net carrying value of the these product rights to $11.0 million. As of September 30, 2005, we also classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights. In addition, we reserved $1.0 million of this off-patent branded inventory on hand as of September 30, 2005 based on its expected realizable amount. We anticipate that a sale of these products will be completed in the fourth quarter of 2005.

On October 28, 2005, subsequent to the third quarter of 2005, we executed an Amended and Restated Co-Development and Commercialization Agreement and a Second Amended and Restated Worldwide Agreement (collectively, the Agreements) with Roche. The Agreements amended the Amended and Restated Worldwide Agreement dated October 1, 2003 and the Co-Development and Commercialization Agreement dated September 14, 2004 between Roche and PDL (the Prior Agreements).

The Agreements expand the existing relationship between us and Roche to include the co-development and commercialization of daclizumab for organ transplant patients on longer term maintenance therapy (transplant maintenance). The Agreements provide that we will receive a $10 million upfront payment and may receive up to $145 million in development and commercialization milestone payments if the development of daclizumab in transplant maintenance is successful. We will share global development costs equally with Roche. We will have the option to co-promote daclizumab for transplant maintenance in the United States and will share in the profits in the United States, and we will receive royalties on net sales of the product in transplant maintenance outside the United States.

The Agreements also provide that we will not exercise the option, under the Prior Agreements, to promote Zenapax for prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2007. The Agreements also amended the royalty obligations of Roche with respect to future sales of Zenapax in the existing transplant indication by including a revenue threshold below which royalties are not due.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

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 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. In addition, as a result of the acquisition of ESP Pharma, we recognize revenues from product sales, net of estimated allowances for cash discounts, product returns and rebates. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated discounts, product returns, bad debts, and rebates.

We enter into patent license, collaboration and humanization agreements that may contain multiple elements, such as upfront license fees, reimbursement of research and development expenses, milestones related to the achievement of particular stages in product development and royalties. 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 licensee confirms that we have met the requirements under the terms of the agreement, and when payment is reasonably assured. Changes in the allocation of the contract value between deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract. For example, as we did not establish fair value for all undelivered elements of the Co-Development and Commercialization Agreement with Roche (the Roche Collaboration Agreement), including milestones and the reimbursement of research and development expenses, we are recognizing the $17.5 million upfront license fee that we received from Roche over the term of the Roche Collaboration Agreement as services are provided. Similarly, we did not establish fair value for all undelivered elements of the multiple products of the Collaboration Agreement with Biogen Idec (the Biogen Idec Collaboration Agreement). We are recognizing the $40.0 million upfront license fee, milestones and the

reimbursement of research and development expenses that we received from Biogen Idec over the term of the Biogen Idec Collaboration Agreement as services are provided with respect to the specific products under development to which the upfront license fees, if any, and reimbursement relate.

In addition, we enter into non-monetary 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 non-monetary 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 estimating 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 we exchange with 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.

Sales Allowances and Rebate Accruals

We record estimated reductions to product sales for expected returns of products under our current policies, chargebacks, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are based on contractual terms, historical utilization rates experienced by ESP Pharma and expectations regarding future utilization rates for these programs. Estimates for product returns, including new products, are based on an on-going analysis of industry and historical return patterns experienced by ESP Pharma and the companies from which ESP Pharma acquired their products. Our current estimates include monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, reviewing inventory data available to us in monitoring channel inventory levels, the purchase of third-party data to monitor prescriptions as well as, for new products, a review of our products we have sold through the same or similar channels. In addition, our estimates are based on the historical chargeback data we receive from wholesalers and the applicable customer chargeback rates, returns and rebate thresholds we have from Wyeth and Centocor with respect to *Cardene* IV and *Retavase*, respectively. Further, we monitor the activities and clinical trials of our key competitors and assess the potential impact on our future sales and return expectations where necessary. If conditions become more competitive for any of the markets served by our drugs or if other circumstances change, we may take actions to increase our product return estimates or we may offer additional customer incentives. This would result in an incremental reduction of future revenue at the time the return estimate is changed or new incentives are offered. Product sales receivable allowances for chargebacks, returns and rebate accruals require substantial judgment. Actual results may differ from our estimates and could impact our earnings in any period in which an adjustment is made, based on actual results.

We also maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is based on our analysis of several factors including, but not limited to, contractual payment terms, historical payment patterns of our customers experienced by ESP Pharma and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region, and a review of the local economic environment and its potential impact on government funding and reimbursement practices. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an inability to make payments, additional allowances may be required. We believe that the allowance for doubtful accounts is adequate to cover anticipated losses under current conditions; however, significant deterioration in any of the above factors could materially change these expectations and result in an increase to our allowance for doubtful accounts.

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.

Goodwill and Other Intangible Assets

The valuation in connection with the initial purchase and the ongoing evaluation for impairment of goodwill and other 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 in the purchase price allocation, 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. During the third quarter of 2005, we recorded an impairment charge of $15.2 million in the third quarter of 2005 to reduce the net carry value of the intangible assets for our off-patent branded product rights to its fair value (see Note 10 to the Financial Statements in Part I, Item 1 of this Quarterly Report).

RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2005 and 2004

Revenues

(In thousands)	Three Months Ended September 30, 2005	2004	% Change	Nine Months Ended September 30, 2005	2004	% Change
Product sales, net	$ 43,144	$ —	100%	$ 79,437	$ —	100%
Royalties	26,003	17,131	52%	96,695	63,872	51%
License and other	7,536	2,653	184%	17,127	9,323	84%
Total revenues	$ 76,683	$ 19,784	288%	$ 193,259	$ 73,195	164%

Product sales, net

We acquired marketed products from the acquisition of ESP Pharma, which closed on March 23, 2005. Total product sales in the third quarter of 2005, our second full quarter of ownership of the acquired ESP Pharma products, were $43.1 million. Net product sales of *Cardene* IV, IV *Busulfex* and *Retavase* totaled $38.0 million for the period. Off-patent brand sales for the period totaled $5.1 million. During the quarter, we increased our reserves for estimated product returns by approximately $2.8 million due primarily to inventory levels of the off-patent brand products, in particular *Declomycin*, that are currently in the hands of the wholesaler channel. *Declomycin* sales to the end users have been adversely affected by a significant price difference in the context of the introduction of two generic competitors for this product in the second half of 2004. Total net product sales in the first nine months of 2005 (i.e., from March 23, the date of acquisition, through September 30) were $79.4 million, of which $72.3 million was from the sales of *Cardene* IV, IV *Busulfex* and *Retavase* and the remaining $7.1 million was from the off-patent brand sales.

On March 23, 2005, ESP Pharma completed its acquisition of rights to manufacture, develop, market and distribute *Retavase* in the United States and Canada. We re-launched *Retavase* in April 2005. As a result of this re-launch, we had a stock-out situation on *Retavase*. During May and June 2005, we implemented an allotment program, which provided product to wholesalers that stocked-out and for emergency requests. We are in the process of transferring the product labeling from Centocor to ESP Pharma and we may experience a delay between the time we were allowed to supply product bearing the Centocor label and the time when we are able to release product under the ESP Pharma label.

Royalties

Royalty revenues increased during the three and nine months ended September 30, 2005 compared to the same periods in 2004 due primarily to royalties recognized on sales of Genentech's *Avastin* product, which was launched in the first quarter of 2004. Royalty payments from sales of Genentech's products accounted for 86% and 62% of total royalty revenues during the three and nine months ended September 30, 2005, respectively, up from 81% and 49% in the comparable period of 2004, respectively. Sales of MedImmune's product accounted for 6% and 31% of total royalty revenues for the three and nine months ended September 30, 2005, respectively, down from 9% and 42% in the comparable periods in 2004.

In addition, the increase in royalty revenues is attributable to higher reported product sales for most products in our royalty portfolio during the first nine months of 2005 as compared to the comparable period of 2004. The largest portion of this increase relates to Genentech's *Herceptin* and *Avastin*, and MedImmune's *Synagis* humanized antibody products. Royalty payments from sales of *Herceptin*, *Avastin* and *Synagis* accounted for 41%, 33% and 6% of our royalty revenues for the three months ended September 30, 2005 as compared to 48%, 0% and 9% in the comparable period in 2004, respectively. Royalty payments from sales of *Herceptin*, *Avastin* and *Synagis* accounted for 32%, 21% and 31% of our royalty revenues for the nine months ended September 30, 2005 as compared to 36%, 0% and 42% in the comparable period in 2004, respectively.

We expect that royalty revenues will continue to increase as 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 first nine months of 2005 and 2004 primarily consisted of upfront licensing and patent rights fees, milestone payments related to licensed technology and license maintenance fees. Also included in license and other revenues for the first nine months of 2005 were revenues recognized under our collaborations with Roche and Biogen Idec entered into in September 2004 and August 2005, respectively.

License and other revenues increased 184% to $7.5 million in the third quarter of 2005 from $2.7 million in the corresponding quarter of 2004 primarily due to revenue recognized from our collaboration with Biogen Idec and revenue recognized under our asthma collaboration with Roche.

License and other revenues increased 84% to $17.1 million in the first nine months of 2005 from $9.3 million in the corresponding period of 2004 primarily due to the revenue recognized under our collaborations with Biogen Idec and Roche, with no corresponding revenue during the comparable period in 2004.

Costs and Expenses

(In thousands)	Three Months Ended September 30, 2005	2004	% Change	Nine Months Ended September 30, 2005	2004	% Change
Cost of product sales	$ 22,209	$ —	—	$ 43,481	$ —	—
Research and development	49,480	27,326	81 %	125,080	92,364	35 %
Selling, general and administrative	26,795	7,664	250 %	54,267	23,182	134 %
Impairment charge	15,225	—	—	15,225	—	—
Acquired in-process research and development	—	—	—	79,417	—	—
Total costs and expenses	$ 113,709	$ 34,990	225 %	$ 317,470	$ 115,546	175 %

Cost of Product Sales

Cost of product sales (COS) of $22.2 million and $43.5 million as a percentage of product sales was 51% and 55% for the three and nine months ended September 30, 2005, respectively, with no such costs incurred in 2004. COS largely reflects cost of goods sold, amortization of product rights on *Retavase* and the products acquired from ESP Pharma, royalty expenses, and certain start-up production costs related to the transition of sales, labeling and shipping responsibilities to us from Centocor for *Retavase*. Amortization of product rights was 54% and 57% of COS for the three and nine months ended September 30, 2005, respectively, with no such costs incurred in 2004. For the full year 2005, due principally to the amortization of product rights for our marketed products, we continue to expect COS to be in the range of approximately 55% to 58% of product sales, with continued quarter-to-quarter variability based on product mix changes and production results, acknowledging that there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing, or inventory related issues.

Research and Development

Research and development costs of $49.5 million in the third quarter of 2005 include costs of personnel to support our research and development activities, milestone payments and technology licensing fees, 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 and overhead costs. The increase in the third quarter of 2005 compared to the corresponding quarter of 2004 was primarily due to an increase in clinical development expenses for our major research and development projects of $9.3 million, personnel related costs of $4.9 million, facility-related costs of $2.6 million, production material costs of $2.5 million and outside services costs of $0.5 million, offset partially by a decrease in contract manufacturing costs of $1.5 million and other miscellaneous items of $3.9 million.

The increase in research and development costs during the first nine months of 2005 compared to the same period in 2004 was primarily due to increases in research and development personnel-related costs of $14.8 million, clinical development expenses for our major research and development projects of $9.9 million, facility-related costs of $6.9 million, production material costs of $5.3 million and outside services costs of $1.4 million. These increases were partially offset by decreases in contract manufacturing services of $6.3 million and research and development licensing costs of $3.3 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.

Below is a summary of products and the latest 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, 2005	2004
Current Product Candidates						
Daclizumab					$ 28,347	$ 22,907
	Asthma	Phase I	Roche	2006		
	Asthma	Phase IIa	Roche	Completed 2004		
	Multiple Sclerosis	Phase II	Biogen Idec	2008		
Ularitide (1)					7,584	N/A
	Decompensated Congestive Heart Failure	Phase II	CardioPep	Completed 2005		
Terlipressin (2)					2,098	N/A
	Type 1 Hepatorenal Syndrome	Phase III	Orphan Therapeutics	2006		
HuZAF					3,235	6,441
	Crohn’s Disease	Phase II	—	Completed 2005		
Nuvion						
	Severe steroid-refractory ulcerative colitis	Phase I/II	—	2005	20,091	15,902
	Crohn’s Disease	Phase II	—	2006		
M200					20,286	15,834
	Solid tumors	Phase II	Biogen Idec	2006		
Other (3)			—		43,439	31,280
	Total Research and Development Expenses					

	$ 125,080	$ 92,364

(1) We assumed development responsibility in Q2 2005. The Phase II study was completed by CardioPep in Europe. PDL has worldwide development and commercialization rights to this product.
(2) Orphan Therapeutics has development responsibility for this molecule; PDL has exclusive marketing rights in the U.S. and Canada.
(3) 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 expensive, and costs may fluctuate unexpectedly," "We are subject to extensive government regulation, which requires us to invest significant resources in development, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize 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 and the marketing and sale of our products could result in violations of law or regulations" 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 a charge of approximately $305,000, including an adjustment in the fourth quarter of 2004 related to the extension of a sublease of the facilities, included in research and development expenses in the Consolidated Condensed Statement of Operations, $288,000 of which was in the nine months ended September 30, 2004. The restructuring charge included approximately $164,000 of severance-related amounts, $97,000 of which was included in the nine months ended September 30, 2004; $119,000 of committed costs for our New Jersey leased facility (net with expected proceeds from a short-term sublease entered into in October 2004), $169,000 of which was included in the nine months ended September 30, 2004, 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, partially offset by expected proceeds from a short-term sublease entered into in October 2004. The actual future cash requirements were adjusted downward from the accrual at June 30, 2004 due to subleasing the facility. The balance of the severance costs was paid during the third quarter of 2004, and the balance of the facility-related costs was paid during the third quarter of 2005.

Selling, General and Administrative Expenses

Selling, general and administrative costs of $26.8 million in the third quarter of 2005 included costs of personnel, professional services, consulting and other expenses related to our selling and administrative functions and an allocation of facility costs. Selling, general and administrative expenses for the three months ended September 30, 2005 increased 250% to $26.8 million from $7.7 million during the comparable period in 2004. This increase was primarily due to increased personnel-related expenses of approximately $9.7 million, outside services of approximately $10.2 million and facility-related expenses of $1.5 million. These increases were partially offset by a reduction in miscellaneous expenses of $2.3 million. Approximately 79% of this personnel increase was attributable to the addition of the ESP Pharma sales, sales management, operations and marketing team located in our New Jersey offices.

The increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared to the corresponding period in 2004 period was primarily due to increased personnel-related expenses of approximately $17.7 million, outside services expenses of approximately $16.6 million and facility-related expenses of $1.5 million which were partially offset by miscellaneous expenses of $4.7 million. We expect that selling, general and administrative expenses will continue to increase slightly for the remainder of 2005, as compared to the first three quarters of 2005 as we operate our expanded sales force and support staff and initiate or continue promotional programs for our products.

Asset Impairment Charge

The asset impairment charge recorded in the third quarter of 2005 was to write down the carrying amount of the product rights of our off-patent branded products to their fair value based on a recent revaluation. We acquired these product rights from ESP Pharma as part of the acquisition of ESP Pharma in March 2005. In June 2005, we engaged a financial advisor to market our off-patent branded products for sale. During the third quarter of 2005, we received inquires from multiple potential buyers to acquire the off-patent branded products and the related inventory. Based on the indications of interests that we have received, we concluded that the net carrying value of these product rights and the related inventory was impaired at September 30, 2005 and recorded an impairment charge of $15.2 million to reduce the carrying amount of these product rights to $11.0 million. As of September 30, 2005, we also classified these product rights and the related inventory as held for sale and ceased the amortization of these product rights. In addition, we reserved $1.0 million of this off-patent branded product inventory on hand as of September 30, 2005 based on its expected realizable amount. We anticipate that a sale of these products will be completed in the fourth quarter of 2005.

Acquired In-Process Research and Development

In connection with the March 2005 acquisition of ESP Pharma, we recorded charges for acquired in-process research and development of $79.4 million due to ESP Pharma's incomplete research and development programs that had not yet reached technological

feasibility as of March 23, 2005 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 2005 was follow:

Program	Description	Status of Development	Value Assigned (in thousands)
Terlipressin	A synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin for hepatorenal syndrome (HRS)	Our third-party licensor, Orphan Therapeutics holds the IND and is conducting a Phase III trial in patients with type I HRS in the United States	$ 23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	Our third-party licensor, CardioPep, has completed SIRIUS II, a double-blind, placebo-controlled Phase II study	$ 55,652
			$ 79,417

The nature of the remaining efforts for completion of ESP Pharma's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist which could prevent completion of development, including the uncertainty and timing of patient enrollment and uncertainties related to the results of the clinical trials, and obtaining FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that these potential products will be approved in the United States or the European Union or whether marketing approvals will have significant limitations on their use. The acquired products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals and the fact that the cost of sales to produce these products in a commercial setting has not been determined. As a result, we may make a strategic decision to discontinue development of a given product if we do not believe successful commercialization is possible. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows using a present value discount rate of 14%. This discount rate is a significant assumption and is based on our estimated weighted-average cost of capital taking into account the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets. In determining the value of the in-process research and development, the assumed commercialization dates for these potential products begins in 2007.

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. There have been no significant changes to the acquired in-process research and development daclizumab projects as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2004.

Interest and Other Income, Net and Interest Expense

(In thousands)	Three Months Ended September 30, 2005	2004	% Change	Nine Months Ended September 30, 2005	2004	% Change
Interest and other income, net	$ 2,027	$ 2,822	(28)%	$ 6,835	$ 7,689	(11)%
Interest expense	(2,671)	(1,193)	124%	(7,522)	(3,929)	91%

Interest and Other Income and Expense

Interest income for the three and nine months ended September 30, 2005 decreased from the comparable periods in 2004 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 and nine months ended September 30, 2005 increased from the comparable periods in 2004 as a result of both our 2.00%, $250.0 million Convertible Senior Notes and our 2.75%, $250.0 million Convertible Subordinated Notes being outstanding during the first nine months of 2005, compared to only our 2.75%, $250.0 million Convertible Subordinated Notes being outstanding in the first nine months of 2004. We capitalized approximately $1.0 million and $2.9 million of our interest cost in the three and nine months ended September 30, 2005, respectively, compared to $1.0 million and $2.7 million in the three and nine months ended September 30, 2004, respectively.

Income Taxes

We recorded a tax provision of approximately $1.7 million and $12,000 for the three months ended September 30, 2005 and 2004, respectively. We recorded a tax provision of approximately $1.8 million and $68,000 for the nine months ended September 30, 2005 and 2004, respectively. Taxes during the three and nine months ended September 30, 2005 are primarily related to state income taxes on income earned by ESP Pharma, federal alternative minimum taxes on the consolidated income, and foreign taxes on income earned by our foreign operations. Taxes during the three and nine months ended September 30, 2004 are primarily related to foreign taxes on income earned by our foreign operations and foreign withholding tax in connection with a license maintenance fee. We recorded a $10.1 million federal deferred tax asset related to the carry back of ESP Pharma's tax loss for the period from January 1, 2005 through March 23, 2005, the date of the ESP Pharma acquisition. This $10.1 million deferred tax asset was recorded as a reduction of the goodwill from the ESP Pharma acquisition (see Note 6 to the Financial Statements in Part I, Item 1 of this Quarterly Report).

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, 2005, we had cash, cash equivalents, marketable securities and restricted investments in the aggregate of $332.7 million, compared to $397.1 million at December 31, 2004.

Net cash provided by operating activities for the nine months ended September 30, 2005 was approximately $29.2 million, compared to net cash used in operating activities of $11.5 million in the corresponding period in 2004. The $29.2 million net cash provided by operating activities in the first nine months of 2005 was primarily attributable to: non-cash expenses related to acquired in-process research and development of $79.4 million, depreciation and amortization of $39.3 million, an impairment charge of $15.2 million related to revaluation of off-patent brands, a goodwill adjustment of $9.8 million related to the ESP Pharma acquisition and an increase in deferred revenue of $39.3 million resulting from the $40.0 million upfront license fee received from Biogen Idec, which was offset by a net loss of $126.7 million and an increase in accounts receivable of $26.2 million from product sales.

Net cash used in investing activities was $311.2 million for the nine months ended September 30, 2005, compared to $212.8 million in the comparable period in 2004. The $311.2 million net cash used for investing activities in the first nine months of 2005 was primarily attributable to $433.0 million in cash payments (net of cash received) related to the ESP Pharma and *Retavase* acquisitions in March 2005 and $32.5 million in capital expenditures, which were partially offset by $153.9 million in maturities of our marketable securities. Capital expenditures in the first nine months of 2005 and 2004 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, 2005 was $372.3 million, compared to $13.4 million in the comparable period in 2004. The $372.3 million net cash provided by financing activities in the first nine months of 2005 was primarily due to the issuance of 2.00%, $250 million Convertible Senior Notes in February 2005 and the $100 million from the issuance of common stock to Biogen Idec and $31.1 million from stock option exercises.

We estimate that our existing capital resources, will be sufficient to fund our current and future level of operations. Our future capital requirements will depend on numerous factors, including, among others, continued growth in sales of our marketed products; royalties from sales of products by third-party licensees, including *Synagis*, *Herceptin*, *Xolair*, *Raptiva*, *Mylotarg*, and *Avastin*; our ability to enter into additional collaborative, humanization, patent license and patent rights agreements; interest income; 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 and qualifying our manufacturing facilities; our ability to obtain and retain funding from third parties under collaborative arrangements; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; successful integration of acquired businesses, including the transition to PDL existing relationships with partners, distributors, third-party vendors, manufacturers, and customers of acquired companies; 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, construction, contract manufacturing and other agreements as of September 30, 2005 are as follows:

	Payments due by period				
(In thousands)	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
CONTRACTUAL OBLIGATIONS (1)					
Operating leases	$ 4,146	$ 5,698	$ 607	$ 400	$ 10,851
Long-term debt	1,288	2,289	2,278	4,650	10,505
Convertible debentures	11,875	23,750	260,000	255,000	550,625
Construction contracts	5,311	1,237	—	—	6,548
Contract manufacturing and other	1,691	—	—	—	1,691
Total contractual obligations	$ 24,311	$ 32,974	$ 262,885	$ 260,050	$ 580,220

(1) This table does not include (a) any milestone payments from us to third parties which may become payable under research collaborations or license agreements as the timing and likelihood of such payments are not known, or (b) any royalty payments from us to third parties as the amounts of such payments and/or likelihood of such payments are not known in any period presented above.

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, as well as other risks and uncertainties, 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. Additional risks not currently known to us also may harm our business.

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, 2005, we had an accumulated deficit of approximately $400.2 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 invest in life cycle management of our existing products, 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 not achieve sustained positive cash flow from operations that we have currently projected. The amount of net losses and the time required to reach sustained profitability from our proprietary products are highly uncertain.

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:

- many 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 life cycle management initiatives for our existing products;
- we invest in staffing and operations to meet our manufacturing requirements;
- we expand our commercial infrastructure to market our products;
- 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 additional sales of existing products, new agreements with third-party collaborators, significant royalties on sales of products licensed under our intellectual property rights or other uncertain sources of revenue, we will continue to incur operating losses and may require additional capital to fully execute our business strategy.

If Cardene IV® sales do not continue to grow, our results of operations will suffer.

Cardene IV has accounted for a significant portion of the operating income and growth in sales of ESP Pharma. Cardene IV faces a competitive marketplace with branded and generic intravenous anti-hypertensive products being marketed in the U.S. and it may be harder to continue to penetrate this market at the recent rate of growth. While we expect to increase committed sales and marketing resources in order to ensure the continued growth of Cardene IV, there can be no assurance that we can continue the rapid growth rate that ESP Pharma achieved. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive and other related drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for Cardene IV to continue its success, we will have to maintain and expand its position in the marketplace against these competitors' drugs.

Retavase is sold in a declining market and if our planned sales and promotional efforts do not increase or at least maintain market acceptance, our results of operations will suffer.

Retavase is expected to account for a significant portion of our operating income and potential growth in cash flow from operations. Retavase is sold into the thrombolytic market that has recently been declining due to the more widespread use of stents and gpIIb/IIIa inhibitor products. Moreover, Retavase competes for use in the management of acute myocardial infarction with TNKase and Activase from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than PDL. While we believe that our planned investment in additional promotional efforts may increase the market acceptance of Retavase, there can be no assurance that we can increase the market share of Retavase, or that even if we are able to increase our market share, that the anti-thrombolytic market will not decline significantly regardless of our efforts. In addition, the product was previously marketed on behalf of Centocor by Scios, Inc. (Scios), a Johnson & Johnson company. We will require the continued cooperation of Centocor and Scios to successfully transfer the product and the manufacturing of the product to us and there can be no assurance that we will be successful in achieving this transition or our projected sales levels.

We are required to undertake the complex manufacturing of Retavase through use of a number of third parties, and the transition may result in delays in obtaining regulatory approval or marketing for Retavase.

We will be required to manufacture Retavase for sale and distribution no later than 2011. Retavase is a biologic product currently manufactured through a multi-step process, including custom materials from Centocor, Diosynth RTP Inc. and Roche. While the rights to Retavase included the acquisition of at least 12 months of inventory, the manufacturing of this product for use as therapeutics in compliance with regulatory requirements will be complex, time-consuming and expensive. We will be required to effect the transfer of manufacturing from Centocor in a timely manner. The eventual transfer of manufacturing could result in delays in regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position. We are in the process of transferring the product labeling from Centocor to ESP Pharma and we may experience a delay between the time we were allowed to supply product bearing the Centocor label and the time when we are able to release product under the ESP Pharma label, and a delay if significant, could affect our revenues from Retavase.

We rely on third-party suppliers to provide ESP Pharma the products for sale. If we are unable to continue those manufacturing arrangements successfully or at a reasonable cost, our potential future results could suffer.

We have not manufactured any of the ESP Pharma products and are not familiar with the manufacturing process for these

products. We have assumed from ESP Pharma long-term agreements with various third parties to supply the ESP Pharma products. If there are supply problems with the third party manufacturers, in particular Cardene IV and Retavase, there may not be sufficient supplies of Cardene IV or Retavase to meet commercial demand, in which case our future results could suffer.

In addition, reliance on a third-party manufacturer entails risks, including reliance on the third party for regulatory compliance and adhering to the FDA's current Good Manufacturing Practices (cGMP) requirements, the possible breach of the manufacturing agreement by the third party, and the possibility of termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient to us. Failure of the third party manufacturers or us to comply with applicable regulations, including FDA pre- or post-approval inspections and cGMP requirements, could result in sanctions being imposed on us. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operational restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Achieving future profitability or sustaining cash flow positive results of operations will depend in significant part upon the continuing success of ESP Pharma's products.

PDL has incurred losses since inception. In order for PDL to achieve our goal to be cash flow positive in the fourth quarter of 2005 and sustainably cash flow positive on a full-year basis beginning in 2006, as currently projected, we will need to achieve continued growth from Cardene IV, IV Busulfex® and Retavase as well as continued growth in royalties from products licensed under PDL intellectual property rights.

Our product revenues are substantially dependent on a limited number of wholesalers and distribution partners, and such revenues may fluctuate from quarter to quarter based on the buying and return patterns of these wholesalers and distribution partners.

We sell our products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the U.S. During the year ended December 31, 2004, revenues from the sales of ESP Pharma products to its three largest U.S. wholesalers totaled approximately 87% of its net product sales. Our reliance on a small number of wholesalers and distribution partners could cause revenues to fluctuate from quarter to quarter based on the buying and return patterns of these wholesalers and distribution partners. In addition, as of September 30, 2005, these three U.S. wholesalers represented approximately 80% of ESP Pharma's outstanding accounts receivable. If any of these wholesalers fails to pay on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

Increased leverage as a result of our sale of the 2005 Notes may harm our financial condition and results of operations.

At September 30, 2005, we had approximately $508.1 million of outstanding debt, including without limitation approximately $250.0 million in principal that remains outstanding under our 2.00% Convertible Senior Notes due February 15, 2012 (the 2005 Notes). In addition to the 2005 Notes, approximately $250.0 million in principal remains outstanding under our unsecured 2.75% Convertible Subordinated Notes due 2023 (the 2003 Notes), and we have debt service obligations related thereto. The 2005 Notes do not restrict our future incurrence of indebtedness and we may incur additional indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

- we will have additional cash requirements in order to support the payment of interest on our outstanding indebtedness;
- increases in our outstanding indebtedness and leverage will increase our vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and
- depending on the levels of our outstanding debt, our ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes may be limited.

Our ability to make payments of principal and interest on our indebtedness depends upon our future performance, which will be subject to general economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control. If we are unable to generate sufficient cash flow from operations in the future to service our debt, we may be required, among other things:

- to seek additional financing in the debt or equity markets;
- to refinance or restructure all or a portion of our indebtedness, including the 2005 Notes or the 2003 Notes;

- to sell selected assets;
- to reduce or delay planned capital expenditures; or
- to reduce or delay planned operating expenditures, such as clinical trials.

Such measures might not be sufficient to enable us to service our debt. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms.

We may not successfully integrate the ESP Pharma business and may not realize the anticipated benefits of the merger.

In March 2005, we completed our acquisition of ESP Pharma, a privately owned company. Achieving the benefits of the merger will depend in substantial part on the successful integration of the two companies' operations and personnel. Prior to the merger, PDL and ESP Pharma operated independently, each with its own operations, corporate culture, locations, employees and systems. PDL and ESP Pharma are now operating as a combined organization and began utilizing common business, information and communication systems, operating procedures, financial controls, compensation practices, training and professional development programs. However, additional activities in many areas are required to achieve full integration and PDL and ESP Pharma will continue to face significant challenges in integrating the organizations and operations in a timely and efficient manner. Some of the challenges and difficulties involved in this integration include:

- demonstrating to the customers of PDL and ESP Pharma that the merger will not result in adverse changes in client service standards or business focus and helping customers conduct business successfully with the combined company;
- coordinating sales and marketing efforts to effectively communicate the capabilities of the combined company;
- coordinating and rationalizing commercialization and development activities to enhance introduction of new products and development programs;
- preserving important relationships of both PDL and ESP Pharma and resolving potential conflicts that may arise, including the establishment of new trade practices and relationships with wholesalers;
- management distraction from the business of the combined company;
- incompatibility of corporate cultures;
- costs and delays in implementing common systems and procedures;
- consolidating and rationalizing corporate and administrative infrastructures, including establishment of appropriate internal controls and staffing levels to manage a much larger business enterprise;
- integrating and documenting processes and controls in conformance with the requirements of the Sarbanes-Oxley Act of 2002; and
- operating the combined company at multiple sites in the United States.

Any one or all of these factors, many of which are outside our control, may increase operating costs or lower anticipated financial performance. In addition, the combined company may lose distributors, suppliers, manufacturers and employees. Achieving anticipated synergies and the potential benefits underlying the two companies' reasons for the merger will depend on the continued successful integration of the two companies.

In addition, the integration of PDL and ESP Pharma is a complex, time consuming and expensive process and has and will continue to require significant attention from management and other personnel, which may distract their attention from the day-to-day business of the combined company. The diversion of management's attention and any difficulties associated with integrating ESP Pharma into PDL could have a material adverse effect on the operating results of the combined company after the merger and the value of PDL shares, and could result in the combined company not achieving the anticipated benefits of the merger. While we have achieved a significant level of integration, it is not certain that we will achieve all aspects of integration successfully, or that all of the anticipated benefits will be realized. Failure to do so could have a material adverse effect on the business and operating results of the combined company.

The issuance of shares of PDL common stock in the acquisition of ESP Pharma substantially reduced the percentage interests of holders of PDL common stock and securities convertible into PDL common stock, and the registered sale of these shares could decrease the market value of our common stock.

Upon completion of the merger, the shares of ESP Pharma preferred stock, common stock and options therefore converted into the right to receive $325.0 million in cash and 9,853,770 shares of PDL common stock. We registered for resale the PDL shares issued in the acquisition of ESP Pharma, which has resulted in the registered sale of, and could result in the further registered sale of, a substantial number of shares of our common stock and which could lead to a decrease in the market price of our common stock.

Delays or problems with our integration of sales, marketing and distribution capabilities with the acquisition of ESP Pharma may hamper continued growth projections for products acquired from the merger.

We are continuing to market and sell the products acquired as part of the ESP Pharma acquisition, including in particular Cardene IV, Retavase and IV Busulfex. Although we have retained most of the hospital-focused sales and related sales infrastructure, prior to the merger we had never sold, marketed or distributed products, and we encounter challenges in the continuing integration of such capabilities from ESP Pharma necessary to continue to successfully promote the ESP Pharma products.

We cannot assure you that our customers will continue their current buying patterns; our customers may delay or defer purchasing decisions in response to changes in practices and policies by PDL. Any such delay or deferral in purchasing decisions by such customers could have a material adverse effect on the business or operating results of the combined company. In addition, as part of the integration of ESP Pharma, we have changed certain trade practices and more effectively enforced trade policies to be more consistent with what we believe to be industry standards and the natural demand for our products. This has resulted in adjustments to reserves and declining or holding orders to align selling patterns with our understanding of the end user demand for our products.

As a result of the ESP Pharma merger, the combined company is a larger and more geographically diverse organization, and if the combined company's management is unable to manage the combined organization efficiently, its operating results will suffer.

As a result of the merger with ESP Pharma, the combined company faces challenges inherent in efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. The inability to manage successfully the geographically more diverse and substantially larger combined organization and the inability to retain or replace key employees could have a material adverse effect on the operating results of the combined company and, as a result, on the market price of PDL's common stock.

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

We have agreements with pharmaceutical and other companies to develop, manufacture and market certain of our potential products. In some cases, we are relying on our partners to manufacture such products and essential components for those products, to design and conduct clinical trials, to compile and analyze the data received from these trials, to obtain regulatory approvals and, if approved, to market these licensed products. As a result, we may have little or no control over the manufacturing, development and marketing of these potential products and little or no opportunity to review the clinical data prior to or following public announcement. In addition, the design of the clinical studies may not be sufficient or appropriate for regulatory review and approval and we may have to conduct further studies in order to facilitate approval.

In particular, we and Biogen Idec have entered into a long-term agreement which became effective in September 2005 under which Biogen Idec became our partner on three of our most advanced clinical programs, M200, *HuZAF*™ and daclizumab in certain indications including multiple sclerosis. The agreement provides for the development, manufacture and potential commercialization of products from these programs with each of Biogen Idec and PDL assuming certain responsibilities and sharing expenses. Because of the broad scope of the collaboration, we are particularly dependent upon Biogen Idec's performance of its obligations under the agreement. The failure of Biogen Idec to perform its obligations, our failure to perform our obligations or to effectively manage the relationship, or a material contractual dispute with Biogen Idec would have a material adverse effect on our prospects or financial results.

We rely on third parties, such as clinical research organizations, medical institutions and clinical investigators, including physician sponsors, to conduct nearly all of our clinical trials, including recruiting and enrolling patients in the trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed or may not be able to obtain regulatory approval for or commercialize our product candidates. If any of the third parties upon whom we rely to conduct our clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by third party contractors is compromised due to their failure to adhere to applicable laws, our clinical protocols or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize any of our product candidates. If our relationships with any of these organizations or individuals terminates, we believe that we would be able to enter into arrangements with alternative third parties. However, replacing any of these third parties could delay our clinical trials and could jeopardize our ability to obtain regulatory approvals and commercialize our product candidates on a timely basis, if at all.

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

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

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

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

If we are unable to favorably assess the effectiveness of internal control 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 (Section 404), our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. The rules governing the standards that must be met for management to assess the effectiveness of our internal control over financial reporting are new and complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal control over financial reporting successfully in 2004. In 2005, we will not only be required to conduct corresponding tests for our new enterprise resource planning software from SAP, but also must review and consider the requirements of Section 404 as applied to our recently acquired operations from ESP Pharma. Since ESP Pharma operated as a private company, they were not required to, and did not complete the documentation, testing and possible remediation efforts that would have been required had they been subject to Section 404. Many of the individuals responsible for operations and finance at ESP Pharma have recently departed and we are in the process of transferring many of the finance functions to PDL from ESP Pharma. As it is not possible for us to conduct an assessment of ESP Pharma's internal control over financial reporting prior to the management report for Section 404 compliance, we are permitted and have elected to exclude the ESP Pharma operations from the Section 404 compliance requirements for the year ending December 31, 2005. However, there can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting as of the end of 2005. The Section 404 compliance process has resulted, and will continue to result, in increased expenses and the devotion of significant management resources. During our review of the results of operation for the quarter ended

September 30, 2005, we identified a material weakness in our internal controls over financial reporting as defined in Public Company Accounting Oversight Board (PCAOB) Standard No. 2 related to our failure to effectively and timely implement an existing internal control with respect to a non-recurring item. In particular, with respect to the asset impairment of our off-patent branded products, we failed to timely assess the existence of indicators of impairment of these intangible assets in accordance with our existing internal controls.

If we cannot correct the material weakness we have identified prior to the end of fiscal year 2005, or if we experience other problems that prevent the favorable assessment of the effectiveness of our internal control over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment in the future, investor confidence and our stock price could be adversely affected.

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. In particular, our product sales and royalty revenues may be unpredictable and may fluctuate since they depend upon:

- the seasonality and rate of growth of sales of existing and licensed products;
- the existence of competing products;
- the market launch of recently acquired products;
- the response of wholesalers at announced or anticipated price changes for our products;
- uncertainty resulting from the purchase practices of wholesalers and inventory levels at wholesalers;
- product returns, reimbursements and rebates which could differ from our estimates and accruals;
- the continued safety of approved products;
- the marketing and promotional efforts of our licensees from whom we receive royalty payments;
- the timing of royalty reports, some of which are required quarterly and others semi-annually;
- our ability to successfully defend and enforce our patents;
- the effect of taxes and estimates or adjustments to estimates for federal and state taxes that may impact our reported net income in any particular quarter; and
- the effect of new accounting, pronouncements or interpretations of existing guidance, in particular as they may affect the accounting treatment of reimbursement of research and development expenses under collaborative arrangements.

We receive royalty revenues on sales of the product Synagis, which product is marketed by MedImmune. 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 will begin recognizing expense for outstanding employee stock options beginning in 2006, 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. (Exelixis) 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.

More than half 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 antibody 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: (i) the scope and validity of our second European patent; and (ii) 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.

At an oral hearing in February 2005, the Opposition Division of the European Patent Office decided to revoke the claims in our second European antibody humanization patent. The Opposition Division based its decision on formal issues and did not consider substantive issues of patentability. We have appealed the decision to the Technical Board of Appeal at the European Patent Office in July 2005. The appeal will suspend the legal effect of the decision of the Opposition Division during the appeal process, which is likely to take several years.

We intend to vigorously defend the European patents 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 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.

In regard to our Japanese humanization patent, in December 2004, the Japanese Supreme Court denied our petition for review of the Tokyo High Court decision upholding revocation of the patent by the Japanese Patent Office. The Japanese Supreme Court decision concludes the proceedings in the matter and the Japanese Patent Office decision to revoke our patent is final.

In October 2004, the Japanese Patent Office issued a patent to our first divisional humanization patent application. This patent claims a method of producing a humanized antibody specifically reactive with the human interleukin-2 (IL-2) receptor and the composition of matter directed to the Zenapax (daclizumab) antibody product. Although we have additional divisional patent applications pending in Japan, there can be no assurance that any patents will issue from such divisional applications or that the scope of such patents, if any, would be sufficient to cover third party antibody products.

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 we may not be able to market our products at all.

Celltech Therapeutics Limited (Celltech) which has been acquired by UCB Group, for example, 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. At an oral hearing in January 2005, the Opposition Division decided to revoke this patent. Celltech has filed an appeal. We cannot predict whether Celltech's appeal will be successful, 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 its 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, which rights may be exercised under the agreement through 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, 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 have not commercialized any antibody 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. Our antibody product candidates are in various stages of development and many are in an early development stage. If we are unsuccessful in our research efforts to identify and obtain rights to new targets and generate antibody product candidates that lead to the required regulatory approvals and the successful commercialization of products, our ability to develop new products could be harmed.

If we are unable to develop new products, our ability to grow may depend on our success in acquiring or licensing new products and integrating them successfully.

If we are unable to develop new products, we may depend on acquisitions of rights to products from others as our primary source of new products. Risks in acquiring new products include the following:

- we may not be able to locate new products that we find attractive and complementary to our business;
- the price to acquire or obtain a license for these products may be too costly to justify the acquisition; or
- we may be unable to successfully integrate the research, development and commercialization capabilities necessary to bring these products to market.

Clinical development is inherently uncertain and expensive, and costs may fluctuate unexpectedly.

Our development of current and future product candidates, either alone or in conjunction with collaborators, is subject to the risks of failure inherent in the development of new drugs. Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products. Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended use in humans. We have incurred and will continue to incur substantial expense for, and we have devoted and expect to continue to devote a significant

amount of time to, preclinical testing and clinical trials. Despite the time and expense incurred, there can be no assurance that our clinical trials will adequately demonstrate the safety and effectiveness of our product candidates.

Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of potentially new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or failures of our clinical trials as a result of many factors, all of which may increase the costs and expense associated with the trial, including:

- changes in regulatory policy during the period of product development;
- delays in obtaining sufficient supply of materials to enroll and complete clinical studies according to planned timelines;
- delays in obtaining regulatory approvals to commence a study;

- delays in identifying and reach agreement on acceptable terms with prospective clinical trial sites;
- delays in the enrollment of patients;
- lack of efficacy during clinical trials; or
- unforeseen safety issues.

Completion of clinical trials may take several years or more. The length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly according to the type, complexity, novelty and intended use of the product candidate and is difficult to predict. Further, we, the FDA, EMEA, investigational review boards or data safety monitoring boards may decide to temporarily suspend or permanently terminate 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. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to preclinical or clinical trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future. Despite the time and expense incurred, we cannot guarantee that we will successfully develop commercially viable products that will achieve FDA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

We are subject to extensive government regulation, which requires us to invest significant resources in development, and we may not be able to obtain regulatory approvals, which are required for us to conduct clinical testing and commercialize our products.

Our product candidates under development are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, research, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, quality control, adverse event reporting, advertising, promotions, sale and distribution of biopharmaceutical products. If we market our products abroad, they will also be subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain. 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.

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. We may decide, or the FDA may require us, to make changes in our plans and protocols. Such changes may relate, for example, to changes in the standard of care for a particular disease indication, comparability of efficacy and toxicity of potential drug product where a change in the manufacturing process or manufacturing site is proposed, or competitive developments foreclosing the availability of expedited approval procedures. We may be required to support proposed changes with additional preclinical or clinical testing, which could delay the expected time line for concluding clinical trials.

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. The approval process takes many years, requires the expenditure of substantial resources, and may involve post-marketing surveillance and

requirements for post-marketing studies. The approval of a product candidate may depend on the acceptability to the FDA of data from our clinical trials. Regulatory requirements are subject to frequent change. Delays in obtaining regulatory approvals may:

- adversely affect the successful commercialization of any drugs that we develop;
- impose costly procedures on us;
- diminish any competitive advantages that we may attain; and
- adversely affect our receipt of revenues or royalties.

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.

The "fast track" designation for development of any of our products may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood the product will receive regulatory approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA "fast track" designation for a particular indication. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although we have obtained a fast track designation from the FDA for Nuvion for the treatment of intravenous steroid-refractory ulcerative colitis and our partner Orphan Therapeutics has received fast track designation from the FDA for Terlipressin for Hepato-Renal Syndrome, Type 1, receipt of fast track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that Nuvion will receive regulatory approval for the treatment of intravenous steroid-refractory ulcerative colitis.

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 clinical strategies that seek to advance potential products through clinical development as rapidly as possible. For example, our recent projection for regulatory approval of Nuvion in the U.S. has been revised to reflect recent discussions with the FDA that will result in certain delays in the timeline for potential approval due to the need for additional Phase II/III safety data. 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 licensees or others. In February 2005, Biogen Idec and Elan announced that they had voluntarily suspended supplying, marketing and the sale of Tysabri, a drug approved to treat multiple sclerosis and which is licensed under our humanization patents. Financial analyst and investor expectations, as well as our own financial plans beginning in 2005, included potential royalties from the sale of Tysabri. There can be no assurance that Tysabri will be returned to the market, the timing of such return, if ever, or that even if subsequently marketed and sold, the product will result in our receiving any significant royalties from the sales of Tysabri.

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. To achieve our objectives, we expect to expand our operations and increase the number of our employees significantly. If we are unsuccessful in attracting and retaining qualified personnel, particularly at the management level, our business could be impaired. We have been successful in hiring and retaining key personnel in the past; however, we face significant competition for experienced, management level personnel. In addition, our CFO has announced that he will resign as CFO in October 2005. While we expect to retain him as an employee through the fiscal year end, we have not yet identified a replacement. If we do not timely identify and retain a CFO, or if other positions in finance remain or become vacant, our ability to operate effectively, including our ability to report on and attest to, the effectiveness of our internal control over financial reporting as of the end of 2005, could be adversely affected.

Our own ability to manufacture our antibody products on a commercial scale is uncertain, which may make it more difficult to sell our products.

The manufacture of antibodies for use as therapeutics in compliance with regulatory requirements is complex, time-consuming and expensive. We will need to manufacture such antibody therapeutic products in a facility and by an appropriately validated process that comply with FDA, European, and other regulations. Our manufacturing operations will be subject to ongoing, periodic unannounced inspection by the FDA and state agencies to ensure compliance with good manufacturing practices. If we are unable to manufacture product or product candidates in accordance with FDA and European good manufacturing practices, we may not be able to obtain regulatory approval for our products.

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 also 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 manufacturing plant. We may encounter problems with the following:

- production yields;
- quality control and assurance;
- availability of qualified personnel;
- availability of raw materials;
- adequate training of new and existing personnel;
- on-going compliance with our standard operating procedures;
- on-going compliance with FDA regulations;
- production costs; and
- development of advanced manufacturing techniques and process controls.

Failure to successfully operate our manufacturing plant, or to obtain regulatory approval or to successfully produce commercial supplies on a timely basis could delay commercialization of our products.

In addition, as we implement validation of our Brooklyn Park, Minnesota manufacturing facility, we are implementing an enterprise resource management software platform to support our operations, 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.

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

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 form the drug material previously produced. Changing the manufacturing site is considered to be a change in the manufacturing process, therefore moving production to our Brooklyn Park manufacturing facility from our Plymouth facility or from third parties will entail manufacturing changes. Further, any significant manufacturing changes for the production of our product candidates could result in delays in development or regulatory approval or in the reduction or interruption of commercial sales of our product candidates. Our inability to maintain our manufacturing operations in compliance with applicable regulations within our planned time and cost parameters could materially harm our business, financial condition and results of operations.

With respect to our M200 antibody product, ICOS Corporation (ICOS) has manufactured all of the drug material contemplated for use in our current Phase II clinical studies. We plan to assume responsibility for manufacturing M200 for use in Phase III clinical studies and commercial supply, if required. We will need to show that the M200 drug material we produce will be sufficiently similar to the ICOS-produced drug material to use in future clinical studies in order to avoid delays in development or regulatory approval for this antibody product.

Additionally, when we assume responsibility for manufacturing daclizumab marketed under the trade name 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 our material and 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 older material and the newer material after making manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

Our 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, are developing, 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. For example, we are aware that The Medicines Company has a product currently in development, clevidipine, which is an intravenous, short-acting calcium channel antagonist being developed in late-stage clinical trials for the short-term control of high blood pressure in the hospital setting. There can be no assurance that the ongoing or future clinical studies will not show superior benefits than those obtained with Cardene IV, or that The Medicines Company's sales and marketing efforts will not negatively impact Cardene IV. In addition, 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 AG (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. As a result of Novartis' relationship with Roche, Roche may not devote significant resources to the marketing and sales of Zenapax, which could harm our business.

We may be unable to obtain or maintain regulatory approval for our products and the marketing and sale of our products could result in violations of law or regulations.

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.

Even if marketing approval from the FDA is received, the FDA may impose post-marketing requirements, such as:

- labeling and advertising requirements, restrictions or limitations, such as the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our product candidates;
- adverse event reporting;
- testing and surveillance to monitor our product candidates and their continued compliance with regulatory requirements; and

- inspection of products and manufacturing operations and, if any inspection reveals that the product or operation is not in compliance, prohibiting the sale of all products, suspending manufacturing or withdrawing market clearance.

The discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, may result in restrictions of the products, including withdrawal from manufacture. Additionally, certain material changes affecting an approved product such as manufacturing changes or additional labeling claims are subject to further FDA review and approval. The FDA may revisit and change its prior determination with regard to the safety or efficacy of our products and withdraw any required approvals after we obtain them. Even prior to any formal regulatory action requiring labeling changes or affecting manufacturing, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety and efficacy develop.

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 are required to comply with the applicable FDA cGMP regulations and other regulatory requirements. Good manufacturing practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities, including our facility, must pass an inspection by the FDA before initiating commercial manufacturing of any product. Pharmaceutical product manufacturing establishments are also subject to inspections by state 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. The FDA enforces post-marketing regulatory requirements, such as cGMP requirements, through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to pass an inspection could disrupt, delay or shut down our manufacturing operations.

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. 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 potential antibody products that we may obtain and manufacture for ourselves, including, for example, Zenapax.

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 Biologics License Application (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. In their regulation of advertising, the FDA, the Federal Trade Commission (FTC) and the Department of Health and Human Services (HHS) may investigate whether particular advertising or promotional practices are false, misleading or deceptive. These agencies may impose a wide array of sanctions on companies for such advertising practices. Additionally, physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of "off-label" use. Companies cannot promote FDA-approved pharmaceutical or biologic products for off-label uses. If our advertising or promotional activities fail to comply with applicable regulations or guidelines, we may be subject to warnings or enforcement action. In addition, there may be a similar risk with respect to all products currently developed and marketed by ESP Pharma, including Cardene IV, IV Busulfex, and Retavase.

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. If we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including:

- delays;
- warning letters;
- fines;
- clinical holds;
- product recalls or seizures;
- changes to advertising;

- injunctions;
- refusal of the FDA to review pending market approval applications or supplements to approval applications;

- total or partial suspension of product manufacturing, distribution, marketing and sales;
- civil penalties;
- withdrawals of previously approved marketing applications; and
- criminal prosecutions.

If our products do not gain market acceptance among the medical community, our revenues would be adversely affected and might not be sufficient to support our operations.

Our product candidates may not gain market acceptance among physicians, patients, third-party payers and the medical community. We may not achieve market acceptance even if clinical trials demonstrate safety and efficacy, and the necessary regulatory and reimbursement approvals are obtained. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of our product candidates;
- their potential advantage over alternative treatment methods;
- reimbursement policies of government and third-party payers; and
- marketing and distribution support for our product candidates, including the efforts of our collaborators where they have marketing and distribution responsibilities.

Physicians will not recommend therapies using our products until such time as clinical data or other factors demonstrate the safety and efficacy of such procedures as compared to conventional drug and other treatments. Even if we establish the clinical safety and efficacy of therapies using our antibody product candidates, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our antibody products is effective for certain indications. Antibody products, including our product candidates as they would be used for certain disease indications, are typically administered by infusion or injection, which requires substantial cost and inconvenience to patients. Our product candidates, if successfully developed, will compete with a number of drugs and therapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payers and the medical community may not accept or utilize any product candidates that we, or our customers, develop. The failure of our products to achieve significant market acceptance would materially harm our business, financial condition and results of operations.

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 products sold by us or the use of products during research and development efforts or after commercialization results in adverse effects. This risk exists even with respect to any products that receive regulatory approval for commercial sale. While we maintain liability insurance for our products, it may not be sufficient to satisfy any or all liabilities 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. The FDA and other health care policies may change, and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates. 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 payers 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. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

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

Market prices for securities of biotechnology companies, including ourselves, have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. For example, during the period from January 1, 2005 to November 7, 2005, our common stock closed as high as $29.92 per share and as low as $13.85 per share. 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:

- our financial results;
- developments or disputes as to patent or other proprietary rights;
- disappointing sales of approved products;
- approval or introduction of competing products and technologies;
- withdrawal from the market of an approved product from which we receive royalties;
- results of clinical trials;
- failures or unexpected delays in obtaining regulatory approvals or unfavorable FDA advisory panel recommendations;
- changes in reimbursement policies;
- delays in manufacturing or clinical trial plans;

- fluctuations in our operating results;
- disputes or disagreements with collaborative partners;
- developments in our relationships with customers;
- market reaction to announcements by other biotechnology or pharmaceutical companies, including market reaction to various announcements regarding products licensed under our technology;
- 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.

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 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. For example, the FASB recently enacted SFAS 123R, which will require us to adopt a method of determining the compensation expense of our employee stock options and report them in the captions of our financial statements. The compensation expense reported under SFAS 123R will have a significant adverse effect on our reported financial condition and may impact the way we conduct our business.

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.

We may not have the ability to raise the funds to repurchase the 2003 Notes on the repurchase date or to finance any repurchase offer required by the indenture.

In August 2010, August 2013 and August 2018, respectively, holders of the 2003 Notes may require us to repurchase all or a portion of their 2003 Notes at 100% of their principal amount, plus any accrued and unpaid interest to, but excluding, such date. For 2003 Notes to be repurchased in August 2010, we must pay for the repurchase in cash, and we may pay for the repurchase of 2003 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 2003 Notes may require us to repurchase all or a portion of the holder's 2003 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 2003 Notes or make our repurchase of 2003 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 2003 Notes, we could seek the consent of the lender to purchase the 2003 Notes or could attempt to refinance the debt covered by the credit agreement. If we do not obtain a consent, we may not repurchase the 2003 Notes. Our failure to repurchase tendered 2003 Notes would constitute an event of default under the indenture for the 2003 Notes, which might also constitute a default under the terms of our other debt, including the 2005 Notes. In such circumstances, our financial condition and the value of our securities could be materially harmed.

We may not have sufficient cash to purchase the 2005 Notes, if required, upon a fundamental change.

Holders of the 2005 Notes may require us to purchase all or any portion of their 2005 Notes upon a fundamental change, which generally is defined as the occurrence of any of the following: (1) our common stock is not traded on a national securities exchange or listed on The Nasdaq National Market; (2) any person acquires more than 50% of the total voting power of all shares of our capital stock; (3) certain mergers, consolidations, sales or transfers involving us occur; or (4) our board of directors does not consist of continuing directors. In certain situations, holders of the 2005 Notes will not have a repurchase right even if a fundamental change has occurred. In addition, we may not have sufficient cash funds to repurchase the 2005 Notes upon such a fundamental change. Although there are currently no restrictions on our ability to pay the purchase price, future debt agreements may prohibit us from repaying the purchase price. If we are prohibited from repurchasing the 2005 Notes, we could seek consent from our lenders at the time to repurchase the 2005 Notes. If we are unable to obtain their consent, we could attempt to refinance their debt. If we were unable to obtain consent or refinance the debt, we would be prohibited from repurchasing the 2005 Notes upon a fundamental change. If we were unable to purchase the 2005 Notes upon a fundamental change, it would result in an event of default under the indenture. An event of default under the indenture could result in a further event of default under our other then-existing debt. In addition, the occurrence of the fundamental change may be an event of default under our other debt, which could have a significant adverse affect on our financial condition.

If any or all of our outstanding 2003 Notes or 2005 Notes are converted into shares of our common stock, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

Our 2003 Notes and 2005 Notes are convertible, at the option of the holder, into shares of our common stock at varying conversion prices. We have reserved shares of our authorized common stock for issuance upon conversion of our 2003 Notes and the 2005 Notes. If any or all of our 2003 Notes or the 2005 Notes are converted into shares of our common stock, our existing stockholders will experience immediate dilution and our common stock price may be subject to downward pressure. If any or all of our 2003 Notes or 2005 Notes are not converted into shares of our common stock before their respective maturity dates, we will have to pay the holders of such notes the full aggregate principal amount of the 2003 Notes or 2005 Notes, respectively, then outstanding. Any such payment would have a material adverse effect on our cash position.

Charges to earnings and related amortization of assets resulting from our acquisitions may adversely affect the market value of PDL's common stock following the merger.

In accordance with U.S. generally accepted accounting principles, we accounted for the acquisition of ESP Pharma, our acquisition of Retavase and our acquisition of Zenapax using the purchase method of accounting, which resulted in charges to earnings in the year of acquisition and which will result in ongoing expenses due to the amortization and depreciation of certain assets acquired in those transactions. Under the purchase method of accounting, we allocated the total estimated purchase price to ESP Pharma's net tangible assets, amortizable intangible assets and in-process research and development based on their fair values as of the date of completion of the merger, and recorded the excess of the purchase price over those fair values as goodwill. The portion of the estimated purchase price of ESP Pharma allocated to in-process research and development in the amount of $79.4 million was expensed by the combined company in the first quarter of 2005. PDL will incur additional depreciation and amortization expense over the useful lives of certain of the net tangible and intangible assets acquired in connection with the acquisition transactions. In addition, to the extent the value of goodwill becomes impaired in the future, PDL may be required to incur material charges relating to the impairment of goodwill. These depreciation, amortization, in-process research and development and potential impairment charges could have a material impact on the combined company's results of operations and the market value of PDL's common stock.

Failure to achieve revenue targets or raise additional funds in the future may require the combined company to delay, reduce the scope of or eliminate one or more of its planned activities.

The acquisition of ESP Pharma and certain rights to Retavase required cash payments of approximately $435.5 million. While we believe we have sufficient funds for our anticipated operations, we will need to generate significantly greater revenues to achieve and then maintain profitability on an annual basis. The product development, including clinical trials, manufacturing and

regulatory approvals of product candidates currently in development, and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future funding requirements, which may be significantly greater than we expect, depend upon many factors, including:

- the extent to which Cardene IV is commercially successful;
- the extent to which Retavase sales can be maintained or increased from recent historical levels;
- the progress, level and timing of research and development activities related to clinical trials we are conducting or that are being conducting in collaboration with our partners, including clinical trials with respect to daclizumab, Nuvion, ularitide and M200;
- the cost and outcomes of regulatory submissions and reviews;
- the continuation or termination of third party manufacturing or sales and marketing arrangements;
- the cost and effectiveness of our sales and marketing programs;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights;
- our ability to extend the patent protection of our currently marketed products; and
- the establishment of additional strategic or licensing arrangements with other companies, or acquisitions.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

Our industry is highly competitive. Our success will depend on our ability to acquire and develop products and apply technology, and our ability to establish and maintain markets for our products. Potential competitors in the U.S. and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions.

In addition, product sales from ESP Pharma products face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of its products. Many of the marketed products are generic versions of brand-name products with declining total sales levels. Additionally, some of our brand-name products are subject to competition from generic products. As a result, we face competition for our marketed products from brand-name pharmaceutical companies and from companies focused on generic pharmaceutical markets. In addition, competitors may succeed in developing products and technologies that are more effective or less costly than our products, or that would render our products obsolete or noncompetitive.

For the year ended December 31, 2004, approximately 34% of the ESP Pharma net product sales resulted from the sale of the off-patent products Tenex®, Sectral®, Ismo® and Declomycin. These products historically accounted for a majority of the cash flow from operations of ESP Pharma. We do not consider these products as strategic assets and we are in the process of selling them. The related intangible assets were classified as held for sale with a fair market value less than the carrying amount as of September 30, 2005. As such, an impairment loss of approximately $15.2 million was recognized in the three months ended September 30, 2005 (see Note 10 of the Financial Statements in Part I, Item 1 of this Quarterly Report). If sales of Cardene IV and Retavase do not perform as planned and we are unable to maintain the cash flow returns from or successfully divest these off-patent products, our ability to achieve positive cash flow from operations could be delayed.

Our ability to generate future revenue from products will be affected by reimbursement and drug pricing.

Acceptable levels of reimbursement of drug treatments by government authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, our combined portfolio of product candidates. We cannot be sure that reimbursement in the U.S. or elsewhere will be available for any products that we may develop or, if already available, will not be decreased in the future. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize products, and may not be able to obtain a satisfactory financial return on products.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the U.S. and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including our products. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that are successfully developed and approved. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

We will spend considerable time and money complying with federal and state regulations and, if we are unable to fully comply with such regulations, we could face substantial penalties.

We may be subject, directly or through our customers, to extensive regulation by both the federal government, and the states and foreign countries in which we conduct our business. Laws that may directly or indirectly affect our ability to operate our business include, but are not limited, to the following:

- the federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and

- state law equivalents to the Anti-Kickback Law and False Claims Act, which may not be limited to government reimbursed items.

If our operations are found to be in violation of any of the laws described above or the other governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if the hospitals, physicians or other providers or entities with whom we do business are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

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 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, 2005, 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, 2004.

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, 2005 and 2004, there was no material foreign currency exchange impact on our Consolidated Condensed Statements of Operations from our intercompany transactions. As of September 30, 2005, 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, 2005, our CEO and CFO, 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. Although we identified a material weakness in our internal controls as described below, management believes that our disclosure controls and procedures were sufficient to ensure that the financial data included in this Quarterly Report on Form 10-Q are fairly stated in all material respects.

Changes in internal controls. During our review of the results of operation for the quarter ended September 30, 2005, we identified a material weakness in the operation of our internal controls over financial reporting as defined in Public Company Accounting Oversight Board ("PCAOB") Standard No. 2 related to our failure to effectively and timely operate an existing internal control with respect to a non-recurring item. In particular, with respect to the asset impairment of our off-patent branded products, due in principal part to staffing resource limitations and the recent addition of new personnel to supplement our existing finance organization, we failed to timely assess the existence of indicators of impairment of these intangible assets in accordance with our existing internal controls.

We have discussed this matter with our independent auditors and our Audit Committee and are implementing increased staffing plans, including the retention of consulting resources through at least the close of the first quarter of 2006 and timelier review processes to ensure timely compliance with our existing internal controls. This remediation effort has already commenced and our expectation is that this material weakness will be remediated in the fourth quarter of 2005. We continue to improve and refine our internal controls and our compliance with existing controls is an ongoing process.

Also, in April 2005, we implemented a new enterprise resource planning software, SAP, in part in order to increase the automation of our internal controls over financial reporting. We are in the process of evaluating and assessing whether this change in our internal controls has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Although we have expended significant resources, such evaluation and assessment is ongoing and we plan to test this system for our 2005 fiscal year.

There were no other changes in our internal controls over financial reporting during the quarter ended September 30, 2005 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, 2004. No significant changes in the status of disclosed items have occurred since December 31, 2004.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Our collaboration agreement and purchase agreement with Biogen Idec became effective as of the closing on September 12, 2005 (see "Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; Significant Events"). As previously disclosed on a Current Report on Form 8-K filed on September 12, 2005, at the closing, Biogen Idec purchased 4,058,935 shares of PDL common stock for aggregate proceeds to PDL of approximately $100 million (the "Stock Sale"). The Stock Sale was an unregistered sale of shares, and was made in reliance upon Section 4(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering, to a single person, Biogen Idec, an accredited investor.

ITEM 6. EXHIBITS

2.1 Amended and Restated Agreement and Plan of Merger by and among the Company, Big Dog Bio, Inc., a Delaware corporation and wholly owned subsidiary of the Company, and ESP Pharma Holding, dated as of March 22, 2005. (Incorporated by reference to Exhibit 2.1 to Registration Statement on Form S-3 filed March 25, 2005.)

2.2 Asset Purchase Agreement between Centocor, Inc., a Pennsylvania corporation, and ESP Pharma, Inc., a Delaware corporation and wholly owned subsidiary of ESP Pharma Holding Company, Inc., dated as of January 31, 2005. (Incorporated by reference to Exhibit 2.2 to Current Report on Form 8-K filed March 25, 2005.) (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)

3.1 Restated Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K filed March 31, 1993.)

3.2 Certificate of Amendment of Certificate of Incorporation. (Incorporated by reference to Exhibit 3.3 to Annual Report on Form 10-K filed March 14, 2002.)

3.3 Amended and Restated Bylaws of Protein Design Labs, Inc. effective as of June 8, 2005. (Incorporated by reference to Exhibit 99.3 to Current Report on Form 8-K filed June 14, 2005.)

4.1 Indenture between the Company and J.P. Morgan Trust Company, National Association, a national banking association, dated July 14, 2003. (Incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-3 filed September 11, 2003.)

4.2 Indenture between the Company and J.P. Morgan Trust Company, National Association, as trustee, dated as of February 14, 2005. (Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed February 14, 2005.)

4.3 Registration Rights Agreement between the Company and Goldman, Sachs & Co., Citigroup Global Markets Inc. and UBS Securities LLC dated as of February 14, 2005. (Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed February 14, 2005.)

10.1 Collaboration Agreement between the Company and Biogen Idec, dated as of September 12, 2005. (Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.)

10.2 Transition Agreement dated as of September 15, 2005 between the Company and Glen Sato. (Incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed September 19, 2005.)

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 8, 2005

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

/s/ George Jue
George Jue
Vice President, Finance and Corporate Controller
(Principal Accounting Officer)

EXHIBIT 10.1

Execution Version

CONFIDENTIAL PROVISIONS REDACTED

COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (the "**Agreement**") is entered into as of September 12, 2005 (the "**Effective Date**") by and between Protein Design Labs, Inc., a Delaware corporation having its offices at 34801 Campus Drive, Fremont, California 94555 ("**PDL**"), and Biogen Idec MA Inc., a Massachusetts corporation having offices at 14 Cambridge Center, Cambridge, Massachusetts 02142 ("**Biogen Idec**"). PDL and Biogen Idec may each be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, PDL possesses worldwide rights to develop, manufacture, market, and sell certain proprietary antibodies directed at certain antigens (such antigens defined below as "Collaboration Targets") and;

WHEREAS, PDL has research and development programs for such antibodies as well and for certain compounds relating to the Collaboration Targets; and

WHEREAS, Biogen Idec and PDL wish to collaborate in the research, development, manufacturing and commercialization of products for the Collaboration Targets, including such antibodies and compounds, under the terms and conditions set forth below.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the Parties, intending to be legally bound, agree as follows:

ARTICLE 1

DEFINITIONS

The following capitalized terms, whether used in the singular or the plural, shall have the following meanings as used in this Agreement unless otherwise specifically indicated:

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*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

1.1 **"α5β1"** means [****].

1.2 **"α5β1 Target Field"** means the diagnosis, treatment or prevention of human diseases.

1.3 **"α5β1 Target Future Product"** means [****].

1.4 **"α5β1 Target Product"** means [****].

1.5 **"Affiliate"** means any corporation or other business entity controlled by, controlling, or under common control with another entity, with "control" meaning: (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of, or at least fifty percent (50%) interest in the income of, such corporation or other business entity, or (b) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance. For purposes of clarity, Affiliates of Biogen Idec shall include Biogen Dompé SRL and Biogen Dompé AG.

1.6 **"Annual Workplan/Budget"** means, as to a Collaboration Product the detailed schedule of Development activities and budgets prepared pursuant to Section 3.3.

1.7 **"Antibody"** means a molecule comprising or containing: (a) one or more immunoglobulin variable domains; (b) fragments, variants, modifications or derivatives of molecules described in the foregoing clause (a); and (c) the nucleic acid consisting of a sequence of nucleotides encoding (or complementary to a nucleic acid encoding) an antibody. Antibody shall include any antibody monospecific and bispecific antibodies; less than full-length antibody forms such as Fv, Fab, and $F(ab')_2$; and any antibody or fragment that is conjugated or fused to any other composition, including for example, a toxin, radionuclide, small molecule, polypeptide or polypeptide fragment. The term Antibody includes any human, humanized, primatized, chimeric or other antibody.

1.8 **"Antibody Product"** means any pharmaceutical product having an Antibody as an active ingredient.

1.9 **"Approved Budget"** means the then-current JSC approved aggregate annual budget for the current calendar year for the Development and/or Commercialization of all Collaboration Products.

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

1.11 "Biogen Idec Indemnitees" shall have the meaning set forth in Section 15.1.

1.12 "Biogen Idec Inventions" means all Inventions that (a) relate to or are useful with any Antibody Product or Non-Antibody Product that are directed against or incorporate a Collaboration Target, (b) are made during the Term by one or more employees of Biogen Idec or its Affiliates or persons contractually required to assign or license patent rights covering such inventions to Biogen Idec or its Affiliates, in the course of performing Biogen Idec's obligations, or exercising Biogen Idec's rights, under this Agreement, and (c) are not Joint Inventions.

1.13 "Biogen Idec Know-How" means all Know-How that is (a) Controlled by Biogen Idec or its Affiliates at any time during the Term; (b) used by or on behalf of Biogen Idec or its Affiliates in the development or commercialization of a Collaboration Product and (c) reasonably necessary or useful for PDL to (i) perform its obligations under this Agreement or (ii) develop or commercialize a Collaboration Product or Royalty Product in the Field; provided that Biogen Idec Know-How shall not include methods of manufacturing, production and test methods, procedures and batch records, manufacturing and testing summary data, process and assay validation information, designing, developing or preparing Antibodies including methods of humanizing Antibodies, methods of reducing the immunogenicity of Antibodies, methods of modifying effector function, and methods of increasing the affinity or half-lives of Antibodies, unless necessary for PDL to perform its Development or Commercialization obligations hereunder.

1.14 "Biogen Idec Patent Rights" means Patent Rights that claim Technology Controlled by Biogen Idec or its Affiliates at any time during the Term and that relate in whole or in part to the Collaboration Targets or the manufacture, use or sale of Products. Biogen Idec Patent Rights shall not include Joint Patents but shall include Biogen Idec Target Patent Rights. As of the Effective Date, to Biogen Idec's knowledge, there are no Biogen Idec Patent Rights.

1.15 "Biogen Idec Target Patent Rights" means Patent Rights that claim Technology Controlled by Biogen Idec or its Affiliates at any time during the Term and that relate in substantial part to the Collaboration Targets or in substantial part to the manufacture, use or sale of Products.

1.16 "Biogen Idec Technology" means Biogen Idec Patent Rights and Biogen Idec Know-How.

1.17 "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

1.18 "Change of Control" means with respect to a Party: (i) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (ii) a merger, reorganization or consolidation involving such Party in which the voting

securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (iii) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.

1.19 "Clinical Supplies" shall mean supplies of Collaboration Product or Royalty Products, as the case may be, in suitable form, whether Manufactured by PDL or by Biogen Idec, as specified under this Agreement or under any Manufacturing agreement between the Parties, Manufactured in compliance with GMP, if required given the intended use, and ready to be used for the conduct of pre-clinical and/or human clinical trials of such Product in the Field by the Parties pursuant to the Development Plan and Annual Workplan/Budget.

1.20 "Collaboration" means the Parties' program of collaborative Development, and Commercialization of Products contemplated by this Agreement.

1.21 "Collaboration Committee" or "**Committee"** means any of the JSC, JDCs, JCCs, JPC or JFC, or any other committee formed with the approval of such other committees.

1.22 "Collaboration Invention" means a Joint Invention, Biogen Idec Invention or PDL Invention.

1.23 "Collaboration Product" means a Product being jointly Developed and Commercialized by the Parties under this Agreement pursuant to a Development Plan or a Commercialization Plan. For the avoidance of doubt, a Collaboration Product shall not be a Royalty Product.

1.24 "**Collaboration Product Profit**" means the profits or losses resulting from the Commercialization of Collaboration Products in the Profit Sharing Territory and shall be equal to [****].

1.25 "Collaboration Target" means [****].

1.26 "Combination Product" shall have the meaning set forth in Exhibit C.

1.27 "Combination Product Amount" shall have the meaning set forth in Exhibit C.

1.28 "Commercial Supplies" shall mean supplies of Collaboration Product or Royalty Product, as the case may be, in suitable final packaged form, as specified under a Commercial Supply Agreement, Manufactured in compliance with GMP, and ready to be offered for commercial sale for use in the Field in the Territory by Biogen Idec and/or PDL, and/or their Affiliates, or permitted licensees or sublicensees.

1.29 "Commercial Supply Agreement" shall have the meaning set forth in Section 8.3(a).

1.30 "Commercialization" means all activities undertaken relating to the manufacture, marketing, distribution, offer for sale and sale of a Product in the Field, including pre-marketing, advertising, education, planning, marketing, promotion, distribution, market and product support, post-Regulatory Approval product support and related medical affairs.

1.31 "Commercialization Plan" shall have the meaning set forth in Section 6.1(a).

1.32 "Confidential Information" means all Know-How, information (whether in written, oral, electronic, visual, tangible, or other form) and materials, including biological and other tangible materials, that are disclosed by one Party to the other Party prior to the Effective Date or during the Term and are either identified as confidential at the time of disclosure or should reasonably be believed to be of the type of information that would be considered confidential under the circumstances.

1.33 "Controlled" means, with respect to a Party and its Affiliates, and any intellectual property right, that the Party owns or has a license to such intellectual property right and has the ability to grant to the other Party a license or sublicense to such intellectual property right 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 license or sublicense.

1.34 "Controlling Party" shall have the meaning set forth in Section 12.5(b)(vi).

1.35 "Co-Promoting Party" shall have the meaning set forth in Section 7.1(c).

1.36 "**Co-Promotion Option**" shall have the meaning set forth in Section 7.1(a).

1.37 "Co-Promote Product" shall have the meaning set forth in Section 7.4.

1.38 "Cost of Clinical Supplies" shall have the meaning set forth in Exhibit C.

1.39 "Cost of Goods Manufactured for Sale" or **"COGM"** shall have the meaning set forth in Exhibit C.

1.40 "Cost of Sales" shall have the meaning set forth in Exhibit C.

1.41 "Daclizumab Product" means [****].

1.42 "Detail" or "Detailing" means a face-to-face presentation by a Party's sales representative, to one or several medical professional(s) having prescribing authority in the applicable territory in the Field, as well as to other mutually agreed individuals or entities that have significant impact or influence on prescribing decisions in the applicable territory in the Field, where the principal objective of such presentation is to emphasize the features and function of such Collaboration Product in the Field in a balanced manner. A Detail does not include a reminder or sample drop.

1.43 "Development" means all research and pre-Regulatory Approval development and regulatory activities in the Field regarding a Product. This includes (i) research, preclinical testing, toxicology, formulation, manufacturing-related technology development, and clinical studies of Products; and (ii) preparation, submission, review, and development of data or information for the purpose of submission to a governmental authority to obtain Regulatory Approval of Products, and outside counsel regulatory legal services related thereto. Development shall include development and regulatory activities for additional Indications for a Product after Regulatory Approval of such Product but shall not include Post-Approval Clinical Trials or Phase 4 Trials with respect to an approved Indication.

1.44 "Development Expenses" shall have the meaning set forth in Exhibit C.

1.45 "Development Plan" shall have the meaning set forth in Section 3.3(a).

1.46 "Development Program" means any of the following: (a) the program of Development contemplated by this Agreement for [****], (b) the program of Development contemplated by this Agreement for [****], and (c) the program of Development contemplated by this Agreement for [****], in each case as such programs may be revised or amended from time to time.

1.47 "Diligent Efforts" means reasonable and good faith efforts by a Party to accomplish such objective as that Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that, with respect to the Development or Commercialization of a Collaboration Product or Royalty Product, as the case may be, such efforts shall be similar to those efforts and resources commonly used by a Party for a similar pharmaceutical product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential in the applicable market taking into account efficacy, safety, approved labeling, the competitiveness of all products in the applicable market, the

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patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the product including the royalties payable to licensors of patent or other intellectual property rights, alternative products and other relevant factors. Diligent Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Product, and it is anticipated that the level of effort shall be different for different markets, and shall change over time, reflecting changes in the status of the Product and the market(s) involved.

1.48 "Drug Approval Application" means a Biologics License Application or an equivalent application for Regulatory Approval required before commercial sale or use of a pharmaceutical product in a field in a regulatory jurisdiction.

1.49 "EU Territory" 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, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

1.50 "Executive" means the Chief Executive Officer of a Party or such other executive officer designated by such person. If the Chief Executive Officer position for either Party is vacant or does not exist, then the person having the most nearly equivalent position at such Party (or such individual's designee) shall be deemed to be the Executive of such Party.

1.51 "**Existing Product**" means any one or more of the Daclizumab Product, the Fontolizumab Product or the Volociximab Product.

1.52 "Field" means: [****].

1.53 "First Commercial Sale" means, for each Collaboration Product or Royalty Product, as the case may be, in each country, the first sale for end use or consumption to a Third Party of such Product in the country by a Party, its Affiliate, or its sublicensee, after the granting of Regulatory Approval in the relevant Field for the Collaboration Product or Royalty Product, as the case may be, by the relevant governing authorities. First Commercial Sale excludes any sale or other distribution for use in a clinical trial or other Development activity.

1.54 "Fontolizumab Product" means [****].

1.55 "FTE Rate" shall have the meaning set forth in Exhibit C.

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1.56 "**Future Product"** means [****].

1.57 "GMP" means current Good Manufacturing Practices, as defined under the rules and regulations of the United States Food and Drug Administration, as the same may be amended from time to time.

1.58 "Gross Sales" shall have the meaning set forth in Exhibit C.

1.59 "IFN-γ" means [****].

1.60 "IFN-γ Target Field" means the diagnosis, treatment or prevention of human diseases.

1.61 "IFN-γ Target Future Product" means [****].

1.62 "IFN-γ Target Product" means [****].

1.63 "[****] Product" means the [****].

1.64 "IL-2R" means (a) the protein commonly known as the IL-2 receptor alpha subunit "p55" "TAC antigen", "CD25 antigen "T-Cell Growth factor receptor", "TCGFR" and (b) fragments of the foregoing.

1.65 "IL-2R Target Field" means the diagnosis, treatment or prevention of human diseases, but [****].

1.66 "IL-2R Target Future Product" means [****].

1.67 "IL-2R Target Product" means [****].

1.68 "Independent Indication" means, with respect to a particular Collaboration Product, any Indication for which a Party has exercised its opt-out right pursuant to Section 4.1 and shall include all Opt Out Indications, provided that such Party has not exercised its opt-in right for such Indication pursuant to Section 4.4 (after which such Indication shall cease to be an Independent Indication).

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1.69 "Independent Product" means a former Collaboration Product for which a Party terminated its participation in such Product pursuant to Section 4.1, and as to which no Indication is (i) being developed under the Collaboration, or (ii) is the subject of a proposal made in writing to the JSC under Section 3.10(a) as to which the JSC has not made a decision.

1.70 "Indication" means an illness or sickness; or any interruption, cessation or disorder of a particular bodily function, system or organ; in any case regardless of the severity, frequency or route of any treatment.

1.71 "Initial Development Program Budget" means the budget attached hereto as part of the initial draft Development Plan attached as Exhibit 3.3.

1.72 "Invention" means any process, method, composition of matter, article of manufacture, discovery or finding that is conceived and/or reduced to practice (whether or not patentable).

1.73 "Joint Commercialization Committee" or "JCC" shall have the meaning set forth in Section 2.4(a).

1.74 "Joint Development Committee" or "JDC" shall have the meaning set forth in Section 2.3(a).

1.75 "Joint Finance Committee" or "JFC" shall have the meaning set forth in Section 2.5(a).

1.76 "Joint Inventions" means all Inventions that are jointly made during the Term 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) Biogen Idec employee or person contractually required to assign or license patent rights covering such inventions to Biogen Idec.

1.77 "Joint Patent Committee" or "JPC" shall have the meaning set forth in Section 2.6(a).

1.78 "Joint Patent Rights" means all Patent Rights that claim or cover Joint Inventions.

1.79 "Joint Steering Committee" or "JSC" shall have the meaning set forth in Section 2.2(a).

1.80 "Know-How" means Inventions, discoveries, trade secrets, information, experience, data, formulas, procedures, technology and results (whether or not patentable), which at the time of use constitute Confidential Information, including discoveries, formulae, materials including biological materials, practices, methods, knowledge, know-how, processes, experience and test data (including physical, chemical, biological, toxicological, pharmacological, clinical, and veterinary data), dosage regimens, control assays, product specifications, analytical and quality control

data, marketing, pricing, distribution cost and sales data or descriptions.

1.81 "Losses" shall have the meaning set forth in Section 15.1.

1.82 "Manufacturing" means any activities related to the manufacturing of a Collaboration Product or Royalty Product, as the case may be, or any ingredient thereof, including manufacturing process development, technology transfer, and scale-up, establishment of manufacturing capacity, evaluation, qualification and validation of manufacturing processes and facilities, manufacturing active ingredients or supplies of such Product for Development, manufacturing such Product for commercial sale, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, and quality assurance activities related to manufacturing, ongoing stability tests and regulatory activities related to any of the foregoing.

1.83 "Manufacturing Party" shall have the meaning set forth in Section 8.1.

1.84 "Milestone Indication" means any Indication as to which a separate Drug Approval Application is required for approval in a jurisdiction. By way of example, (i) for ophthalmology Indications, macular degeneration and diabetic retinopathy are two separate Milestone Indications, (ii) with respect to autoimmune disease indications, Crohn's disease and ulcerative colitis are two separate Milestone Indications and (iii) with respect to cancer Indications, "Milestone Indication" means a cancer of a particular organ or any metastatic progression thereof, including as distinct Milestone Indications, breast cancer, prostate cancer, colon cancer, rectal cancer, ovarian cancer, uterine cancer, gastric cancer, bladder cancer, brain cancer, bile duct cancer, pancreatic cancer, kidney cancer, stomach cancer, head-and-neck cancer, esophageal cancer, liver cancer, and lung cancer.

1.85 "MS" means multiple sclerosis.

1.86 "Net Sales" shall have the meaning set forth in Exhibit C.

1.87 "Non-Antibody Product" means any pharmaceutical product having as an active ingredient any synthetic molecule or biologic molecule other than an Antibody, including a compound that has a molecular weight that is less than or equal to 1000 daltons, fusion protein (other than an Antibody), antisense molecule, siRNA, nucleic acid, peptide, polypeptide (other than an Antibody) or fragment thereof.

1.88 "Non-Developing Party" shall have the meaning set forth in Section 4.1(a).

1.89 "North American Territory" means the United States (including its possessions and territories) and Canada.

1.90 "Ongoing Development Expense" shall have the meaning set forth in Exhibit C.

1.91 "Operating Expenses" shall have the meaning set forth in Exhibit C.

1.92 "Opt Out Indications" shall have the meaning set forth in Section 4.1(b)(iii).

1.93 "Other Out-of-Pocket Costs" shall have the meaning set forth in Exhibit C.

1.94 "Patent Expenses" means the sum of all out-of-pocket expenses reasonably incurred by a Party to prepare, file, prosecute and maintain PDL Target Patent Rights, Biogen Idec Target Patent Rights and Joint Patent Rights, including the costs of interferences/oppositions proceedings with respect to such Patent Rights, provided in each case such expenses have been incurred in accordance with Sections 12.4 and 12.5 and subject to Section 12.7 (b) (vii) below. In addition, Patent Expenses shall include the costs of freedom to operate searches and analyses with respect to Collaboration Products, to the extent such searches or analyses have been authorized by the JPC and approved by the JSC.

1.95 "**Patent Rights**" means (a) all patents and patent applications in any country or supranational jurisdiction, and (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications.

1.96 "PDL Inventions" means all Inventions that (a) relate to or are useful with any Antibody Product or Non-Antibody Product that are directed against or incorporate a Collaboration Target, (b) are made during the Term by one or more employees of PDL or its Affiliates or persons contractually required to assign or license patent rights covering such inventions to PDL or its Affiliates, in the course of performing PDL's obligations, or exercising PDL's rights, under this Agreement, and (c) are not Joint Inventions.

1.97 "PDL Know-How" means all Know-How that is (a) Controlled by PDL or its Affiliates at any time during the Term and (b) reasonably necessary or useful for Biogen Idec to (i) perform its obligations under this Agreement; or (ii) develop or commercialize a Collaboration Product or a Royalty Product in the Field; provided that PDL Know-How shall not include methods of manufacturing, production and test methods, procedures and batch records, manufacturing and testing summary data, process and assay validation information, designing, developing or preparing Antibodies including methods of humanizing Antibodies, methods of reducing the immunogenicity of Antibodies, methods of modifying effector function, and methods of increasing the affinity or half-lives of Antibodies unless necessary for Biogen Idec to perform its Development or Commercialization obligations or to exercise its rights hereunder.

1.98 "PDL Patent Rights" means Patent Rights that claim Technology Controlled by PDL or its Affiliates at any time during the Term and that relate in whole or in part to the Collaboration Targets or the manufacture, use or sale of Products. PDL

Patent Rights shall not include Joint Patents but shall include the Queen Patents and PDL Target Patent Rights. As of the Effective Date, to PDL's knowledge, all PDL Patent Rights are listed on Exhibit A hereto.

1.99 "PDL Target Patent Rights" means Patent Rights that claim Technology Controlled by PDL or its Affiliates at any time during the Term and that relate in substantial part to the Collaboration Targets or the manufacture, use or sale of Products. PDL Target Patent rights shall not include the Queen Patents.

1.100 "PDL Technology" means PDL Patent Rights and PDL Know-How.

1.101 "Phase 1 Trial" means, as to a specific pharmaceutical product, a well conducted and lawful study in humans of the safety of such product, which is prospectively designed to generate sufficient data (if successful) to commence a Phase 2 Trial (or foreign equivalent) of such product, as further defined in Federal Regulation 21 C.F.R. 312.21(a), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase 1 Trial shall be deemed initiated upon the enrollment of the first patient.

1.102 "Phase 2 Trial" means, as to a specific pharmaceutical product, a well conducted and lawful study, conducted anywhere in the world in diseased humans, of the feasibility, safety, dose ranging and efficacy of such product, that is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Trial (or foreign equivalent) of such product, as further defined in 21 C.F.R. 312.21(b), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. For the avoidance of doubt, a Phase 2 Trial requires enrollment of patients with the applicable disease or condition and is aimed to provide a measure of efficacy in addition to short-term tolerability. A Phase 2 Trial shall be deemed initiated upon the enrollment of the first patient.

1.103 "Phase 3 Trial" means, as to a specific pharmaceutical product, a well conducted and lawful study in humans performed to gain evidence of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product and provide an adequate basis for physician labeling, as described in 21 C.F.R. 312.21(c), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase 3 Trial shall be deemed initiated upon the enrollment of the first patient.

1.104 "Phase 4 Trial" means any clinical trial in an Indication to be conducted after a Regulatory Approval which was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval.

1.105 "Physician Group" means a category of physicians and other medical professionals to whom one or more Products is being Promoted, or will be Promoted if then-current Development activities are successful. For purposes of this definition, all oncologists (without regard to whether they treat a particular type or stage of cancer)

shall be a single Physician Group.

1.106 "Post-Approval Clinical Trial" shall have the meaning set forth in Exhibit C.

1.107 "Product" means [****].

1.108 "Profit Sharing Territory" means, with respect to a particular Product, those countries or territories outside the Royalty Territory, if any, for such Product.

1.109 "Promotion" or "Promote" means the marketing and advertising of a Collaboration Product in the relevant Field in the applicable territory in accordance with the relevant Commercialization Plan, including medical education, information and communication, market development and medical liaison activities, but not including Detailing.

1.110 "Queen Patents" means those issued patents and patent applications Controlled by PDL that claim priority under 35 USC §120 to U.S. Patent Application Serial No. [****].

1.111 "Recipient" shall have the meaning set forth in Section 14.2.

1.112 "Regulatory Approval" means, with respect to a particular regulatory jurisdiction, 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 commercial sale of Products in such regulatory jurisdiction.

1.113 "Regulatory Filings" means all applications, filings, dossiers and the like submitted to a regulatory authority for the purpose of obtaining Regulatory Approval from that regulatory authority. Regulatory Filings shall include all Drug Approval Applications.

1.114 "[****]" means the [****] except to the extent such rights are later included within the scope of this Agreement pursuant to Section 3.8.

1.115 "Responsible Commercialization Party" means the Party having the responsibilities set forth in Article 6 for the execution and implementation of the JSC-approved Commercialization Plan for the Commercialization of a particular Collaboration Product, but excluding regulatory activities specifically assigned to the Responsible Regulatory Party hereunder.

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1.116 "Responsible Development Party" means the Party having the responsibilities set forth in Article 3 for the execution and implementation of the JSC-approved Development Plan for the Development of a particular Collaboration Product, but excluding any regulatory or Manufacturing activities.

1.117 "Responsible Regulatory Party" means the Party having the responsibilities set forth in Article 5 for the execution and implementation of the regulatory activities set forth in the JSC-approved Development Plan for a particular Collaboration Product.

1.118 "[****]" means [****].

1.119 "[****] Agreements" means (a) [****], and (b) [****].

1.120 "ROW Territory" means all parts of the Territory not included in the North American Territory or EU Territory.

1.121 "Royalty Product" means (a) an Independent Product; (b) a Collaboration Product with respect solely to any Independent Indication; or (c) with respect solely to the ROW Territory, a Collaboration Product, an Independent Product or Independent Indication.

1.122 "Royalty Territory" means, with respect to a particular Product, those countries or territories in which such Product is a Royalty Product.

1.123 "Sales Costs" shall have the meaning set forth in Exhibit C.

1.124 "Sales Returns & Allowances" shall have the meaning set forth in Exhibit C.

1.125 "Strategic Plan" means, on a Collaboration Product-by-Collaboration Product basis, a written document establishing, for such Collaboration Product, a specific multi-year global strategic plan and budget.

1.126 "Sublicensing Revenues" means [****] approved pursuant to Section 3.7(c) [****].

1.127 "Technology" means any technical and other information, discoveries, inventions, modifications, improvements, data, results, designs, formulae, ideas, analyses, methods, techniques, assays, research plans, procedures, tests, processes (including manufacturing processes, specifications and techniques), laboratory records,

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chemical, pharmacological, toxicological, clinical, analytical and quality control data, reports, summaries, and information contained in submissions to, and information from, regulatory authorities (in each case whether patentable or not).

1.128 "Term" shall have the meaning set forth in Section 16.1.

1.129 "Territory" means all the countries of the world, and their territories and possessions.

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

1.131 "Third Party License" means (a) any of the license agreements set forth on Exhibit B and (b) any license agreement entered into by a Party with a Third Party after the Effective Date that the Parties (or the JSC, to the extent authorized) agree in writing is necessary for the Development, Manufacture or Commercialization of one or more Products in the applicable territory under this Agreement.

1.132 "Third Party License Fees" shall mean license fees, royalties and other amounts incurred by a Party under a Third Party License or in-license after the Effective Date.

1.133 "Transplant Field" means all indications that involve the suppression of rejection of transplanted organs, bone marrow or other tissue, including, solid organ transplantation (including tolerance induction and xenotransplantation), bone marrow transplantation, graft versus host disease and cell transplantation.

1.134 "Valid Claim" means a claim in any (a) [****]; or (b) [****].

1.135 "Volociximab Product" means [****].

Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, and (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import.

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ARTICLE 2

GOVERNANCE OF THE COLLABORATION

2.1 Scope of the Agreement. Pursuant and subject to the terms of this Agreement, within the Field and the Territory, the Parties agree to engage in Development activities with the goal of obtaining Regulatory Approval for Collaboration Products, as soon as reasonably practicable. Each Party agrees, during the Term, to Develop Collaboration Products only under the terms of this Agreement except as contemplated under the terms of the [****] Agreements. The Parties' intent is to Develop Collaboration Products as expeditiously as reasonably practicable with the resources and responsibilities allocated between the Parties on the basis of each Party's respective capabilities and availability of adequate capacities. Unless otherwise specified in this Agreement, the guiding principles to be followed by the Parties are attached hereto as Exhibit 2.1.

2.2 Joint Steering Committee.

(a) Formation and Purpose. As of the Effective Date, the Parties shall create a Joint Steering Committee (the "**JSC**") to oversee the overall strategy of the Development and Commercialization of Collaboration Products and carry out the functions described in this Section 2.2. The purposes of the JSC shall be to provide overall strategic decision-making and oversight of the Development and Commercialization of Collaboration Products, including the development of a Strategic Plan, a [****] high-level budget forecast and Approved Budget (consistent with the Development Plans to be prepared pursuant to Section 3.3), oversight of the activities of the Collaboration Committees, review of recommendations from the Collaboration Committees regarding strategic and aggregate budget issues, allocation of financial and other resources among collaboration projects, and resolution of any matters not resolved by any other Collaboration Committee. The JSC shall operate by the procedures set forth in this Section 2.2 and in Section 2.7. The members of the JSC appointed by a party shall collectively exercise one vote as to any matter upon which a vote is taken

(b) Membership of the JSC. Each Party shall designate representatives who are employees of such Party or an Affiliate of such Party (not to exceed [****] for each Party) with appropriate expertise to serve as members of the JSC. Each representative may serve on more than one Committee as appropriate in view of the individual's expertise and may be substituted by another person with notice

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to the other Party. Each party may replace any or all of its representatives at any time upon prior written notice to the other Party.

(c) Specific Responsibilities of the JSC. In addition to its general responsibilities set forth in Section 2.2(a), the JSC shall, in particular:

(i) prepare and approve a Strategic Plan for the Collaboration and all Collaboration Products, a [****] high-level budget forecast and an Approved Budget for the Collaboration, and within such Approved Budget, make high-level budget allocations among particular Development Programs. Such Strategic Plan will guide the management of the Collaboration, and strategic decision-making regarding Collaboration Products. The Strategic Plan shall be in a form to be determined by the JSC (it being understood that the Parties will endeavor to approve such Strategic Plan, [****] high-level budget forecast, and Approved Budget within [****] following the Effective Date);

(ii) review and approve the Development Plan and Commercialization Plan for each Collaboration Product, and the Annual Workplans/Budget including any amendments and revisions thereto, submitted to it by the JDC and JCC, respectively, as soon as reasonably practicable after receipt thereof, but in no event later than the dates specified in Section 3.3(c);

(iii) review and approve decisions to terminate Collaborative efforts on Collaboration Products, including with respect to specific Indications;

(iv) review and approve decisions to proceed with the Development of any Future Products as part of a Development Plan therefor;

(v) establish subcommittees pursuant to Section 2.7(c), oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;

(vi) attempt to resolve disputes or disagreements arising in any other Collaboration Committee or pursuant to Section 5.2(a);

(vii) review and approve any changes in the Responsible Regulatory Party, the Responsible Development Party, the Responsible Commercialization Party or the Manufacturing Party, when and as necessary;

(viii) [****]; and

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(ix) perform such other functions as the Parties may agree in writing or as otherwise assigned by this Agreement.

(d) Meetings of the JSC. The JSC shall meet at least twice every calendar year, on such dates and at such times as agreed to by PDL and Biogen Idec, with all scheduled in-person meetings to alternate between Fremont, California and a Biogen Idec site to be designated by Biogen Idec prior to such meeting, or at other locations as determined by the JSC. In addition, either Party may convene a special meeting of the JSC by no less than ten (10) business days' prior written notice. Meetings may be held by audio or video conference with the consent of each Party, provided that at least one (1) meeting per calendar year shall be held in person. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JSC meetings, subject to such representative's or consultant's written agreement to comply with the requirements of this Agreement. 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 three (3) representatives of each Party are present or participating.

2.3 Joint Development Committees.

(a) Formation and Purpose. Within thirty (30) days after the Effective Date, the Parties shall create a Joint Development Committee (the "**JDC**") for each Development Program to oversee the Development of the Existing Products in such program. In addition, within thirty (30) days after a decision by the JSC to Develop a Future Product, the JSC shall decide whether to create a JDC to oversee the Development of such Future Product hereunder or include such Development within the scope of an existing JDC. The purposes of each JDC shall be to (i) review and recommend to the JSC Development Plans and Annual Workplan/Budgets prepared by the Responsible Development Party for its particular Collaboration Products and (ii) monitor and facilitate, as necessary, the implementation of the Development Plans by the Parties. Each JDC shall operate by the procedures set forth in this Section 2.3 and in Section 2.7.

(b) Membership of the JDC. Each Party shall designate representatives who are employees of such Party or an Affiliate of such Party (not to exceed six (6) for each Party) with appropriate expertise to serve as members of each JDC. Each Party shall include representatives from the functions for which it is the Responsible Party. Each representative may serve on more than one Committee as appropriate in view of the individual's expertise and may be substituted by another person with notice to the other Party. Each party may replace any or all of its representatives at any time upon prior written notice to the other Party.

(c) Specific Responsibilities of the JDC. In addition to its general responsibilities set forth in Section 2.3(a), the JDC shall, in particular:

(i) consult with the Responsible Development Party on its preparation of a Development Plan and the Annual Workplans/Budget for each

Collaboration Product, including with respect to budgets, clinical trial strategy, Regulatory Approval requirements and clinical supply requirements;

(ii) review and recommend to the JSC for approval each Development Plan as soon as reasonably practicable after receipt thereof, but in no event later than the dates specified in Section 3.3(c);

(iii) review and recommend to the JSC for approval the Annual Workplan/Budget proposed by the Responsible Development Party as soon as reasonably practicable after receipt thereof, but in no event later than the dates specified in Section 3.3(c);

(iv) review changes to the Development Plan proposed by the Responsible Development Party and recommend to the JSC for approval as soon as reasonably practicable after receipt thereof, but in no event later than the dates specified in Section 3.3(c);

(v) establish subcommittees pursuant to Section 2.7(c), oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;

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

(vii) perform such other functions as the Parties may agree in writing or as otherwise assigned by this Agreement.

(d) Meetings of the JDC. The JDC shall meet as frequently as members of the JDC determine is required (but in no event, less frequently than once every month during the first six (6) months following the Effective Date and once every Calendar Quarter thereafter), on such dates and at such times as agreed to by PDL and Biogen Idec, with all scheduled in-person meetings to alternate between a PDL site and a Biogen Idec site as designated by the respective Party prior to such meeting prior to such meeting, or at 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 two (2) meetings per calendar year shall be held in person. Additional consultant's or representatives may from time to time, by mutual consent of the Parties, be invited to attend JDC meetings, subject to such consultant's or representative's written agreement to comply with the requirements of this Agreement. Each Party shall be responsible for its own expenses for participating in each JDC. Meetings of the JDC shall be effective only if more than one-half of the representatives of each Party are present or participating.

2.4 Joint Commercialization Committees.

(a) Formation and Purpose. The Parties shall form a Joint Commercialization Committee (the "**JCC**") for such Collaboration Product to oversee the Commercialization thereof not later than the date that is six (6) months prior to the

anticipated commencement of the first Phase 3 Trial with respect to a Collaboration Product or such earlier date as the JSC may determine. The purpose of each JCC shall be to (i) review and recommend to the JSC Commercialization Plans prepared by the Responsible Commercialization Party for its particular Collaboration Products and (ii) monitor and facilitate, as necessary, the implementation of such Commercialization Plans by the Parties. Each JCC shall operate by the procedures set forth in this Section 2.4 and in Section 2.7.

(b) Membership of the JCC. Each Party shall designate representatives who are employees of such Party or an Affiliate of such Party (not to exceed three (3) for each Party) with appropriate expertise to serve as members of each JCC. Each Party may replace any or all of its representatives at any time upon prior written notice to the other Party. Each representative may serve on more than one Committee as appropriate in view of the individual's expertise and may be substituted by another person with notice to the other Party.

(c) Specific Responsibilities of the JCC. In addition to its general responsibilities set forth in Section 2.4(a), the JCC shall, in particular:

(i) promptly following the formation of each JCC, develop and recommend to the JSC a Strategic Plan for the Commercialization of the applicable Collaboration Product prior to the submission by the Responsible Commercialization Party of a Commercialization Plan for such Product;

(ii) consult with the Responsible Commercialization Party on its preparation of a Commercialization Plan for each Collaboration Product, including budgets to be included therein;

(iii) review and recommend to the JSC for approval each annual Commercialization Plan as soon as reasonably practicable after receipt thereof, but in no event later than the dates specified in Section 3.3(c);

(iv) review changes to the Commercialization Plan proposed by the Responsible Commercialization Party and recommend to the JSC for approval as soon as reasonably practicable after receipt thereof, but in no event later than the dates specified in Section 3.3(c);

(v) review initial Collaboration Product launch concepts for such Collaboration Product Promotional material prior to the creation and use thereof;

(vi) serve as a forum for discussion of issues presented by a Party with respect to the Commercialization of Collaboration Products;

(vii) establish subcommittees pursuant to Section 2.7(c), oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees;

(viii) present disputes not resolvable by the JCC to the JSC for

resolution; and

(ix) perform such other functions as the Parties may agree in writing or as otherwise assigned by this Agreement.

(d) Meetings of the JCC. The JCC shall meet as frequently as members of the JCC determine is required (but in no event, less frequently than once every Calendar Quarter), on such dates and at such times as agreed to by PDL and Biogen Idec, with all scheduled in-person meetings to alternate between a PDL site and a Biogen Idec site as designated by the respective Party prior to such meeting, or at other locations as determined by the JCC. Meetings may be held by audio or video conference with the consent of each Party, provided that at least two (2) meetings per calendar year shall be held in person. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JCC meetings, subject to such representative's or consultant's written agreement to comply with the requirements of this Agreement. Each Party shall be responsible for its own expenses for participating in each JCC. Meetings of each JCC shall be effective only if more than one-half of the representatives of each Party are present or participating.

2.5 Joint Finance Committee.

(a) Formation and Purpose. Within thirty (30) days after the Effective Date, the Parties shall create a single Joint Finance Committee (the "**JFC**") for the Collaboration. The JFC shall operate under the direction of the JSC to provide services to and consult with the JDC and the JCC in order to address the financial, budgetary and accounting issues that arise in connection with the Development Plans and updates thereto as described in Exhibit C, as well as Commercialization Plans and updates thereto. Additionally, the JFC will lead the economic analysis to help drive decisions on future Collaboration investments, and lead the reporting and reconciliation processes outlined in Exhibit C. The JFC shall operate by the procedures set forth in this Section 2.5 and in Section 2.7.

(b) Membership of the JFC. Each Party shall designate two (2) employees of such Party or an Affiliate of such Party. Each Party may replace any or all of its representatives at any time upon prior written notice to the other Party. Such representatives will include individuals with expertise and responsibilities in the areas of accounting, cost allocation, budgeting and financial reporting. Each representative may serve on more than one Committee as appropriate in view of the individual's expertise.

(c) Meetings of the JFC. The JFC shall meet as frequently as members of the JSC determine is required (but in no event, less frequently than twice every calendar year), on such dates and at such times as agreed to by PDL and Biogen Idec, with all scheduled in-person meetings to alternate between a PDL site and a Biogen Idec site as designated by the respective Party prior to such meeting, or at other locations as determined by the JFC. All meetings shall be held in person or by audio or videoconference. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JFC meetings, subject to such

representative's or consultant's written agreement to comply with the requirements of this Agreement. Each Party shall be responsible for its own expenses for participating in the JFC. Meetings of the JFC shall be effective only if all representatives of each Party are present or participating.

2.6 Joint Patent Committee.

(a) Formation and Purpose. Within thirty (30) days after the Effective Date, the Parties shall create a single Joint Patent Committee (the "**JPC**") for the Collaboration. The purposes of the JPC shall be to prepare, file and prosecute the PDL Patent Rights, the Biogen Idec Patent Rights and the Joint Patent Rights, as described in and subject to the terms of Article 12. The JPC shall operate by the procedures set forth in this Section 2.6 and in Section 2.7.

(b) Membership of the JPC. Each Party shall designate an employee of such Party or an Affiliate of such Party with appropriate expertise to serve as members of the JPC. Each Party may replace any or all of its representatives at any time upon prior written notice to the other Party. Each representative may serve on more than one Committee as appropriate in view of the individual's expertise.

(c) Specific Responsibilities of the JPC. In addition to its general responsibilities set forth in Section 2.6(a), the JPC shall, in particular be responsible for:

(i) Managing continued prosecution of the PDL Patent Rights, the Biogen Idec Patent Rights and the Joint Patent Rights as described and in accordance with the terms of Article 12;

(ii) Reviewing invention disclosures and publications in accordance with the terms of Article 12 and Section 14.3;

(iii) Reviewing and managing licensing, enforcement activities and conflicts involving intellectual property rights to the extent provided in Article 12;

(iv) Providing advice, periodic updates and reports to the JSC regarding intellectual property matters;

(v) Using reasonable efforts to provide a freedom to operate analysis relating to Collaboration Products prior to the Phase 2 Trial completion;

(vi) Using good faith efforts to keep the Parties informed as to material developments with respect to the prosecution of, and any adversarial proceedings involving intellectual property rights, to the extent a Party's representative on the JPC concludes that such prosecution or proceeding directly affects a Collaboration Product; and

(vii) Performing such other functions as the Parties may agree in writing or as otherwise assigned by this Agreement.

(d) Meetings of the JPC. The JPC shall communicate on such dates and at such times as agreed upon by its members but in no event, less frequently than once every other Calendar Quarter. Meetings may be held by audio or video conference with the consent of each Party, provided that at least two (2) meetings per calendar year shall be held in person with all scheduled in-person meetings to alternate between a PDL site and a Biogen Idec site

as designated by the respective Party prior to such meeting, or at other locations as determined by the JPC. Each Party may permit visitors to attend meetings of the JPC. Each Party shall be responsible for its own expenses for participating in the JPC. Meetings of the JPC shall be effective only if the representative of each Party is present or participating.

(e) Decisions; Actions Without Meetings. Subject to Article 12 below, any approval, determination or other action of the JPC shall require unanimous agreement of both members of the JPC. In the event that a decision can not be reached by the JPC, then the matter shall be referred to the respective senior management of the in-house legal department of each Party. In the event such senior management is unable to resolve the matter, then the matter will be resolved pursuant to Section 2.8 (b) and (c) and Article 17. Unless otherwise agreed by the Parties, decisions of the JPC shall be determined in a manner designed to ensure a reasonable scope of protection for the PDL Patent Rights, the Biogen Idec Patent Rights and the Joint Patent Rights, to obtain broad patent protection for Collaboration Products and to strengthen the Parties' ability to broadly protect and enforce such Patent Rights against infringers within the scope of Collaboration Products.

2.7 General Committee Procedures.

(a) Chairperson. Each Collaboration Committee will be led by a representative of one of the Parties (the **"Chairperson"**), appointed as follows: [****] shall select from its representatives a Chairperson for each of the Committees for the period commencing on the Effective Date and ending on [****] and [****] shall select from its representatives a Chairperson for each of the Committees for the period commencing on [****] and ending on [****]. Thereafter, selection of the Chairperson for each of the Committees will [****].

(b) Responsibilities. The Chairperson shall have only those responsibilities set forth in this Section 2.7(b). The Chairperson of each Collaboration Committee shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of such Collaboration Committee, provided, that a Chairperson shall call a meeting of the applicable Collaboration Committee promptly upon the written request of either Party to convene such a meeting. In addition, each

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Chairperson shall bear the responsibility for preparing written draft minutes of that Collaboration Committee's meetings in reasonable detail and for distributing such draft minutes to all members of that Collaboration Committee for comment and review within [****] after the relevant meeting. The members of the Collaboration Committee shall have [****] to provide comments. Each Chairperson shall incorporate timely received comments and distribute revised minutes to all members of that Collaboration Committee for their final review and approval within [****] after the relevant meeting.

(c) Subcommittees. From time to time, each Committee may establish and delegate duties to other committees or sub-committees on an "as-needed" basis to oversee particular projects or activities. Each such subcommittee shall be constituted and shall operate as the JSC, JDC, JCC, JFC or JPC, as the case may be, determines; provided, that each Party shall have the right to equal representation on any such subcommittee. Subcommittees may be established on an ad hoc basis for purposes of a specific project for the life of a Collaboration Product, or on such other basis as the applicable Committee may determine. Each subcommittee and its activities shall be subject to the oversight, review and approval of, and shall report to, the Committee that established such subcommittee. In no event shall the authority of the subcommittee exceed that specified for the relevant Committee in this Article 2.

(d) Limitations of Committee Powers. Each Committee shall have only such powers as are specifically delegated to it hereunder and shall not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, no Committee shall have any power to amend this Agreement. Any amendment to the terms and conditions of this Agreement shall be implemented pursuant to Section 18.3 below.

(e) Authority. The Parties agree that, in voting on matters as described in this Article 2, it shall be conclusively presumed that each voting member of the JSC or other Committee has the authority and approval of such member's respective senior management in casting his or her vote.

2.8 Committee Decision-Making.

(a) Consensus; Good Faith; Action Without Meeting. Subject to the terms of this Section 2.8, each Committee will take action by [****], assuming a quorum for such Committee is present. Consistent with Exhibit 2.1, the members of each Committee shall act in good faith to cooperate with one another to reach agreement with respect to issues to be decided by the Committee. Action that may be taken at a meeting of a Committee also may be taken without a meeting if a written

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consent setting forth the action so taken is signed by all of the Committee representatives of each Party.

(b) Failure to Reach Consensus by a Collaboration Committee. If a Collaboration Committee is unable to reach [****] within [****] of its initial consideration of any matter over which such Committee has authority and responsibility, then the Committee shall escalate the matter to the JSC for decision; provided, that such Committee may escalate the matter to the JSC prior to the expiration of such [****] with the consent of both Parties.

(c) [****]:

(i) With respect to any [****] shall [****] with respect to all matters, except as described below in clause (ii) and (iv) and provided that [****];

(ii) Each Party shall possess final decision-making authority with respect to Manufacturing processes during the time that such Party is the Manufacturing Party under this Agreement, but for avoidance of doubt in each case, such authority does not include the ability to terminate Manufacturing of a Product in contravention of the terms of any Clinical Supply arrangement or a Commercial Supply Agreement or to unilaterally alter the terms of any Clinical Supply arrangement or Commercial Supply Agreement including quantities or forecasts.

(iii) [****].

(iv) [****].

2.9 Compliance with [****] Agreements. PDL shall have no obligation to act in any way that would breach its obligations under the [****] Agreements.

2.10 [****].

ARTICLE 3

DEVELOPMENT OF COLLABORATION PRODUCTS

3.1 Overview. The Collaboration between the Parties is divided into three Development Programs, one for each Collaboration Target. This Article 3 describes the rights and obligations of the Parties with respect to the Development of Collaboration Products within the various Development Programs, including both Existing Products and Future Products.

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3.2 Responsible Development Party. Subject to the roles of the various Collaboration Committees described in Article 2, the allocation of primary responsibility for the creation of Development Plans and the implementation of Development activities of Collaboration Products described in such Development Plans shall be given to the Responsible Development Party. The allocation of such responsibilities shall be as follows:

	[****]	**[****]**	**[****]**	**[****]**	**[****]**
North American Territory	[****]	[****]	[****]	[****]	[****]
EU Territory and ROW Territory	[****]	[****]	[****]	[****]	[****]

3.3 Development Plan.

(a) Scope. All Development of Collaboration Products shall be conducted pursuant to a Collaboration Product specific, multi-year, global development plan and budget (in each case, a **"Development Plan"**), which shall set forth all anticipated Development activities and timelines, allocate responsibility for carrying out such activities between PDL and Biogen Idec and include an associated [***] development budget with respect to each such Collaboration Product, plus a forecast of the total, multi-year costs of any clinical trials included within such plan. Primary responsibility for developing and implementing each such Development Plan shall reside with the Responsible Development Party for its respective Collaboration Product. The non-Responsible Development Party will have the right to consent to any Development activities assigned to such Party under the terms of a Development Plan. The initial draft Development Plans, including the Initial Development Program Budget, for the Existing Products are attached hereto as Exhibit 3.3. The Parties intend that the draft Development Plans attached in Exhibit 3.3 will serve as the Development Plans until first Development Plans are prepared and approved pursuant to Section 3.3(b).

(b) Development Plan and First Annual Workplan/Budget. The Responsible Development Party shall in consultation with the relevant JDC pursuant to Section 2.3(c)(i) prepare a Development Plan for each Existing Product as soon as practicable following the Effective Date, and each such Development Plan, when

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approved, shall supersede the applicable draft Development Plan attached as Exhibit 3.3. The Responsible Development Party will also prepare a draft of an Annual Workplan/Budget for [****] after consultation with the relevant JDC, specifying in detail the Development activities to be performed during the year, designation of which Party is responsible for each task, staffing levels (which levels shall be reasonably necessary for the attainment of the Development goals, as applicable), any approved use of Third Party contractors required to carry out such activities, a budget setting forth the estimated expenditures required to carry out such activities and a timeline for completion of such activities. Such draft will be prepared as soon as practicable following the Effective Date.

(c) Yearly Updates and Subsequent Annual Workplan/Budget. The Responsible Development Party shall, on an annual basis, update the Development Plan to reflect any changes necessary given the progress and the results of the Development work as of such date or any change in strategy, timelines, or long range plans going forward. In addition, prior to the start of each year, the Responsible Development Party shall prepare an Annual Workplan/Budget which shall specify in detail the Development activities to be performed during such year, designation of which Party is responsible for each task, staffing levels (which levels shall be reasonably necessary for the attainment of the Development goals, as applicable), any approved use of Third Party contractors required to carry out such activities, a budget setting forth the estimated expenditures required to carry out such activities, a timeline for

completion of such activities and annual production requirements, as specified in Section 8.2. Each update to the Development Plan and adoption of each Annual Work-plan/Budget under this paragraph and any modifications and updates under paragraph (d) below shall automatically be deemed to constitute an amendment to the Development Plans upon JSC approval and ratification of the meeting minutes related thereto, and shall not constitute an obligation of either Party until such approval and ratification. The schedule for yearly updates to the Development Plan and the drafting and approval of each Annual Workplan/Budget commencing with the calendar year [****], shall occur no later than the dates set forth below:

EVENT	TIMING
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

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(d) Interim and Annual Workplan/Budget Modifications and Updates. The Responsible Development Party shall review each Annual Workplan/Budget on a [****] during the course of each year to review actual activities and expenditures compared to plan and to determine if any changes are necessary given the progress and the results of the Development work as of such date. Other interim modifications to each Annual Workplan/Budget during the course of the year may also be adopted by the Responsible Development Party, as necessary, but shall be subject to the approval of the JSC if material. All changes to any Annual Work-plan/Budget shall be subject to review and approval of the JSC where such modifications exceed the authority delegated to the Responsible Development Party by the JSC or under this Agreement.

3.4 Standards of Conduct; Diligence.

(a) Each Party shall perform the Development activities for which it is responsible under the Development Plan in good scientific manner and in compliance with applicable laws, rules and regulations. Each Party will keep the other Party fully informed regarding the progress and results of such Party's Development activities with respect to the Collaboration Products through the Collaboration Committee meetings.

(b) Each Party shall use Diligent Efforts to execute and carry out the activities assigned to it in the Development Plan within each Annual Workplan/Budget; [****].

(c) The Parties shall cooperate in good faith to establish appropriate and consistent medical information support relating to Collaboration Products.

3.5 Shared Development Expenses.

(a) Payment of Development Expenses. Subject to a Party's right to opt out as set forth in Article 4, all Development Expenses or Other Out of Pocket Costs shall be shared between Biogen Idec and PDL as provided below and in accordance with Exhibit C, so that Biogen Idec bears fifty percent (50%) of such costs and PDL bears fifty percent (50%) of such costs, provided that such costs were part of an Annual Workplan/Budget, or were incurred pursuant to the draft Development Plans attached as Exhibit 3.3 prior to approval of a Development Plan under Section 3.3(b), or were otherwise approved by the JSC. There shall be a Reconciliation Statement, prepared by the Responsible Development Party as set forth in Section A.2.2 of Exhibit C, of such costs which are to be shared and which are incurred during a reporting period by each Party, in accordance with Section A.2.2 of Exhibit C, with a payment by one Party to the other, pursuant to Section A.5 of Exhibit C, to the extent necessary so that each Party bears its appropriate percentage of such shared Development Costs. [****].

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(b) Development Cost Accounts. Subject to the limitations set forth in Section 3.6, each Party shall charge all Development Expenses or Other Out-of –Pocket Costs so incurred by it or its Affiliates on its books and records to enable the tracking of expenses incurred in connection with each Development Plan and each Annual Workplan/Budget (each, a **"Development Cost Project Account"**). Within [****] after the end of each Calendar Quarter, each Party shall submit to the other Party a written summary of all expenses charged to its Development Cost Project Account during such Calendar Quarter, which summary shall be accompanied by reasonable supporting documentation for such expenses. Each Party shall provide the other Party with interim [****] reports of [****] estimates of current Calendar Quarter charges within [****] after the end of [****] in a Calendar Quarter (other than the [****], for which only a quarterly report will be due).

3.6 Excluded Development Expenses. Notwithstanding the terms of Section 3.5, [****] will bear any [****], incurred by the Parties primarily in connection with the Development of any and all Royalty Products for approval and sale in the ROW Territory.

3.7 Third Parties.

(a) Contractors. Any Third Party retained by a Party to perform Development activities must be approved in advance in writing by the other Party, unless such Third Party is specifically named in a Development Plan. Each Party shall remain liable for the performance of its obligations hereunder which it delegates to such Third Parties. Any Third Parties performing Development activities hereunder shall be subject to confidentiality and non-use obligations at least as stringent as those set forth in Article 14 and must comply with the terms of Article 12.

(b) Intellectual Property. The Parties intend not to knowingly introduce to any Collaboration Product any Technology that is not Controlled by a Party, except with the prior approval of the JPC and the JSC. If the JSC in consultation with the JPC determines that a license to certain Third Party technology is reasonably necessary to advance the successful Development of a Collaboration Product, then the JSC shall [****]. Upon approval of the terms of such Third Party license, the [****] may execute such Third Party license and any payments that become due pursuant to a Third Party License agreement executed pursuant to this Section 3.7(b) will, during the course of Development of the applicable Collaboration Products, be treated as [****].

(c) Sublicensing. The JSC may elect to license the further Development or Commercialization of a Collaboration Product to a Third Party in one or more Indications and/or territories. In such event, the JSC shall designate a Party to negotiate the terms on which such a Third Party license would be granted and to serve

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as the primary point of contact with the applicable Third Party sublicensee following the execution of the license agreement, provided that the JSC may condition approval of such sublicense upon submission of the final agreement with the Third Party to the JSC for final approval. The parties acknowledge that any grant of rights to a distributor shall not constitute a license of Development or Commercialization rights hereunder.

3.8 [****]. If, after the Effective Date, [****]. If the Parties fail to agree on the payment and other terms under which such [****] would be included within this Agreement prior to the termination of the Negotiation Period, then such [****] shall not be included within the scope of this Agreement and [****] shall have no further obligation to [****] in respect of such rights except as set forth in this Section 3.8. If the Parties were unable to execute an agreement prior to the termination or expiration of the Negotiation Period, [****] will not, for a period of [****] from the termination or expiration of the Negotiation Period, enter into a license or other agreement with a Third Party providing for the development or commercialization of such [****] on terms which are in the aggregate less favorable to [****] than the last bona fide offer made in writing by [****] to [****] without first offering to [****] for a period of [****] the right to include the [****] within the scope of this Agreement upon such alternative terms.

3.9 Development of Products in the ROW Territory.

(a) Responsibility. Biogen Idec shall be solely responsible, at its sole cost and expense and at its sole discretion, for the Development of any Royalty Product in the ROW Territory. Biogen Idec shall use Diligent Efforts in proceeding with the development and registration of Royalty Products in Japan.

(b) Updates. Biogen Idec will inform PDL of the status of Biogen Idec's Development and Commercialization of Royalty Products in the ROW Territory through [****] progress reports submitted in writing to PDL. In addition, upon reasonable notice to Biogen Idec, it will provide PDL with copies of any information or data reasonably requested by PDL and reasonably necessary for the development or commercialization of Royalty Products. Through the JSC, Biogen Idec shall advise and consult with PDL with respect to any significant issues or questions raised by any regulatory authorities in the ROW Territory with respect to a Royalty Product that Biogen Idec believes would have an adverse impact on the corresponding Collaboration Product in the Profit Sharing Territory.

(c) Regulatory Cross-Referencing. Biogen Idec will allow the Responsible Regulatory Party in a Territory to cross-reference, in furtherance of JSC-approved activities under this Agreement, Biogen Idec regulatory filings and clinical data

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with respect to any Royalty Product developed or commercialized by Biogen Idec in the ROW Territory and will grant PDL reasonable access during normal business hours to such regulatory filings and clinical data.

3.10 Consideration of Future Products and Additional Indications or New Formulations of Collaboration Products; Scope and Exclusivity

(a) Future Products Brought to Joint Steering Committee

(i) From time to time during the Term, the JSC shall consider proposals that the Parties jointly Develop and Commercialize any (A) new Product as a Future Product in accordance with the terms of this Agreement; (B) additional Indication for an existing Collaboration Product; or (C) new formulation of an existing Collaboration Product.

(ii) Either Party may initiate the foregoing proposal at any time during the Term. In addition, the Parties must initiate a proposal with respect to a Product under the circumstances discussed below. A Party initiating a proposal under this Section 3.10 shall be deemed a **"Proposing Party**."

(1) A Party must bring a proposal to the JSC that the Parties Collaborate on [****] at the following times:

(a) With respect to a [****], prior to negotiation of such license; or

(b) With respect to all other Products that are [****], after the Proposing Party has performed Development on such Product, [****];

(2) PDL must [****] at the following times:

(a) With respect to a [****]; or

(b) With respect to all other Products that are [****], after PDL has performed Development on such Product, [****];

(b) Consequences of JSC Consideration of Future Products and Additional Indications or New Formulations of Collaboration Products

(i) Full Approval. If the JSC approves the addition of a new Product as a Future Product or an additional Indication for an existing Collaboration Product or a new formulation of an existing Collaboration Product, then such Product

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shall be a Collaboration Product and the JSC shall appoint a Responsible Development Party that shall create a new Development Plan for such Collaboration Product or update the applicable Development Plan to include the Development activities to be performed by the Parties in the case of an additional Indication for or new formulation of an existing Collaboration Product. The JSC will take into consideration a Party's current abilities, expertise and infrastructure when appointing new Responsible Development Parties and will make such appointments accordingly. The Responsible Development Party for each such Collaboration Product shall implement such Development activities as contemplated by this Article 3. Any such Development Plan or update shall be prepared and approved in accordance with the provisions of Articles 2 and 3.

(ii) Partial Approval. If, after a proposal is made under Section 3.10(a), the JSC does not approve the addition of a new Product as a Future Product or an additional Indication for an existing Collaboration Product or a new formulation of an existing Collaboration Product, but determines that such Product or additional Indication or formulation should be subject to further evaluation then such Product or additional Indication or formulation shall be subject to this Section 3.10(b)(ii). At the request of the Proposing Party, the JSC shall develop a proposed work plan, which shall include specific goals (such as a clinical trial, with primary endpoints) for such Product or additional Indication or formulation and the Proposing Party shall provide all information reasonably requested by the JSC that would be material to making a determination as to whether such proposed work plan should be approved and to the appropriateness of the proposed goals. If the JSC agrees that if the specific goals set forth in work plan are met, the Indication, formulation or new Product would become a Collaboration Product, then the following shall apply:

(1) The Proposing Party shall have the right to undertake the work specified in the work plan at its own expense;

(2) If the Proposing Party carries out the work plan and meets all of the JSC-approved specific goals, then

(a) the other Party shall reimburse the Proposing Party an amount equal to [****] of the Development Expenses related to such trial that such Party would have otherwise been responsible for if the JSC had approved such trial as part of the Development Plan, and

(b) the formulation, Indication or new Product shall be developed jointly by the Parties and the JSC shall take the actions described in Section 3.10(b) in respect of such new Collaboration Product or additional Indication or new formulation of an existing Collaboration Product.

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(3) If the JSC-approved specific goals are not met, the Proposing Party shall be solely responsible for all related costs without the right of reimbursement from the other Party and neither Party will be allowed to continue development except in the following circumstances:

(a) If [****] is the Proposing Party, it may [****];

(b) If [****] is the Proposing Party [****] it may [****].

For purposes of clarity, the Parties agree that if the JSC is unable to agree on the specific goals for the foregoing work plan or is unable to agree that if the work plan meets its goals the Parties would jointly Develop the new product as a Future Product or an additional clinical indication for an existing Collaboration Product or a new formulation of an existing Collaboration Product, such disagreement shall not be subject to dispute resolution hereunder and shall be considered final.

(iii) No Approval. If, after a proposal is made under Section 3.10(a), the JSC does not approve the addition of a new Product as a Future Product or an additional Indication for an existing Collaboration Product or a new formulation of an existing Collaboration Product, and does not determine that such Product or additional Indication or formulation should be subject to further evaluation, [****] except in the following circumstances, and provided that the Proposing Party did not block the approval of any such proposal:

(1) If [****] is the Proposing Party, it may [****];

(2) If [****] is the Proposing Party [****], it may [****].

Any such Product which is permitted to be pursued outside the Collaboration shall not be subject to the terms, obligations, rights and responsibilities in this Agreement.

(c) Lapse of Obligations [****]. The obligations to propose [****] under this Section 3.10 shall lapse as to any [****].

3.11 Transfer of Materials. During the Term, the Parties anticipate that each Party will transfer certain of its proprietary tangible research materials to the other Party. Each Party agrees during the Term that it will use such materials of the other Party only for the purposes set forth in this Agreement, and will not transfer such materials to any Third Party, except in compliance with Section 14.1 and Section 14.2 of this Agreement. Each Party shall have the right to use proprietary tangible research materials provided

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to it by the other Party during the Term and in furtherance of the purposes set forth in this Agreement, solely for the purposes hereunder. Such proprietary materials received from the other Party which are directly related to Collaboration Products may be transferred to Third Parties only with consent of the JDC and JPC, subject to the form of material transfer agreements or collaboration agreements, as applicable, covering such materials, such form agreements to be drafted and agreed upon by the JPC.

ARTICLE 4

OPT OUT RIGHTS; ROYALTY PRODUCTS

4.1 Opt Out Rights for Collaboration Products or Indications

(a) Opt Out Right. Each Party will have the option to terminate its participation in the Development and Commercialization of one or more Collaboration Products as set forth in this Section 4.1 (the Party exercising such right referred to as the "**Non-Developing Party**"). A Non-Developing Party may terminate its participation with respect to: (i) [****]; (ii) [****]; (iii) [****]; or (iv) [****], everywhere in the world; provided, however, that (A) [****] and (B) [****].

(b) Limitations. The rights of each party to terminate its participation pursuant to this Section 4.1 shall be subject to the following limitations:

(i) [****] may not exercise its opt out rights described in this Section 4.1 with respect to [****].

(ii) [****] can opt out of Development or Commercialization except at one of the points shown at Exhibit 4.1(b)(ii) with respect to the Existing Products and at such other points as determined by the Parties with respect to other Collaboration Products or as provided in Section 4.1(b)(iv). The Parties agree that they will include such opt out points in the Development Plans for other Collaboration Products at the time of preparation thereof.

(iii) If a Party elects to opt out of an Indication for a Collaboration Product, it shall automatically be deemed to have opted out of all other Indications for which that Collaboration Product would be marketed to the same Physician Group (collectively the "**Opt Out Indications**") and if a Party opts out of an oncology Indication it shall be deemed to have opted out of all oncology Indications.

(iv) If a Party elects to opt out of Commercialization, the election shall not be effective until [****] after written notice of such election (or such earlier date

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as specified in writing by the Independent Development Party (as defined in Section 4.1(d) below)) and may not be made until [****] following the [****]. A party may not opt out of Commercialization of a Collaboration Product if the opt out would result in a higher profit to the Party electing to opt-out, based on a comparison of the royalty payments and Collaboration Product Profit payments that such Party would have received in the four full calendar quarters prior to the election.

(v) Neither Party can elect to opt out of Development or Commercialization with respect to a Product if such Party has received notice pursuant to Section 16.2 that it is in material breach of this Agreement with respect to such Product and it has not cured such breach or resolved in its favor any dispute regarding whether there was a breach or whether such breach was cured.

(c) Timing. Subject to the limitations in Section 4.1(b) a Party may exercise its opt out right with respect to Development of a particular Collaboration Product or an Opt Out Indication(s) of a particular Collaboration Product at the decision points described in Section 4.1(b). The Non-Developing Party shall provide written notice to the other Party of its decision to exercise such right (the **"Opt Out Notice"**) during the time period described in each opt out point.

(d) Effects of Exercise. Effective upon timely delivery of an Opt Out Notice, (i) the Party that is not the Non-Developing Party will be deemed the **"Independent Development Party"** with respect to the applicable Independent Product or Independent Indication, (ii) the Non-Developing Party will be deemed the "**Non-Developing Party**" with respect to the applicable Independent Product or Independent Indication and responsibility shall be as set forth in Section 4.3, (iii) if such exercise was made with respect to [****], such Collaboration Product will become an Independent Product in [****], and (iv) if such exercise was made with respect to [****]. In any event, the further Development of such [****] by the Independent Development Party will be subject to the terms set forth in Sections 4.2 and 4.3. For purposes of the following Section 4.2, [****] is not [****] with respect to the [****].

4.2 Development of Independent Products and Independent Indications.

(a) Generally. For each Independent Product and Independent Indication, the Independent Development Party will have the right, at its own option and expense, to plan and conduct the Development of and to Commercialize such Independent Product or Independent Indication, as the case may be, in accordance with the terms of Sections 4.2, 4.3 and 4.5.

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(b) Transition of Development Activities. Upon a Party giving the Opt Out Notice with respect to a Collaboration Product or one or more Indications of a Collaboration Product, the applicable Development Plan or Commercialization Plan, as the case may be, for such Collaboration Product or Indication, as the case may be, shall automatically be amended to provide that the Parties shall carry out and share the costs with respect to only those particular Development or Commercialization activities under the applicable Development Plan or Commercialization Plan, respectively, that have commenced on or before the date of such Opt Out Notice. By way of example, an activity for purposes of this Section would include a clinical trial that has commenced. Notwithstanding the foregoing, the Non-Developing Party shall transfer responsibility for such ongoing activities to the Independent Development Party as of the date of such Opt Out Notice or as soon as reasonably practicable after such date.

4.3 Rights and Obligations Upon Opt-Out.

(a) Prior to the Opt-In Trigger. Prior to the date of the Opt-In Trigger, the Independent Development Party shall be obligated to Develop the Independent Indication, at its sole cost (subject to Section 4.2(b)), and shall use Diligent Efforts in such development. The Independent Development Party shall keep the JSC reasonably informed regarding matters that would adversely affect Development or Commercialization of the Collaboration Product in other Indications then being Developed or Commercialized by the Parties jointly.

(b) Following the Opt-In Trigger and As to Independent Products. The Independent Development Party will assume unilateral control over the Development and Commercialization of (i) an Independent Product after opt out has occurred as to such Product, and (ii) as to an Independent Indication from and after the date of the Opt-in Trigger if such option is not exercised by the other Party, except that:

(1) The Independent Development Party shall give the JSC annual updates regarding the status and results of any development and commercialization activities conducted regarding an Independent Indication.

(2) If PDL is the Independent Development Party, then PDL shall use Diligent Efforts to Develop and Commercialize such Independent Product or Independent Indication.

(3) If Biogen Idec is the Independent Development Party, then Biogen Idec shall use Diligent Efforts to Develop and Commercialize such Independent Product or Independent Indication.

(4) If [****] is the Independent Development Party and [****] PDL, at its option, may [****].

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(c) Manufacturing. If the Non-Developing Party as to a Product is responsible for Manufacturing the applicable Collaboration Product pursuant to Article 8, then such Non-Developing Party will continue to supply the Independent Development Party with clinical and/or commercial supply of the applicable Collaboration Product until such time as the Parties have effected a technology transfer of the applicable Manufacturing process, at the Independent Development Party's request, and the Independent Development Party has validated such process in its or its CMO's designated facility and has all necessary regulatory approvals to Manufacture and such Manufacture has commenced. The Non-Developing Party shall use commercially reasonable efforts to effect a technology transfer of the applicable Manufacturing process to the Independent Development Party or its designated CMO as soon as practicable, but in no event more than [****] after the Opt Out Notice is delivered The Non-Developing Party shall supply such Product to the Independent Development Party during the [****] at a cost of [****] Between [****] and [****], the Non-Developing Party shall supply such Product to the Independent Development Party at a cost of [****]. Between [****] and [****], the Non-Developing Party shall supply such Product to the Independent Development Party at a cost of [****].

(d) Remaining Program Obligations. The portion of the applicable Development Program with respect to which the Non-Developing Party has not exercised its option to opt out will continue unaffected by such opt out.

(e) Data Transfer. Commencing at the time of delivery of the Opt Out Notice, the Non-Developing Party promptly shall provide, at the sole cost of the Non-Developing Party, the Independent Development Party with copies of all data and information, and samples of all tangible items,

comprising Know-how and other Technology of the Non-Developing Party relating to such Independent Product or Independent Indication, as the case may be.

(f) Assignment of Regulatory Filings. The Non-Developing Party promptly shall, as applicable, assign or make available by cross-reference to the Independent Development Party, at the Non-Developing Party's sole cost, all registrations for such Independent Product (at the time of exercising its opt out rights) or Independent Indication (an assignment shall only occur after the expiration of the Non-Developing Party's right to opt in; a cross reference right shall be available from the time of exercise of the Non-Developing Party's opt out rights until the expiration of such party's opt in rights or longer, as appropriate), as the case may be, and shall notify the appropriate Regulatory Authorities and take any other action reasonably necessary to effect such transfer of ownership or access to regulatory filings; provided, however, that a Non-Developing Party shall not have any obligation to assign to the Independent

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Development Party the Drug Master File for any Independent Product if and for so long as the Non-Developing Party is engaged in the Manufacture of such Independent Product on behalf of the Independent Development Party or with respect to Indications or territories for which such Non-Developing Party has retained rights.

(g) Obligations with Respect to Third Party Contracts. Each Party shall include provisions in its contracts with Third Parties entered into after [****] and specifically related to Development or Commercialization of a Collaboration Product or an Indication of a Collaboration Product that would permit (i) [****] or (ii) [****]. Except as otherwise set forth in this Article 4, the Non-Developing Party shall use Diligent Efforts to effect assignment (and full release of the Non-Developing Party) or the granting of a sublicense or equivalent right of access (and partial release of the Non-Developing Party) to the Independent Development Party, whether through novation or sublicensing of such contracts or otherwise, of any and all rights under any contract between the Non-Developing Party and any Third Party that are necessary for Independent Development Party to continue with Development or Commercialization of such Collaboration Product or Indication, as the case may be, and the Independent Development Party shall reasonably cooperate in connection therewith. If such assignment, novation or sublicense is not permissible, the Parties shall discuss in good faith potential alternatives that would enable the Independent Development Party to exercise the rights and obligations of the Non-Developing Party under such contracts with respect to such Independent Product while minimizing the continuing obligations of the Non-Developing Party.

(h) Technical Assistance. During the period commencing with delivery of an Opt Out Notice and ending [****] following the effective date of such Opt Out Notice, the Non-Developing Party shall provide reasonable technical assistance as requested by the Independent Development Party to effectuate an orderly transition of the Development and Commercialization of such Independent Product or Independent Indication, as the case may be, to the Independent Development Party. Such assistance shall be at the expense of the Non-Developing Party until the effective date of the Opt Out Notice and thereafter shall be at the expense of the Independent Development Party.

(i) Termination of License Rights. Unless and until the Non-Developing Party decides to Opt-in pursuant to the Opt In Trigger described herein, it shall have no further rights under the licenses provided to it under Article 11 with respect to such Independent Product or Independent Indication.

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(j) Transfer of Trademarks. If the Non-Developing Party owns the Product Trademarks (as defined in Section 12.13(a)) relating to the Independent Product (or Independent Indication, if there are Product Trademarks that relate specifically to such Indication), ownership of such Product Trademarks shall be transferred to the Independent Development Party in the Territories as to which the opt out occurs.

4.4 Rights to Opt In to Independent Indication During Development.

(a) General. Subject to the terms of this Section 4.4, a Non-Developing Party will have the option to opt-in to the independent development of an Independent Indication on a one-time basis, exercisable by providing a notice in writing to the Independent Development Party within (i) the [****] (the **"Opt In Trigger"**) [****] or (ii) the [****]. Within [****] of receipt of such written notice, the Independent Development Party shall provide to the Non-Developing Party a package of data and other information concerning the Independent Indication reasonably necessary to permit the Non-Developing Party to make an informed decision on its desire to opt in to Development and Commercialization in the manner set forth in this Agreement (the **"Data Package"**). Following receipt of the Data Package, the Non-Developing Party shall have [****] within which to elect to opt-in. Any such election shall become effective upon receipt by the Independent Development Party of a final written determination by the Non-Developing Party stating its decision to opt-in. Failure to deliver timely notice of an intent to opt-in shall be conclusively deemed to be a waiver of such rights.

(b) Limitations. A Non-Developing Party shall not have the right to opt in to the Commercialization of a Collaboration Product in the event that it delivers an Opt Out Notice for such Product at any time following final regulatory approval for the marketing of such Collaboration Product anywhere in the Territory.

(c) Expense Reimbursement. Upon exercise of an opt in right as described in this Section 4.4, the Non-Developing Party shall reimburse the Independent Development Party for [****] of that portion of the Development Expenses that would have been incurred by the Non-Developing Party, had such Party not opted out, during the period in which such Party had opted out.

(d) **Effects of Opt In**. Upon exercise of an opt in right and payment of all amounts due under subsection (c) above, the Independent Indication shall cease being an Independent Indication and will automatically return to the scope of the Collaboration. Thereafter, the Parties shall continue Development and Commercialization of such Indication jointly as described in this Agreement; provided, that for the [****] following the exercise of an opt in right, the Party that had been the

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Independent Development Party shall be the Responsible Development Party, notwithstanding the provisions of Section 3.2 and the Parties shall agree on the allocation of responsibilities thereafter.

4.5 Royalty Products.

(a) Effective upon the exercise of a Party's opt-out right with respect to a Collaboration Product, either on a Product or Indication basis, the applicable Product will be a Royalty Product. The Independent Development Party will pay the Opt-Out Party the royalty payments described in Section 9.5 for such Royalty Product.

(b) With respect to Collaboration Products developed by [****], [****] is the Independent Development Party and [****] is the Non-Developing Party, such Products are Royalty Products with respect to the [****] and the [****] is within the Royalty Territory for such Products. [****] will pay to [****] the royalty payments described in Section 9.5 for all such Royalty Products Commercialized in the [****].

ARTICLE 5

REGULATORY

5.1 Responsible Regulatory Party. Subject to the roles of the various Committees described in Article 2, the allocation of Responsible Regulatory Party for Collaboration Products under this Agreement is as follows:

(a) [****] will be the Responsible Regulatory Party in the [****] and the [****] for all Collaboration Products; and

(b) [****] will be the Responsible Regulatory Party in the [****] for all Collaboration Products during the Development of such Collaboration Product. At the time of receipt of first Regulatory Approval for the [****].

5.2 Regulatory Filings for Collaboration Products.

(a) The Responsible Regulatory Party identified in Section 5.1 above shall primarily be responsible for preparing and filing all Regulatory Filings and seeking all Regulatory Approvals in the relevant territory, including preparing all reports necessary as part of a Drug Approval Application. All Regulatory Filings for all Collaboration Products shall be filed in the name of the Responsible Regulatory Party for a particular Territory. The Parties anticipate that Regulatory Filings for the EU and North America Territories will be based on a common set of technical documents. Such

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common set of technical documents shall be prepared by the Responsible Development Party (or collectively by both of the Responsible Development Parties where there are two for a Collaboration Product). The Responsible Regulatory Party and the Responsible Commercialization Party (to the extent they are different Parties) shall jointly prepare all Regulatory Filings. All reasonable comments of the Responsible Commercialization Party for an applicable Collaboration Product shall be incorporated into such Regulatory Filing for any Collaboration Product. The Responsible Regulatory Party shall, at all times, consult with the Responsible Commercialization Party on all communications and other dealings with the regulatory agencies relating to such Collaboration Product in the applicable territory. However, the Manufacturing Party shall be solely responsible for all communications and other dealings with the regulatory agencies throughout the world pertaining to the Manufacture of such Collaboration Products. The Responsible Regulatory Party and the Responsible Commercialization Party shall jointly develop and implement procedures for drafting and review of Regulatory Filings for the relevant Collaboration Products in the applicable territory, which procedures shall provide for sufficient time for the Responsible Commercialization Party to provide comments to such Regulatory Filings. If the Parties are unable to resolve any disputes related to such Regulatory Filings content or strategy, such disputes shall be resolved as set forth in Article 2 hereof. In addition to the right to cross-reference set forth in Section 3.9(c), the other Party shall have the right of cross-reference to all such Regulatory Filings or Regulatory Approvals obtained hereunder for purposes of Collaboration Products.

(b) The Responsible Regulatory Party shall promptly provide the other Party with a copy (which may be wholly or partly in electronic form) of all Regulatory Filings with respect to such Collaboration Products that it makes hereunder. The Responsible Regulatory Party will provide the other Party with reasonable advance notice of any meeting with any regulatory agency relating to Development, Commercialization and/or any Drug Approval Application in the relevant territory, and the other Party shall have the right to observe and, if the Parties mutually agree in advance or if such Party is the Responsible Commercialization Party, participate in any such meeting. The Responsible Regulatory Party also shall promptly furnish the other Party with copies of all material correspondence or minutes of material meetings with any regulatory agency relating to Development, Regulatory Filings and/or a Drug Approval Application in the relevant territory. As between the Parties, the Responsible Regulatory Party shall be the initial legal and beneficial owner of all Regulatory Filings and related approvals in the relevant territory for such Collaboration Product. The Responsible Regulatory Party shall assign all Regulatory Filings in the North American Territory to the Responsible Commercialization Party promptly following filing of the NDA (or its foreign equivalent). No such assignment shall take place in the ROW Territory.

(c) The Manufacturing Party shall provide the Responsible Commercialization Party (if a different Party) with reasonable advance notice of any scheduled regulatory inspection of the Manufacturing Party's Manufacturing facilities for a Product. The Manufacturing Party shall control all interactions with regulatory

authorities with respect to such inspection. The other Party if applicable, shall have the right to be present, but not participate, during such inspection.

5.3 Safety Data. [****] will ensure that [****] has complete access to any and all safety data regarding the [****] or any [****] thereof. [****] will ensure that [****] have complete access to any and all safety data regarding the [****] or any [****]. If and to the extent that a single global safety database is required for the [****], [****] will be the recognized holder of the global safety database for such Product, which will be searched to provide answers to safety queries, for signal evaluation, for the preparation of analyses of similar events and for the preparation of periodic safety update reports.

5.4 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 any of the Collaboration Products or Royalty Products, throughout the world, whether or not determined to be attributable to such Products (**"Adverse Event Reports"**). The Parties shall each identify a person 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. Within a reasonable time after the Effective Date, the Parties shall agree in writing on formal procedures for such exchange in a separate pharmacovigilance agreement. Provided that [****] is under a similar obligation under the [****] Agreements, the Parties agree to engage in good faith negotiations regarding a three-party pharmacovigilance agreement. The Parties acknowledge and agree that such procedures, as well as the Parties' exchange of Adverse Event Reports in general, must not be in contravention with the [****] Agreements relating to safety issues involving the [****] that is a Collaboration Product, or a Royalty Product.

5.5 Copies of Responses. Within a reasonable time frame prior to submission of responses to any regulatory authority on product safety issues regarding a Collaboration Product, 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. [****] acknowledges that such responses may need to be coordinated under the [****] Agreements with respect to the [****] and agrees to use commercially reasonable efforts to facilitate such coordination.

5.6 Regulatory Actions. The Party responsible for interacting with regulators on a specific safety issue regarding a Collaboration Product or Royalty Product shall communicate material action requested by regulators to the other Party without delay.

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Such actions may include, for example, change in label, Dear Doctor letter, trial on hold for clinical safety reasons and the like.

5.7 Other Safety Issues. Either Party may request that specific safety issues be discussed, and the parties will establish a Safety Committee (the "**SC**") consisting of an equal number of representatives from each Party, for such purpose. The role of the SC shall be to advise each Party concerning the collection and evaluation of safety data, and to respond to any significant safety issues raised, or requests made, by regulatory authorities.

ARTICLE 6

COMMERCIALIZATION

6.1 Overview. Subject to the roles of the various Committees described in Article 2, the allocation of primary responsibility for the creation of Commercialization Plans and the implementation of Commercialization activities of Collaboration Products described in such Commercialization Plans shall be given to the Responsible Commercialization Party. The allocation of such responsibilities with respect to the Existing Products shall be as follows:

	[****]	**[****]**	**[****]**
North American Territory	[****]	[****]	[****]
EU Territory	[****]	[****]	[****]
ROW Territory	[****]	[****]	[****]

(a) Commercialization Plans. All Commercialization of Collaboration Products shall be conducted pursuant to a Collaboration Product specific, multi-year, global commercialization plan and budget (in each case, a **"Commercialization Plan"**), which shall set forth the anticipated activities (including market studies, launch plans, Detailing and Promotion) and timelines, and shall allocate responsibility for carrying out such activities between PDL and Biogen Idec. Each Commercialization Plan shall include the plan for: (i) Detailing and Promotion activities for the applicable Collaboration Product in the applicable Indication for the next [****] (as to the initial Commercialization Plan, the [****] following launch) and timelines for performing such activities, (ii) target audience, (iii) anticipated expenses other than personnel,

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(iv) assumptions regarding product profile, (v) sales force size, and (vi) Promotional efforts. Any Commercialization Plan, together with any updates thereto, shall be prepared and approved as follows:

(i) The Responsible Commercialization Party with strategic guidance from the JSC shall prepare the initial Commercialization Plan for a Collaboration Product and submit such plan to the JCC for recommendation for approval and, following such recommendation, to the JSC for its review and approval; provided that the JCC must recommend and the JSC must approve the Commercialization Plan if it is consistent with the then-current Strategic Plan and Approved Budget for that year. The Parties agree and acknowledge that any such Commercialization Plan will reasonably allocate between the Parties the performance of any Post-Approval Clinical Trials for Collaboration Products in the North American Territory, giving equal consideration to each Party's abilities when making such allocation.

(ii) The Responsible Commercialization Party will, from time to time, prepare and submit an update to each Commercialization Plan for its territory for a Collaboration Product as necessary to reflect changes in the progress, strategy, or costs of Commercialization of such Collaboration Product, but in no event more frequently than quarterly.

(iii) the Responsible Commercialization Party for a Collaboration Product will prepare and submit an update to the applicable Commercialization Plan for its territory on an annual basis thereafter until the Parties cease Commercializing the applicable Collaboration Product.

(iv) the Responsible Commercialization Party will lead the implementation of the Commercialization Plan in accordance with the allocation of responsibilities set forth therein.

Once approved by the JSC, a Commercialization Plan shall become effective and supersede any previous Commercialization Plan, if any, as of the date of such approval. Unless the Parties otherwise agree, in the event that a Commercialization Plan is inconsistent with or contradicts the terms of this Agreement, the terms of this Agreement shall prevail.

(b) Commercialization Plans for Additional Collaboration Products. Promptly following the JSC's request for a Commercialization Plan for a particular Collaboration Product, the Responsible Commercialization Party shall create an initial Commercialization Plan for such Collaboration Product. Such Commercialization Plan shall be approved as described in this Section 6.1.

6.2 Commercialization Reports. The Responsible Commercialization Party will keep the JCC fully informed regarding the progress and results of its Commercialization activities under this Agreement.

6.3 Standards of Conduct.

(a) Each Party shall perform, or shall ensure that its Affiliates and permitted sublicensees and Third Party contractors perform, all Commercialization activities assigned to it in a good scientific and ethical business manner and in compliance with applicable laws, rules and regulations.

(b) The Parties shall use Diligent Efforts in Commercializing Collaboration Products.

(c) Each Party shall use Diligent Efforts to execute and carry out the activities assigned to it in the Commercialization Plan within the associated annual budget; provided that if a Party exceeds the associated annual budget by greater than [****] without the prior approval of the JSC, any amount in excess of such number shall not be considered expenses reimbursable hereunder and such Party shall be solely responsible for payment of such excess.

6.4 Sales Force Training. The Responsible Commercialization Party shall develop and conduct training programs for its sales representatives and for the other Party's sales representatives in the event such Party has exercised its Co-Promotion Option hereunder, specifically relating to the Collaboration Products to be Commercialized by such Party. Each Party agrees to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy.

6.5 Branding. Each Product Commercialized under this Agreement shall be Commercialized under and in connection with the trademarks and trade dress selected in accordance with Section 12.13. To the extent that a Party is granted rights under this Agreement to Commercialize a Product, it shall Commercialize such Product solely under and in connection with the trademarks and trade dress selected and approved pursuant to the terms of Section 12.13 (except for a Party's use of its house marks, which do not require such approval).

6.6 Pricing. [****].

6.7 Booking of Sales.

(a) [****] will be solely responsible for the invoicing and booking of sales of [****] that are Collaboration Products in the [****] and the supply and distribution of product in respect to such sales. [****] shall also be responsible for handling inventory, receivables, managing relationships with the trade, returns, reimbursements, and charge-backs, trade-customer complaints and inquiries regarding [****] that are Collaboration Products in the [****].

(b) The JSC will jointly determine which Party will book sales in

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accordance with U.S. GAAP, including handling inventory, receivables, managing relationships with the trade, returns, reimbursements, and charge-backs, trade-customer complaints and inquiries with respect to all other Collaboration Products.

(c) For clarity, each Party's expenses in connection with the activities described in this Section 6.7 will be included as Marketing Costs or Distribution Costs, as appropriate.

6.8 Special Provisions Relating to Sales Tracking for [****].

(a) The Parties recognize that [****] marketed by [****] or its licensees for indications in the [****] may nonetheless be sold in the [****], and [****] marketed by [****] and [****] for indications in the [****] may nonetheless be sold in the [****] (collectively, **"Cross-Field Sales"**). In order to detect and limit these Cross-Field Sales of such Collaboration Products, the Parties agree as follows:

(i) If, at any time following the receipt of Regulatory Approval in the [****] for an [****] that is a Collaboration Product or Royalty Product (Collectively, "**Collaborative Field Products**"), a Party believes that either (i) sales of such Collaborative Field Products are occurring or will occur for uses both inside and outside the [****], or (ii) that sales by [****] of a [****] licensed to it in the [****] by [****] (a "**Non-Collaborative Field Product**") are occurring in any Indication in which a Collaboration Product or Royalty Product is marketed, then such Party may provide notice to the other Party of its desire to track sales of the Collaborative Field Products and the Non-Collaborative Field Products for the relevant Indications in the relevant territory.

(ii) Upon receipt of notice under Section 6.8(a)(i) [****] and [****] shall meet and agree upon a method of tracking sales of each such product **("Sales Tracking Methodology")** for use in the relevant Indications including (A) the acquisition of one or more prescription data products or services (including, by way of example, IMS Xponent or DDD data) or other relevant pharmaceutical sales tracking research services (including, for example, use of random sampling, use of data regarding distribution channels as a proxy for indication-specific sales and development of mathematical models for approximating indication-specific sales) generally recognized in the pharmaceutical industry as having a high degree of accuracy and reliability in the tracking of sales of pharmaceutical products that have a similar nature as and are prescribed by similar physicians as the relevant [****] in the [****] and, if applicable, outside the [****] **(the "Data Services")**, and (B) the methodology for applying any such resulting data and information provided by such Data Services to determine the extent to which sales of the relevant [****] are Cross-Field Sales in the relevant territory. At the request of either Party, any meeting held under this Section 6.8(a) shall include licensees of [****] to whom [****] has granted rights in the [****], provided such licensee

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agrees to be bound to confidentiality provisions similar to those contained in this Agreement.

(b) If [****] (as applicable) are unable to agree on a Sales Tracking Methodology pursuant to Section 6.8(a), then the following default methodologies shall apply:

(i) With respect to each of the U.S., United Kingdom, France, Germany, Italy, or Spain (each a **"Major Regulatory Jurisdiction"**) in which a Collaborative Field Product and a Non-Collaborative Field Product have received Regulatory Approval and in which Data Services are available at a reasonable cost (evaluated in light of the anticipated accuracy of such data and anticipated magnitude of Cross-Field Sales in such country), sales in the Field in such country and sales outside the Field in such country shall be calculated for each Collaborative Field Product and each Non-Collaborative Field Product based on the sales levels reported by the Data Services for such country. For clarity, the sum of sales of a product in the Field and sales of such product outside the Field (both as calculated for such country in accordance with the preceding sentence) shall always be equal to the total sales for such product in the relevant country.

(ii) With respect to each country in which a Collaborative Field Product and a Non-Collaborative Field Product have received Regulatory Approval and to which Section 6.8(b)(i) is inapplicable, the percentage of sales of each Collaborative Field Product attributable to use outside the Field and the percentage of sales of each Non-Collaborative Field Product attributable to use in the Field shall be calculated from total sales of such products based on the assumption that the ratio of Cross-Field Sales to total sales in such country is equal to the ratio of Cross-Field Sales to total sales calculated across all Major Regulatory Jurisdictions in which Cross-Field Sales are evaluated pursuant to Section 6.8(b)(i). If there are no Major Regulatory Jurisdictions in which Cross-Field Sales are evaluated pursuant to Section 6.8(b)(i), then no Sales Tracking Methodology shall apply unless and until the Parties agree on a Sales Tracking Methodology pursuant to Section 6.8(a).

(c) All costs associated with the acquisition and application of such Data Services and Sales Tracking Methodology shall be shared equally by the Parties and any licensee of PDL participating in the negotiations contemplated by Section 6.8(a). All such costs that are attributable to PDL and Biogen Idec shall be included in the Operating Expenses for the applicable [****]. In addition, the Parties shall also meet and confer with respect to: (A) how to account for prescriptions to patients with multiple afflictions, both within and outside the [****]; (B) the right for each Party to audit, on a periodic basis, the application of the Data Services and Sales Tracking

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Methodology; and (C) a mechanism for addressing prescriptions that are tracked back to sole source purchasing agreements.

(d) If in the course of applying the foregoing Sales Tracking Methodology of the Collaborative Field Product and Non-Collaborative Field Product pursuant to this Section 6.8, 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 more than [****] or such [****] as may be agreed under the [****] Agreements [****] (with written notice of such amount to be provided to [****]), the Parties shall confer, together with the [****], regarding an appropriate method either to curtail such Cross-Field Sales and to compensate any affected Party (or affected [****]) for the economic effects thereof. [****] will ensure that [****] is reimbursed for any such Cross-Field Sales as if such Cross-Field Sales were included in Collaboration Product Profit. The Parties shall also negotiate with each other and with such licensee in good faith (provided that such licensee is bound by a substantially similar obligation) to reach an agreement implementing a Sales Tracking Methodology that is as accurate as reasonably possible given the then-available information and the costs associated therewith.

(e) In the event of any unresolved issues, dispute or disagreement under this Section 6.8 the Parties will submit such dispute, issue or disagreement for resolution pursuant to Article 17.

6.9 Other Cross Field Sales. If either Party is marketing a Product for an Independent Indication and cross field sales may be occurring with the same Product that is a Collaboration Product, the Parties shall meet and negotiate in good faith provisions similar to or designed to have the same economic effect as Section 6.8.

6.10 Product Recalls. Decisions with respect to recalls, withdrawals or other corrective actions (**"Recall"**) with respect to any Collaboration Product related to manufacturing or product quality issues shall be handled in accordance with the Commercial Supply Agreement. Decisions with respect to any other Recall related to any Collaboration Product in the Profit Sharing Territory or Royalty Product in its applicable territory shall be made only upon mutual agreement of the Parties; provided, however, that nothing herein shall prohibit either Party from initiating or conducting any Recall (i) mandated by a regulatory authority or applicable law, (ii) which in its reasonable judgment is, or such Party reasonably believes will result in, a Class I or Class II recall (under U.S. Food and Drug Administration regulations or its equivalent outside of the U.S.) or (iii) if a Party is the Independent Development Party in its sole discretion. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such Recall. Except as otherwise provided in this Section 6.10, the Parties will share all costs of a Recall with respect to any Collaboration Product in the Profit Sharing Territory as a Shared Promotion Expense.

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An Independent Development Party shall bear all costs of a Recall with respect to any Royalty Product in the Royalty Territory. Notwithstanding the foregoing, a Party shall bear any and all costs of a recall, market withdrawal or other corrective action with respect to a Collaboration Product in the Territory, including the COGM for the Collaboration Product in question, to the extent the Recall is attributable to the fault of such Party and results from (a) a grossly negligent or reckless act or omission or intentional misconduct of such Party (or its Affiliate, agent or sublicensee), (b) the failure of the Manufacturing Party to perform its responsibilities and Manufacture the Collaboration Product in compliance with specifications or with applicable laws, including applicable Good Manufacturing Practices, or (c) a breach of any laws or the terms of this Agreement.

6.11 [****]. [****] hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to, [****] that are Collaboration Products or Independent Products for any use outside the [****]. Except as permitted pursuant to Section 3.8, [****] hereby covenants that it shall only [****] in the [****] pursuant to the [****] Agreements.

ARTICLE 7

CO-PROMOTION OF COLLABORATION PRODUCTS

7.1 Option to Co-Promote.

(a) Subject to this Section 7.1, PDL and Biogen Idec shall each have the right, to the extent it is not the Responsible Commercialization Party (the "**Co-Promotion Option**") to elect at specified times to Commercialize a particular Indication of a Collaboration Product in either or both of the North American Territory or the EU Territory jointly with the Responsible Commercialization Party for such Collaboration Product.

(b) [****] may exercise its Co-Promotion Option in respect of a particular Territory only if it has and only with respect [****] shall reasonably be expected to be in place at the time of Co-Promotion. [****] may exercise its Co-Promotion Option in respect of a particular Territory only with respect [****] which shall reasonably be expected to be in place at the time of Co-Promotion.

(c) A Party may exercise its Co-Promotion Option with respect to a particular Indication of a Collaboration Product in a particular territory by providing written notice of such exercise to the Responsible Commercialization Party and the JCC. Such exercise must be provided for a particular territory no later than the date

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[****] prior to the anticipated filing date for Regulatory Approval in such territory for such Indication for the Collaboration Product and will be effective [****] following receipt of such notice by the Responsible Commercialization Party. Thereafter, the Party exercising the Co-Promotion Option shall be deemed a co-promoting Party (the "**Co-Promoting Party**") of such Indication for such Collaboration Product in such territory.

(d) If a Co-Promotion Option is exercised, then responsibility for Detailing will be shared on a basis to be determined by the JCC taking into account the resources and capabilities of each Party as well as each Party's prior efforts under Co-Promotion Options previously exercised and the nature of the market and Indication for which the Co-Promotion Option has been exercised. The Parties agree and acknowledge that, in allocating such Detailing activities between the Parties, the JCC shall apply the following principle in the event that both Parties have resources and capabilities in respect of a specific sales force (or neither Party has such resources and capabilities): the JCC shall give first consideration to using [****] and first consideration to using [****].

7.2 Co-Promotion Period. The "**Co-Promotion Period**" will commence upon the Co-Promoting Party's exercise of the Co-Promotion Option and will expire upon the earlier of: (a) termination of the Parties' Commercialization of the applicable Collaboration Product for the applicable Indication in the relevant portion of the Profit Sharing Territory, and (b) [****] following the date that the Co-Promoting Party provides written notice to the Responsible Commercialization Party terminating the Co-Promoting Party's Co-Promotion activities hereunder (or such lesser period of time as the Responsible Commercialization Party is able to satisfactorily fill the sales force commitments previously filled by the Co-Promoting Party) .

7.3 Co-Promotion in Commercialization Plan. The Parties' co-promotion activities for any Collaboration Product in the relevant territory shall be governed by the Commercialization Plan for such Collaboration Product prepared by the Responsible Commercialization Party. Each Commercialization Plan for a Co-Promote Product shall set forth the allocation between the Parties of the co-promotion activities for the Collaboration Product in the applicable territory determined pursuant to Section 7.1(d), the sales and marketing strategy determined by the JSC and the means by which to maximize the overall gross profit from sales of such Collaboration Product.

7.4 Scope. The Co-Promotion by the Co-Promoting Party of any Collaboration Products under this Agreement shall be subject to the terms and conditions set forth in this Article 7. For purposes of this Article 7, a Collaboration Product subject to co-promotion under this Agreement shall be referred to as a "**Co-Promote Product**."

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7.5 Advertising and Promotional Materials.

(a) The Responsible Commercialization Party shall be responsible for designing and supplying all advertising and promotional materials for each Co-Promote Product. The Responsible Commercialization Party shall provide samples of such advertising and promotional materials to the JCC for its information.

(b) Each Party agrees that:

(i) it will instruct its sales representatives to use only promotional materials, Co-Promote Product samples, and literature approved for use under this Section 7.5 for the Promotion of the Co-Promote Product; and

(ii) all written, electronic and visual communications provided by a Party to its sales representatives regarding the positioning, selling messages or product strategy of the applicable Co-Promote Product will be subject to prior review and approval by the Responsible Commercialization Party; provided, that a communication, once approved, need not be re-submitted for approval again prior to its re-use unless the Co-Promote Product labeling applicable to such communication has been changed since such prior approval date.

7.6 Training.

(a) The Responsible Commercialization Party will develop and implement training programs for the Co-Promoting Party's sales representatives as to matters relating specifically to the Co-Promote Product in a manner as set forth in the applicable Commercialization Plan. Training shall be carried out at a time that is mutually acceptable to the Parties, and that is prior to but reasonably near the commencement of the co-promoting Party's co-promotion of the Co-Promote Product. All costs associated with such product-specific training shall be shared equally by the Parties, except that the Co-Promoting Party shall pay all travel costs for its sales representatives to attend such training.

(b) The Responsible Commercialization Party shall provide continuing education regarding each Co-Promote Product for sales representatives of the Co-Promoting Party on substantially the same schedule as it provides continuing education for its own sales representatives for such Co-Promote Product.

7.7 Sales and Distribution of Co-Promote Product.

(a) For each Co-Promote Product, other than [****], the Responsible Commercialization Party shall be solely responsible for handling all returns, recalls,

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order processing, invoicing and collection, distribution, and inventory and receivables. With respect to [****], [****] shall solely be responsible for such activities. The Co-Promoting Party may not accept orders for Co-Promote Product or make sales for its own account or for the Responsible Commercialization Party's account. If the Co-Promoting Party receives any order for a Co-Promote Product, it shall refer such orders to the Responsible Commercialization Party for acceptance or rejection.

(b) The Responsible Commercialization Party shall have the right and responsibility for establishing and modifying the terms and conditions with respect to the sale of the Co-Promote Product, other than [****], including any terms and conditions relating to or affecting the price at which the Co-Promote Product will be sold, discounts available to managed care providers, any discount attributable to payments on receivables, distribution of the Co-Promote Product, and credits, price adjustments, or other discounts and allowances to be granted or refused. With respect to [****], [****] shall solely be responsible for such activities.

ARTICLE 8

MANUFACTURE AND SUPPLY

8.1 Overview. The Party primarily responsible for the Manufacturing Clinical Supplies or Commercial Supplies of Collaboration Products (the "**Manufacturing Party**") will be determined by the JSC (except for the Existing Products, with respect to which such responsibility is allocated by the table below) and shall be subject to the terms of this Article 8 and any Clinical Supply arrangement or Commercial Supply Agreement entered into by the Parties after the Effective Date. Unless determined otherwise by the JSC, the Manufacturing Party for the Existing Products will be as follows:

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

8.2 Clinical Manufacturing.

(a) Clinical Supply. Each Manufacturing Party shall Manufacture a clinical supply of bulk or finished Collaboration Products pursuant to a plan and on terms set by the Manufacturing Party, as approved by the JSC (a "**Supply Plan**"). Notwithstanding the aforementioned, [****] shall ensure a supply of [****] necessary to complete dosing in the [****] as of the Effective Date, provided that such supply shall be not less than [****].

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(b) Supply Plan. The Supply Plan shall be in accordance with the supply schedule dictated by the applicable Development Plan for each Collaboration Product and shall set forth, among other things, the quantities of and specifications for such Collaboration Products to be supplied by the Manufacturing Party for Development purposes and an approximate delivery schedule therefor.

(c) Cost of Clinical Supply. The Manufacturing Party will notify the JDC of the COGM for such Collaboration Products under the applicable Development Program for quantities of Collaboration Products supplied for clinical use.

8.3 Commercial Manufacturing.

(a) Commercial Supply Agreement. No later than [****] prior to the anticipated First Commercial Sale of a Collaboration Product as specified in the Commercialization Plan for such Collaboration Product, PDL and Biogen Idec shall negotiate in good faith one or more definitive supply agreements (each, a "**Commercial Supply Agreement**"). Each such agreement will set forth the specific terms and conditions governing the supply of bulk and/or finished Collaboration Products by the Parties for commercial use. Any Commercial Supply Agreement shall include terms substantially similar to those set forth in Exhibit 8.3 as well as additional reasonable and customary terms relating to commercial supply.

(b) Cost of Commercial Supply. Each Commercial Supply Agreement will provide for a transfer price from the Manufacturing Party to the Collaboration based on the total quantity of finished Collaboration Product ordered per calendar year (including material for Collaboration Product samples) calculated as follows: Transfer Price = [****].

8.4 Exclusivity. Each Responsible Commercialization Party, its Affiliates and sublicensees, shall purchase all of their respective requirements for the supply of Collaboration Products from the Manufacturing Party, unless otherwise agreed in writing by the Parties. The Manufacturing Party may not supply Collaboration Product for use in any field to any party other than the Responsible Commercialization Party, its Affiliates and sublicensees, except that [****] may provide material manufactured by [****] to [****] to support [****].

8.5 Good Manufacturing Practice. Each Collaboration Product, regardless of the form or formulation delivered by the Manufacturing Party, shall be Manufactured by the Manufacturing Party in accordance with GMP and the specifications for such Collaboration Product.

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ARTICLE 9

FINANCIAL TERMS

9.1 Licensing Fee. As partial payment for the rights and licenses granted by PDL pursuant to this Agreement, Biogen Idec shall pay to PDL, within five (5) days following the Effective Date, the following non-refundable and non-creditable license fees with respect to each Collaboration Product, as follows:

(a) With respect to the [****], total license fees of twenty-five million dollars ($25,000,000); and

(b) With respect to the [****], total license fees of fifteen million dollars ($15,000,000).

9.2 Milestone Payments. Biogen Idec shall make the following non-creditable and non-refundable milestone payments to PDL within [****] after the achievement by Biogen Idec of each of the following milestones (or, in the event that any such milestone is achieved by PDL, after PDL shall have given Biogen Idec sufficient written documentation evidencing the achievement of such milestone). For the avoidance of doubt, the milestone payments to be paid under this Section 9.2 shall be paid even following the delivery of an Opt Out Notice by PDL under Article 4 provided that Biogen Idec continues Development of the product. However, such milestone payments shall not be paid following the delivery of an Opt Out Notice by Biogen Idec under Article 4.

(a) Milestone Payments for [****] and [****] that are Collaboration Products or [****]. The following milestone payments shall be paid by Biogen Idec to PDL upon the [****] of each of the designated milestone events for any [****] that are Collaboration Products or [****] for which [****]:

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Milestone Event	Milestone Payment [****]	Milestone Payment [****]	Milestone Payment [****]
[****]	[****]	n/a	n/a
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]

* [****], Biogen Idec shall pay an additional [****] to PDL.

For the avoidance of doubt, the foregoing milestone payments will only be made a maximum of [****] per milestone event, regardless of the number of Collaboration Products, applicable Independent Products or Indications Developed.

(b) Milestone Payments for [****] that are Collaboration Products or Independent Products. The following milestone payments shall be paid by Biogen Idec to PDL upon the [****] occurrence of each of the designated milestone events: (i) for an [****] that is an Antibody Product and a Collaboration Product or Independent Product, and (ii) for an [****] that is a Non-Antibody Product and a Collaboration Product or Independent Product. For clarity, each milestone below will be payable a maximum of [****], [****] for a Product in category (i) and [****] for a Product in category (ii), irrespective of the number of such [****] that may trigger the milestone events.

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

9.3 R&D Funding. Biogen Idec shall make a [****] non-creditable, non-refundable R&D funding payment to PDL within [****] after approval by the JSC of a [****] to the JSC following the Effective Date.

9.4 Profit Sharing. PDL and Biogen Idec shall share equally in the Collaboration Product Profit for each Collaboration Product as set forth Exhibit C. The Parties shall share Collaboration Product Profit hereunder with respect to each Collaboration Product in the Profit Sharing Territory until each such Collaboration Product is permanently withdrawn from and is no longer being sold anywhere in the Profit Sharing Territory or otherwise ceases to be a Collaboration Product.

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9.5 Royalties.

(a) Royalties.

(i) For the term specified below, the Independent Development Party shall pay to the Non-Developing Party incremental royalties on Net Sales of the relevant Royalty Product in the Royalty Territory, at a royalty rate as determined in accordance with the schedules set forth in Exhibit D, as applicable. The term of the Independent Development Party's obligation to pay a royalty under this Section 9.5(a)(i) for a particular Royalty Product (collectively, the "**Royalty Term**") shall expire on a country-by-country and Royalty Product-by-Royalty Product basis, upon the later of:

(1) In the event that Biogen Idec is the Independent Development Party for [****] that is an Antibody Product, (i) [****], and (ii) [****];

(2) In the event that Biogen Idec is the Independent Development Party for any Products other than an [****] that is an Antibody Product (i) [****], and (ii) [****]; or

(3) In the event that PDL is the Independent Development Party, (i) [****], and (ii) [****].

(ii) For purposes of calculating Net Sales under this Section 9.5, the Independent Development Party may make the additional deductions described herein.

(1) In the event that pursuant to a Third Party License, the Independent Development Party must pay such Third Party royalties on sales of the Royalty Product in a particular country in the Royalty Territory, then the Independent Development Party may deduct [****] of such royalties paid to such Third Party from Net Sales of the applicable Royalty Product in such country.

(2) Following the expiration in a particular country in the Royalty Territory of the last to expire Valid Claim of a relevant Patent Right claiming the Manufacture, use or sale of a particular Royalty Product, the royalty rates set forth in Exhibit D with respect to such Royalty Product will be decreased [****] until expiration of the Royalty Term.

(3) If, during the Royalty Term, a Third Party receives regulatory approval for and commences commercial sale of a Generic Product in a country of the Royalty Territory, then the Independent Development Party shall have the right to reduce any royalties due under Section 9.5(a)(i) on account of the sale of such

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Royalty Products for such Indication by [****] during such time as such Third Party continues sales of such Generic Product in such country. As used in this Section, **"Generic Product"** means a Third Party product (a) [****]; and (b) [****]. Notwithstanding the foregoing, Generic Products do not include Royalty Products sold by either Party's sublicensees or distributors pursuant to this Agreement. For the avoidance of doubt, the reduction in royalties pursuant to Section 9.5(a)(ii)(3) for generic competition or Section 9.5(a)(ii)(2) for patent expiration, shall not, in the aggregate, [****].

(b) Special Provision Relating to ROW Territory. With respect to any definitive sublicense agreement under which Biogen Idec grants a Third Party a license to develop or commercialize one or more Royalty Products in the ROW Territory which is entered into prior to the [****], Biogen Idec will pay to PDL [****] of any Sublicensing Revenues received by Biogen Idec in connection with such sublicense agreement(s). As used in this Section 9.5(b) ONLY, **"Sublicensing Revenues"** means any [****], but excluding: (1) [****]; and (2) [****].

(c) Reporting and Payment.

(i) Until the expiration of the Independent Development Party's royalty obligations under Section 9.5, the Independent Development Party agrees, within [****] after the end of each Calendar Quarter, to make payments and written reports to the Non-Developing Party based upon Net Sales of the Royalty Products (substituting "Royalty Products" for "Collaboration Products" in the Net Sales definition) in the relevant Field in the Royalty Territory by the Independent Development Party, its Affiliates or sublicensees during such Calendar Quarter and provide written reports to the Non-Developing Party detailing for the period in question Net Sales by Product, royalty rate and royalty due.

(ii) The information contained in each report under Section 9.5(c)(i) shall be considered Confidential Information of the Independent Development Party. Concurrent with the delivery of each quarterly report, the Independent Development Party shall make the payment due the Non-Developing Party hereunder for the Calendar Quarter covered by such report.

(iii) It is understood that only one royalty payment under Section 9.5 shall be payable on a given unit of Royalty Product disposed of under this Agreement. In the case of transfers or sales of any Royalty Product between the Independent Development Party and an Affiliate or sublicensee of the Independent Development Party, such royalty shall be payable with respect to the sale of such Royalty 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.

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9.6 Provisions Regarding [****]. After the Effective Date, PDL will use Diligent Efforts to renegotiate the terms of that certain License Agreement between [****] to extend the diligence deadline for [****] (as defined in the [****]) to [****]. If, as a result of such renegotiations, the royalty rate payable by PDL on sales of licensed antibody products [****] (and provided the calculation of such royalty remains subject to the same offset provisions as included in the form of the [****] as of the Effective Date, then PDL may not charge as Third Party License Fees hereunder any royalty amount paid under the [****] in [****].

ARTICLE 10

PAYMENT TERMS

10.1 Accounting.

(a) Product Sales Records. Each Party (a "**Selling Party**") agrees to keep complete and accurate records for a period of at least [****] after the relevant payment is owed pursuant to this Agreement, setting forth the sales and other disposition of Collaboration Products or Royalty Products sold or otherwise disposed of pursuant to this Agreement in sufficient detail to enable compensation payable to either Party hereunder to be determined. The Selling Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the other Party to verify reports provided for in Section 9.5. Unless the other Party obtains the prior written consent of the Selling Party, such accounting firms must be selected from among the four largest U.S. accounting firms. Such audit shall not be performed more frequently that [****] nor more frequently than once with respect to records covering any specific period of time. Such examination is to be made at the expense of auditing Party, except in the event that the results of the audit reveal a discrepancy in favor of the Selling Party of [****] or more over the period being audited, in which case reasonable audit fees for such examination shall be paid by the Selling Party.

(b) Expense Records. Each Party (an **"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 9.5(c) setting forth its incurred Development Expenses, Operating Expenses, Ongoing Development Expenses, Other Out-of-Pocket Costs in sufficient detail to enable compensation payable to the other Party (an **"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

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pursuant to Section 9.5(c). 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 U.S. accounting firms. Such audit shall not be performed more frequently that [****]. 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.

10.2 Methods of Payments. All payments due to either PDL or Biogen Idec 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. Payments due on Collaboration Products or Royalty Products distributed in countries or jurisdictions outside of the U.S. shall be made in U.S. Dollars after being converted at the rate of exchange for such country's or jurisdiction's currency in U.S. Dollars as listed in the Wall Street Journal, Eastern Edition on the last business day of the Calendar Quarter in which such sales were made.

10.3 Taxes. If provision is made in law or regulation of any country for withholding of taxes of any type, levies or other charges with respect to the any amounts payable hereunder to a Party, the other Party (a **"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.

ARTICLE 11

LICENSES

11.1 Licenses to Biogen Idec.

(a) Subject to the terms and conditions of this Agreement, PDL and its Affiliates hereby grant to Biogen Idec:

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(i) a worldwide license, under the PDL Technology and Joint Inventions, to conduct Development of the Collaboration Products in the applicable Field in accordance with the Development Plans (which shall not include any Independent Indications for such Products);

(ii) a license, under the PDL Technology and Joint Inventions, to use, import, offer for sale and sell Collaboration Products in the applicable Field and in the North American Territory and EU Territory (i.e., the Profit Sharing Territory) in accordance with the Commercialization Plans (which shall not include any Independent Indications for such Products);

(iii) a worldwide license, under the PDL Technology and Joint Inventions, to make and have made Collaboration Products for which Biogen Idec is the Manufacturing Party, provided that such manufacture is solely for use in the applicable Field;

(iv) a worldwide license, under the PDL Technology and Joint Inventions, to develop, make, have made, use, have used, import, offer for sale and sell, in the applicable Field, Independent Products for which Biogen Idec is the Independent Development Party;

(v) a worldwide license, under the PDL Technology and Joint Inventions, to develop, use, have used, import, offer for sale and sell, in the applicable Field and in the Independent Indications, those Royalty Products for which Biogen Idec is the Independent Development Party with respect to such Indications; and

(vi) a license, under the PDL Technology and Joint Inventions, to use, have used, import, offer for sale and sell, in the applicable Field and in the ROW Territory (i.e., the Royalty Territory), Royalty Products.

(b) The licenses set forth in Sections 11.1(a)(i), (ii) and (iii) shall be exclusive in the Field (except as to PDL) for all PDL Know-How, for all PDL Patent Rights other than the Queen Patents, and with respect to PDL's interest in the Joint Inventions. The licenses set forth in Section 11.1(a)(iv)-(vi) shall be exclusive (even as to PDL) for all PDL Know-How, for all PDL Patent Rights other than the Queen Patents, and with respect to PDL's interest in the Joint Inventions. Subject to all of the restrictions of Section 11.1(a) and this Section 11.1(b), all licenses set forth in Section 11.1(a) are non-exclusive with respect to the Queen Patents.

(c) The licenses set forth in Section 11.1(a) may only be sublicensed to Biogen Idec Affiliates and permitted Third Parties.

11.2 Licenses to PDL.

(a) Subject to the terms and conditions of this Agreement, Biogen Idec and its Affiliates hereby grant to PDL:

(i) a worldwide license, under the Biogen Idec Technology and

Joint Inventions, to conduct Development of the Collaboration Products in the applicable Field in accordance with the Development Plans (which shall not include any Independent Indications for such Products);

(ii) a license, under the Biogen Idec Technology and Joint Inventions, to use, import, offer for sale and sell Collaboration Products in the applicable Field and in the North American Territory and EU Territory in accordance with the Commercialization Plans (which shall not include any Independent Indications for such Products);

(iii) a worldwide license, under the Biogen Idec Technology and Joint Inventions, to make and have made Collaboration Products for which PDL is the Manufacturing Party, provided that such manufacture is solely for use in the applicable Field;

(iv) a worldwide license, under the Biogen Idec Technology and Joint Inventions, to develop, make, have made, use, have used, import, offer for sale and sell, in the applicable Field, Independent Products for which PDL is the Independent Development Party;

(v) a worldwide license, under the Biogen Idec Technology and Joint Inventions, to develop, use, have used, import, offer for sale and sell, in the applicable Field and in the Independent Indications, those Collaboration Products for which PDL is the Independent Development Party with respect to such Indications; and

(vi) a license, under the Biogen Idec Technology and Joint Inventions, to use, have used, import, offer for sale and sell, in the applicable Field and in the ROW Territory Royalty Products, if the right to Develop and Commercialize any Royalty Product in the ROW Territory revert to PDL.

(b) The licenses set forth in Sections 11.2(a)(i), (ii) and (iii) shall be exclusive in the Field (except as to Biogen Idec) for all Biogen Idec Technology and with respect to Biogen Idec's interest in the Joint Inventions. The licenses set forth in Section 11.2(a)(iv)-(vi) shall be exclusive (even as to Biogen Idec) for all Biogen Idec Technology and with respect to Biogen Idec's interest in the Joint Inventions.

(c) The licenses set forth in Section 11.2(b) may only be sublicensed to PDL Affiliates and permitted Third Parties.

11.3 No Implied Licenses. Except as expressly provided in this Agreement, neither Party grants to the other Party any right or license in any intellectual property right, whether by implication, estoppel or otherwise. No implied licenses are granted under this Agreement. Each Party hereby covenants and agrees not to use or

sublicense any of its rights under the licenses set forth in this Article 11 except as expressly permitted in this Agreement. In particular, for the avoidance of doubt, PDL has no right to, and is not hereby granting any license to, [****].

11.4 Affiliates. The licenses granted pursuant to this Article 11 include the right of each licensee to use its Affiliates in exercising such rights and carrying out its obligations under this Agreement; provided that in the event any such Affiliate ceases to meet the definition of an Affiliate (whether due to the transfer or sale of all or substantially all of the assets or stock of such Affiliate or otherwise) then such right with respect to such Affiliate shall terminate

11.5 Third Party Licenses.

(a) Certain license rights granted by one Party to the other Party under this Article 11 may include a sublicense of Patent Rights and/or Know-How of Third Parties under Third Party Licenses. Notwithstanding anything to the contrary in this Agreement, the licenses granted under the provisions of this Article 11 (i) are subject to the applicable terms and conditions of such Third Party Licenses, and (ii) the Party receiving a sublicense under such Third Party License shall, in exercising such sublicense rights, comply with the applicable provisions of such Third Party Licenses. The Parties agree and acknowledge that the licenses granted to Biogen Idec under this Article 11 shall be subject to the following Third Party License provisions (as such Third Party Licenses and specific provisions may be amended from time to time upon notice to and consent of the JPC) and such provisions shall supersede anything to the contrary contained in this Agreement: (i) [****]; (ii) [****]; (iii) [****]; (iv) [****]; (v) [****]; (vi) [****]; (vii) [****]; (viii) [****]; and (ix) [****]. The Parties agree and acknowledge that the provisions of [****] are incorporated by reference herein solely for the benefit of [****]. The Parties agree and acknowledge that a copy of Paragraphs [****] is attached hereto as Exhibit 11.5 and shall be binding on Biogen Idec as if it were a party to the [****].

(b) PDL represents and warrants to Biogen Idec that, as of the Effective Date, (i) [****]; (ii) [****]; (iii) [****]. [****].

(c) With respect to each Third Party License to which a Party is a party, such Party (i) shall use Diligent Efforts to maintain such Third Party License in full force and effect, including without limitation seeking amendments or modifications of such agreements if necessary or useful as agreed by the Parties to continue Development or Commercialization of a Product, (ii) shall not amend, modify or permit to be amended or modified such Third Party License to reduce or impair the right sublicensed hereunder or to increase the obligations or burdens on the other Party hereunder without the other Party's consent, not to be unreasonably withheld**,** except as

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to the [****] as specifically provided herein, (iii) shall provide the other Party with a copy of each notice received by such Party under such Third Party License Agreement material to the rights granted to the other Party under this Agreement and derivative of rights granted under such Third Party License Agreement, and (iv) shall use Diligent Efforts to cause such Third Party License, as to rights licensed hereunder, to convert to a direct license to the other Party hereunder upon the termination of such Third Party License (provided that the other Party agrees to be bound by the terms and conditions of such Third Party License) and subject to the terms of such Third Party Licenses, including the following provisions (as such Third Party Licenses and specific provisions may be amended from time to time upon notice to and consent of the JPC): (a) [****]; (b) [****]; (c) [****]; (d) [****]; and (e) [****].

ARTICLE 12

INTELLECTUAL PROPERTY OWNERSHIP AND PATENT RIGHTS

12.1 Ownership of Intellectual Property.

(a) Generally. [****].

(b) Joint Ownership. All Joint Inventions will be owned jointly by PDL and Biogen Idec.

(c) Inventorship Procedure. The JPC shall, within a reasonable time after the Effective Date, establish and oversee a mutually agreeable procedure for (i) identifying Collaboration Inventions, and (ii) determining inventorship of Inventions made by a Party in connection with the Collaboration, provided that such determination shall be made in accordance with the applicable patent laws relating to inventorship in the country where each patent application is to be filed in instances where U.S. law regarding determinations of inventorship may be at variance with the laws of the said country. All such determinations shall be documented to ensure that any divisional or continuation patent application reflect appropriate inventorship and that inventions and patent rights are assigned to the appropriate assignee.

12.2 Disclosure of Patentable Inventions. Each Party shall provide to the other Party any invention disclosure submitted in the normal course of its business which discloses a Collaboration Invention within [****] after the Party determines that an Invention has been made.

12.3 Patent Due Diligence. Each Party agrees to use good faith efforts to bring to the attention of the JPC in a timely manner any Third Party Patent Right it

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discovers, or has discovered, and which the disclosing Party reasonably believes relates to, the Development or Commercialization of a Collaboration Product.

12.4 Prosecution of Patents

(a) PDL Patent Rights

(i) PDL Target Patent Rights. Decisions regarding the preparation, filing, prosecution and maintenance of PDL Target Patent Rights shall be made by the JPC. PDL shall be responsible, using in-house counsel or outside patent counsel selected by PDL and reasonably acceptable to Biogen Idec to implement the decisions of the JPC regarding the preparation, filing, prosecution and maintenance of such PDL Target Patent Rights. PDL shall provide the JPC with a copy of each patent application within such PDL Target Patent Rights as filed, together with its filing date and serial number. PDL shall keep the JPC advised of the status of all communications, actual and prospective filings or submissions regarding the PDL Target Patent Rights, and shall give the JPC an opportunity to review and comment on any such communications, filings and submissions proposed to be sent to any patent office. PDL shall consult with, and obtain the approval of, the JPC before deciding that it is no longer interested in maintaining or prosecuting the PDL Target Patent Rights contemplated by Section 12.10, provided, however, that if the JPC cannot reach agreement as to whether or not to maintain or prosecute such PDL Target Patent Rights, then PDL shall continue to maintain and prosecute such PDL Target Patent Rights. [****].

(ii) Queen Patents. Decisions regarding the preparation, filing, prosecution and maintenance of the Queen Patents shall be made solely by PDL. Notwithstanding the foregoing, [****]. PDL shall provide the JPC with a copy of each patent application within the Queen Patents that contains claims that specifically relate to a Collaboration Target or Collaboration Product, as filed, together with its filing date and serial number. PDL shall keep the JPC advised of the status of all communications, actual and prospective filings or submissions regarding the [****] and shall give the JPC an opportunity to review and comment on any such communications, filings and submissions proposed to be sent to any patent office. Subject to Section 12.12, PDL shall consult with, and obtain the approval of, the JPC before deciding that [****] or Collaboration Product, provided, however, that if the JPC cannot reach agreement as to whether or not [****].

(iii) Other PDL Patent Rights. Decisions regarding the preparation, filing, prosecution and maintenance of the PDL Patent Rights, to the extent not addressed in Section 12.4(a)(i) or Section 12.4(a)(ii), shall be made solely by PDL.

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(b) Biogen Idec Patent Rights.

(i) Biogen Idec Target Patent Rights. Decisions regarding the preparation, filing, prosecution and maintenance of Biogen Idec Target Patent Rights shall be made by the JPC. Biogen Idec shall be responsible, using in-house counsel or outside patent counsel selected by Biogen Idec and reasonably acceptable to PDL, to implement the decisions of the JPC regarding the preparation, filing, prosecution and maintenance of such Biogen Idec Target Patent Rights. Biogen Idec shall provide the JPC with a copy of each patent application within such Biogen Idec Target Patent Rights as filed, together with its filing date and serial number. Biogen Idec shall keep the JPC advised of the status of all communications, actual and prospective filings or submissions regarding the Biogen Idec Target Patent Rights, and shall give the JPC an opportunity to review and comment on any such communications, filings and submissions proposed to be sent to any patent office. [****].

(ii) Other Biogen Idec Patent Rights. Decisions regarding the preparation, filing, prosecution and maintenance of Biogen Idec Patent Rights that are not Biogen Idec Target Patent Rights shall be made solely by Biogen Idec.

(c) Prosecution of Joint Inventions.

(i) Decisions regarding the preparation, filing and prosecution and maintenance of Joint Patents shall be made by the JPC. Upon the identification of a Joint Invention, the JPC shall (1) promptly discuss such Joint Invention, (2) promptly discuss the desirability of filing a United States patent application covering such Joint Invention, as well as foreign counterparts, and (3) designate the Party (the "Implementing Party") to be responsible for the preparation, filing, prosecution and maintenance of such Joint Patent Rights. The Implementing Party shall be responsible, using in-house or outside counsel reasonably selected by the JPC to implement the decisions of the JPC regarding the preparation, filing, prosecution and maintenance of such Joint Patent Rights. The Implementing Party shall provide the JPC an opportunity to review and comment upon the text of the applications relating to such Joint Patent Rights before filing. The Implementing Party shall provide the JPC with a copy of each patent application within such Joint Patent Rights as filed, together with notice of its filing dates and serial number. The Implementing Party shall keep the JPC advised of the status of all communications, actual and prospective filings or submissions regarding such Joint Patent Rights, shall provide the JPC an opportunity to review and comment on such communications, filings and submissions proposed to be sent to any patent office. The Implementing Party shall also notify the JPC of the grant of any such Joint Patent Rights. The Implementing Party shall not cease the prosecution and/or

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maintenance, or modify the claims, of any such Joint Patent Rights in any country or elect not to file a patent application within such Joint Patent Rights, unless approved by the JPC (which approval shall not be unreasonably withheld).

(d) Patent Term Extensions. PDL shall be responsible to implement the decisions of the JPC regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable to PDL Target Patent Rights or Queen Patents that contain claims that specifically relate to a Collaboration Target or a Collaboration Product, in each case to the extent claiming a Collaboration Product. Biogen Idec shall be responsible to implement the decisions of the JPC regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable to such Biogen Idec Target Patent Rights to the extent claiming a Collaboration Product. The Implementing Party shall be responsible to implement the decisions of the JPC regarding patent term extensions, including, without limitation, supplementary protection certificates and any other extensions that are now or become available in the

future, wherever applicable to Joint Patent Rights to the extent claiming such Royalty Product. Each Party shall reasonably cooperate, as requested by the other Party, to implement such decisions of the JPC. In each instance of patent term extension contemplated by this section, the Parties agree to take all actions necessary to comply with the then-current laws and regulations relating to patent term extensions.

12.5 Patent Interferences/Oppositions

(a) Interferences/Oppositions Between the Parties. If an interference is declared by the U.S. Patent and Trademark Office, or its foreign equivalent, or an opposition exists between one or more PDL Target Patent Rights, Biogen Idec Target Patent Rights or Joint Patent Rights and such declared interference or opposition involves any claims specifically directed to a Collaboration Product, then the Parties shall in good faith establish a mutually agreeable process to resolve such interference or oppositions in a reasonable manner in conformance with all applicable legal standards, but which prejudices neither Party nor diminishes the value of such PDL Target Patent Rights, Biogen Idec Target Patent Rights, or Joint Patent Rights at issue.

(b) Oppositions/Interferences With Third Parties.

(i) PDL Target Patent Rights. Other than as set forth in Section 12.5(a), all decisions relating to interferences or oppositions lodged against PDL Target Patent Rights, including whether to initiate such interferences, appropriate settlement strategy, along with other strategic decisions relating to the PDL Target Patent Rights, shall be made by PDL, subject to the advice and counsel of the JPC. Subject to the provisions of this subsection (i), PDL shall control the conduct of any such interference or opposition. Biogen Idec shall reasonably cooperate, as requested by PDL, with respect to such opposition or interference. PDL shall keep the JPC informed of the progress of any opposition or interference action or proceeding relating to the PDL Target Patent Rights. PDL shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such PDL

Target Patent Rights, and shall provide the JPC an opportunity to review and comment on any such communications, filing and submissions. Notwithstanding the foregoing, [****].

(ii) Queen Patents. All decisions relating to interferences or oppositions lodged against the Queen Patents, including whether to initiate such interferences, appropriate settlement strategy, along with other strategic decisions relating to the Queen Patents, shall be made solely by PDL. Notwithstanding [****]. Subject to the provisions of this subsection (ii), PDL shall control the conduct of any such interference or opposition. Biogen Idec shall reasonably cooperate, as requested by PDL, with respect to such opposition or interference. PDL shall keep the JPC informed of the progress of any opposition or interference action or proceeding relating to such Queen Patents that contain claims that specifically relate to a Collaboration Target or a Collaboration Product. PDL shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such claims in such Queen Patents, and shall provide the JPC an opportunity to review and comment on any such communications, filing and submissions. Notwithstanding the foregoing, [****].

(iii) Other PDL Patent Rights. Decisions relating to interferences or oppositions lodged against Queen Patents or PDL Patent Rights, including whether to initiate such interferences, appropriate settlement strategy, and other strategic decisions relating to the Queen Patents or PDL Patent Rights, to the extent not addressed in Section 12.5(b)(i) or Section 12.5(b)(ii), shall be made by PDL**.**

(iv) Biogen Idec Target Patent Rights. Other than as set forth in Section 12.5(a), all decisions relating to interferences or oppositions lodged against Biogen Idec Target Patent Rights, including whether to initiate such interferences, appropriate settlement strategy, along with other strategic decisions relating to the Biogen Idec Target Patent Rights, shall be made by Biogen Idec, subject to the advice and counsel of the JPC. Subject to the provisions of this subsection (i), Biogen Idec shall control the conduct of any such interference or opposition. PDL shall reasonably cooperate, as requested by Biogen Idec, with respect to such opposition or interference. Biogen Idec shall keep the JPC informed of the progress of any opposition or interference action or proceeding relating to the Biogen Idec Target Patent Rights. Biogen Idec shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such Biogen Idec Target Patent Rights, and shall provide the JPC an opportunity to review and comment on any such communications, filings and submissions. Notwithstanding the foregoing, [****].

(v) Other Biogen Idec Patent Rights. Other than as set forth in Section 12.5(a) and Section 12.5(b)(iv), all decisions relating to interferences or

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oppositions lodged against Biogen Idec Patent Rights that are not Biogen Idec Target Patent Rights, including, without limitation, whether to initiate such interferences, appropriate settlement strategy, along with other strategic decisions relating to such Biogen Idec Patent Rights, shall be made by Biogen Idec.

(vi) Joint Patent Rights and Third Party Patent Rights. Other than as set forth in Section 12.5(a), all decisions relating to interferences or oppositions lodged against Joint Patent Rights, including, without limitation, whether to initiate such interferences, whether to file oppositions against Third Party Patent Rights relevant to a Collaboration Product, appropriate settlement strategy, along with other strategic decisions relating thereto, with respect to the Joint Patent Rights and Third Party Patent Rights shall be made by the JPC. Upon the identification of a potential opposition or interference directly involving the Joint Patent Rights or to the extent such opposition or interference is specifically directed to a Collaboration Product or Third Party Patent Rights (each, an "Adversarial Prosecution Action"), the JPC shall (i) promptly discuss such Adversarial Prosecution Action, including the strategy for conducting such Adversarial Prosecution Action, and (ii) designate the a Party (the "Controlling Party") to be responsible for controlling such Adversarial Prosecution Action, and determine a reasonable allocation between the Parties of the cost of such Adversarial Prosecution Action. The Controlling Party shall be responsible, using outside counsel reasonably selected by the Controlling Party, to implement the decisions of the JPC regarding such Adversarial Prosecution Action. The Party that is not the Controlling Party shall reasonably cooperate, as requested by the Controlling Party, in such Adversarial Prosecution Action. The Controlling Party shall keep the JPC informed of the progress of any such Adversarial Prosecution Action. The Controlling Party shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such Adversarial Prosecution

Action, and shall provide the JPC an opportunity to review and comment on any such communications, filings and submissions. The Controlling Party shall not settle or consent to an adverse judgment in any such Adversarial Prosecution Action with respect to the Joint Patent Rights or Third Party Patent Rights, unless approved by the JPC (which approval shall not be unreasonably withheld).

12.6 Initial Filings if Made Outside of the United States. The Parties agree to use reasonable efforts to ensure that any Patent Right within the PDL Target Patent Rights, Biogen Idec Target Patent Rights or Joint Patent Rights that is filed outside of the United States prior to a United States filing will be in a form sufficient to establish the date of original filing as a priority date for the purposes of a subsequent United States filing.

12.7 Enforcement of Patent Rights.

(a) Notification. If either Party learns of any substantial and continuing infringement of PDL Target Patent Rights, Biogen Idec Target Patent Rights or Joint Patent Rights by a Third Party making, using, offering for sale, selling or importing a product in or outside of the applicable Field, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement.

(b) Enforcement of Patent Rights.

(i) PDL Target Patent Rights. Subject to the further provisions of this subsection (b), decisions regarding the enforcement of PDL Target Patent Rights in an action against an infringement by a Third Party of claims licensed to Biogen Idec under Section 11.1, including the defense of a declaratory judgment action with respect to such potential infringement (each, an "**Enforcement Action**") shall be made by PDL. PDL shall have the first right to implement at its sole expense any Enforcement Actions relating to the PDL Target Patent Rights. Biogen Idec shall reasonably cooperate, as requested by PDL, with respect to such Enforcement Action. PDL shall keep the JPC informed of the progress of any action or proceeding to enforce the PDL Target Patent Rights. PDL shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such PDL Target Patent Rights, and shall provide the JPC an opportunity to review and comment on any such communications, filing and submissions. PDL shall not settle or consent to an adverse judgment in any action or proceeding to enforce such PDL Target Patent Rights that admits the invalidity or unenforceability of such PDL Target Patent Rights unless approved by the Joint Steering Committee (which approval shall not be unreasonably withheld). If PDL fails to institute such a suit or take such action within [****] after a request by Biogen Idec to do so, then Biogen Idec shall have the right at its sole discretion to bring and control such Enforcement Action in the name of either or both Parties, subject to Section 12.10. Such prosecution or defense shall be at Biogen Idec's sole expense unless PDL opts, at its discretion, to reimburse Biogen Idec for a portion ([****]) of all costs or expenses incurred by Biogen Idec with respect to such prosecution or defense.

(ii) Queen Patents. Decisions regarding Enforcement Actions with respect to Queen Patents shall be made solely by PDL. [****] shall be carried out in accordance with subsection (i) above and Section 12.10. For clarity, an Enforcement Action that involves [****] and carried out in accordance subsection (i), Section 12.9, and Section 12.12.

(iii) Additional PDL Patent Right Enforcement. Decisions regarding Enforcement Actions as well as actions for infringement outside the applicable Field and declaratory judgment suits regarding potential infringement outside the applicable Field, with respect to PDL Patent Rights and Queen Patents, to the extent and so long as such Enforcement Actions are not addressed in 12.7(b)(i) or (b)(ii), shall be made by PDL. PDL shall have the right, using outside counsel selected by PDL, to bring and control such Enforcement Actions at its sole expense. Biogen Idec shall reasonably cooperate, as requested by PDL, with respect to such Enforcement Action. PDL shall keep the Joint Patent Committee informed of the progress of any such Enforcement Action with respect to the PDL Patent Rights that are not PDL Target

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Patent Rights or Queen Patents. Notwithstanding the terms of Section 12.7(b)(vii), [****].

(iv) Biogen Idec Target Patent Rights. Subject to the further provisions of this subsection (b), decisions regarding the enforcement of Biogen Idec Target Patent Rights in an action against an infringement by a Third Party, including the defense of a declaratory judgment action with respect to such potential infringement shall be made by Biogen Idec. Biogen Idec shall have the first right to implement at its sole expense any Enforcement Actions relating to the Biogen Idec Target Patent Rights. PDL shall reasonably cooperate, as requested by Biogen Idec, with respect to such Enforcement Action. Biogen Idec shall keep the JPC informed of the progress of any action or proceeding to enforce the Biogen Idec Target Patent Rights. Biogen Idec shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such Biogen Idec Target Patent Rights, and shall provide the JPC an opportunity to review and comment on any such communications, filing and submissions. Biogen Idec shall not settle or consent to an adverse judgment in any action or proceeding to enforce such Biogen Idec Target Patent Rights that admits the invalidity or unenforceability of such Biogen Idec Target Patent Rights unless approved by the Joint Steering Committee (which approval shall not be unreasonably withheld). If Biogen Idec fails to institute such a suit or take such action within [****] after a request by PDL to do so, then PDL shall have the right at its sole discretion to bring and control such Enforcement Action in the name of either or both Parties, except to the extent that such prosecution or defense would conflict with rights granted by Biogen Idec to a Third Party. Such prosecution or defense shall be at PDL's sole expense unless Biogen Idec opts, at its discretion, to reimburse PDL for a portion ([****]) of all costs or expenses incurred by Biogen Idec with respect to such prosecution or defense.

(v) Additional Biogen Idec Patent Right Enforcement. Decisions regarding Enforcement Actions with respect to Biogen Idec Patent Rights that are not Biogen Idec Target Patent Rights shall be made by Biogen Idec. Biogen Idec shall have the right, using outside counsel selected by Biogen Idec, to bring and control such Enforcement Actions at its sole expense. PDL shall reasonably cooperate, as requested by Biogen Idec, with respect to such Enforcement Action. Biogen Idec shall keep the Joint Patent Committee informed of the progress of any such Enforcement Action with respect to the Biogen Idec Patent Rights that are not Biogen Idec Target Patent Rights. Notwithstanding the terms of Section 12.7(b)(vii), Biogen Idec shall retain all Recoveries received from a Third Party in connection with such Enforcement Action.

(vi) **Joint Patent Rights**. Decisions regarding Enforcement Actions with respect to the Joint Patent Rights shall be made by the JPC, upon

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consultation with the Joint Steering Committee. Upon the identification of an infringement of Joint Patent Rights with respect to a Collaboration Product, the JPC shall (i) promptly discuss such infringement, (ii) promptly discuss the strategy for enforcing such Joint Patent Rights, and (iii) designate the Controlling Party to be responsible for controlling an Enforcement Action with respect to such Joint Patent Rights, and determine a reasonable allocation between the Parties of the costs of such Enforcement Action. The Controlling Party shall be responsible, using outside counsel mutually acceptable to both Parties, to implement the decisions of the JPC regarding such Enforcement Action. The non-Controlling Party shall reasonably cooperate, as requested by the Controlling Party, in such Enforcement Action. The Controlling Party shall keep the Joint Steering Committee and the JPC informed of the progress of any action or proceeding to enforce the Joint Patent Rights. The Controlling Party shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such Joint Patent Rights, and shall provide the JPC an opportunity to review and comment on any such communications, filing and submissions. The Controlling Party shall not settle or consent to an adverse judgment in any such Enforcement Action with respect to the Joint Patent Rights, unless approved by the Joint Steering Committee (which approval shall not be unreasonably withheld).

(vii) **Allocation of Recoveries.** All cash amounts (plus the fair market value of all non-cash consideration) received by a Party or its Affiliates from a Third Party in connection with the final judgment, award or (to the extent a sublicense to such Third Party would require the consent of the other Party under this Agreement) settlement of such Enforcement Action ("Recoveries") shall first be applied to reimbursement of the unreimbursed legal fees and expenses of the Parties in connection with such Enforcement Action, and then the remainder shall be divided equally between the Parties, except that [****], [****], such remainder shall be shared [****] to the [****], and [****] to the [****]; provided that the [****] shall receive such share only to the extent the Recoveries were obtained with respect to Patents of such Party (e.g., [****]).

(viii) **Representation by Counsel.** Each Party 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 Party pursuant to this Section 12.7 for infringement in a Field. The amounts borne by such Party pursuant to this Section 12.7(b)(viii) shall not count towards the determination of the allocation between the Parties of any remaining recovery pursuant to Section 12.7(b)(vii).

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12.8 Defense of Infringement Actions.

(a) If PDL and/or Biogen Idec are defendant(s) named in a patent infringement suit filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of Collaboration Products in the Field (a "Defensive Action") decisions regarding such Defensive Actions shall be made by the JPC, upon consultation with the Joint Steering Committee. Upon the identification of a Defensive Action with respect to a Collaboration Product, the JPC shall (i) promptly discuss such Defensive Action, (ii) promptly discuss the strategy for defending such suit, and (iii) designate the Controlling Party to be responsible for controlling said Defensive Action, and determine a reasonable allocation between the Parties of the costs of such Defensive Action. The Controlling Party shall be responsible, using outside counsel mutually acceptable to both Parties, to implement the decisions of the JPC regarding such Defensive Action. The non-Controlling Party shall reasonably cooperate, as requested by the Controlling Party, in such Defensive Action. The Controlling Party shall keep the Joint Steering Committee and the JPC informed of the progress of any action or proceeding in the Defensive Action. The Controlling Party shall keep the JPC advised of all communications, actual and prospective filings or submissions regarding such Defensive Action, and shall provide the JPC an opportunity to review and comment on any such communications, filing and submissions. The Controlling Party shall not settle or consent to an adverse judgment in any such Defensive Action, unless approved by the Joint Steering Committee (which approval shall not be unreasonably withheld).

(b) 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 Collaboration Products in a Field throughout the world. The Parties shall discuss such information and decide how to handle such matter.

12.9 Third Party Intellectual Property.

(a) In the event that PDL or Biogen Idec (the "Acquiring Party") proposes to apply to a Collaboration Product Technology that the Acquiring Party obtained from a Third Party that is not included automatically within the definition of Biogen Idec Technology or PDL Technology prior to the Effective Date (and hence included in the licenses granted by the Acquiring Party pursuant to Article 11) or otherwise acquired by the Acquiring Party, the Acquiring Party shall disclose the same to the Joint Steering Committee, including any royalty or other payment obligations determined in accordance with United States GAAP that would apply to the Collaboration Product as a result of the Development or Commercialization of such

Collaboration Products hereunder. The Joint Steering Committee shall determine, [****] whether or not the Joint Steering Committee agrees that the intellectual property so acquired should be applied to the Collaboration Products, and if the Joint Steering Committee so determines, the agreement under which the Acquiring Party acquires such intellectual property shall be a Third Party License for purposes of this Agreement. To the extent the agreement is

not so included within the Third Party Licenses hereunder, the subject matter of such agreement shall not be within the definition of PDL Technology or Biogen Idec Technology hereunder (and therefore the licenses granted by the Acquiring Party pursuant to Article 11 shall not include such subject matter).

(b) Manufacturing Technology.

(i) PDL-Lead Manufacturer. Notwithstanding the foregoing, with respect to Collaboration Products or Royalty Products for which PDL is the Manufacturing Party under Article 8 above, PDL shall have the right to decide which Third Party Technology will be used in such Manufacturing, and any agreement pursuant to which PDL acquired or acquires such technology shall be deemed a Third Party License.

(ii) Biogen Idec-Lead Manufacturer. Notwithstanding the foregoing, with respect to Collaboration Products or Royalty Products for which Biogen Idec is the Manufacturing Party under Article 8 above, Biogen Idec shall have the right to decide which Third Party Technology will be used in such Manufacturing, and any agreement pursuant to which Biogen Idec acquired or acquires such technology shall be deemed a Third Party License.

(c) Third Party Licenses. Notwithstanding the provisions of this Article 12, the rights and obligations of the Parties under this Article 12, with respect to Patents licensed pursuant to a Third Party License, shall be subject to the rights of the applicable Third Party licensor/licensee pursuant to such Third Party License and the applicable Parties' obligations to such Third Party pursuant to such Third Party License. Without limiting the foregoing, the Parties agree and acknowledge that the provisions set forth in this Article 12 shall be subject to the following Third Party License provisions (as such Third Party Licenses and specific provisions may be amended from time to time upon notice to and consent of the other Party, if required, pursuant to Section 11.5(c)(ii)) and such provisions shall supersede anything to the contrary contained in this Agreement: (i) [****]; (ii) [****]; (iii) Article 5 of the UCSD License Agreement; (iv) [****]; (v) [****]; (vi) [****]; (vii) [****]; (viii) [****]; and (ix) [****]. The Parties further agree and acknowledge that PDL does not have any rights to prosecute or enforce the Patent

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Rights licensed to it pursuant to the following Third Party Licenses and therefore no portion of Article 12 shall be interpreted as granting Biogen Idec or the JPC or JSC rights to file, prosecute (including interferences and oppositions), maintain, enforce or defend such Patents or receive information or provide input with respect to such Patent Rights: [****]; [****]; [****]; [****]; and [****].

12.10 Rights pursuant to the [****] Agreements.

(a) The Parties acknowledge that, pursuant to the [****] Agreements, [****] has certain rights to file, prosecute (including interferences and oppositions), maintain, enforce and defend certain PDL Patent Rights that are licensed by or to PDL pursuant to the [****] Agreements. Notwithstanding anything to the contrary, Biogen Idec's, JPC's and JSC's rights pursuant to this Article 12 with respect to such PDL Patent Rights are subject to such [****] rights to file, prosecute, maintain, enforce and defend the certain PDL Patent Rights that are licensed by or to PDL pursuant to [****] Agreement. For clarity, PDL shall not be required pursuant to this Article 12 to provide Biogen Idec or the JPC or JSC with any patent filing, prosecution (including interferences and oppositions), maintenance, enforcement or defense associated-rights that conflict with [****] rights under the [****] Agreements or that would constitute a breach of PDL's obligations to [****] under the [****] Agreements, provided however, no additional rights shall accrue to Biogen Idec unless and until Biogen Idec obtains a license pursuant to Section 3.8. The Parties acknowledge that certain of Biogen Idec's, JPC's and JSC's rights under this Article 12 that relate to PDL Patent Rights that are licensed by or to PDL pursuant to the [****] Agreements. The Parties further acknowledge that such rights of Biogen Idec, JPC or JSC derive solely from those rights retained by PDL under the [****] Agreements.

(b) PDL hereby agrees and acknowledges that, notwithstanding any other provisions of this Agreement, Biogen Idec will not be obligated to pay any royalties due to [****] pursuant to the [****] Agreements for sales of Collaboration or Royalty Products, except as expressly stated in this Agreement.

12.11 Patent Marking. Each Party agrees to comply with the patent marking statutes in each country in which Collaboration Products or Royalty Products are sold by such Party, its Affiliates and/or sublicensees. Notwithstanding the foregoing, prior to the launch of each Product, the JPC will formulate a marking strategy for such Product in cooperation with qualified outside counsel and in cooperation with the guidelines of the appropriate governmental agencies regulating the Manufacture or sale of Products, including determining the appropriate patent marking, if any, to be used with such Product.

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12.12 Limited Rights to Humanization Technology Claims in Queen Patents. Nothing in this Article 12 shall be interpreted as granting Biogen Idec, the JPC or the JSC any rights with respect to the filing, prosecution (including interferences and oppositions), maintenance, enforcement or defense of primarily those claims in the Queen Patents that are directed toward the humanization of antibodies or humanized antibodies in general (as opposed to particular humanized antibodies or humanized antibodies directed at a particular target). For example and without limiting the foregoing, PDL shall not have any obligation to: (a) keep Biogen Idec or the JPC advised of the status of communications, actual and prospective filings or submissions primarily regarding such claims; (b) consult with Biogen Idec or the JPC on matters that primarily relate to such claims; (c) give Biogen Idec or the JPC access to or an opportunity to review and comment on any portion of patent office or patent litigation communications, filings or proposed submissions that pertain primarily to such claims; or (d) obtain JSC approval of a settlement or consent to an adverse judgment with respect to any admission of invalidity or unenforceability primarily of such claims.

12.13 Trademark Selection and Ownership.

(a) Ownership of Trademarks. The Responsible Commercialization Party for the North American Territory, as the "Responsible Trademark Party," shall own, throughout the world, all trademarks and trade dress, and all registrations therefor, selected under Section 12.13(b) and used or intended to be used on or in connection with a Product under this Agreement (the "Product Trademarks"). Accordingly, with respect to the Existing Products, [****] shall be the Responsible Trademark Party for [****], and [****] shall be the Responsible Trademark Party for [****] and [****]. All goodwill attributable to a Product Trademark generated by the Commercialization of a Product under this Agreement bearing a Product Trademark shall inure to the benefit of the Responsible Trademark Party.

(b) Selection and Procurement of Trademarks. The Responsible Trademark Party for a Product to be Commercialized under this Agreement shall select, subject to approval by the Joint Commercialization Committee, a minimum of [****] trademarks in each of the North American Territory and EU Territory and appropriate corresponding trade dress for such Product (whether as a Collaboration Product or Royalty Product). Any determination regarding the selection of such trademarks and trade dress shall take into account the objectives of the Parties, both within and outside the Collaboration, when making any determinations and exercising any rights it may have with respect to selecting the trademark and trade dress for a Product. All uses of trademarks and trade dress to identify and/or in connection with the Commercialization of a Product under this Agreement shall comply with all applicable laws (including,

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without limitation, those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries).

(c) Prosecution and Enforcement; Expenses. The Responsible Trademark Party shall be responsible for procurement and maintenance of trademark registrations for the Product Trademarks throughout the Territory, except that the Responsible Trademark Party may cease trademark registration procurement activities for any Product Trademark in any country in the Royalty Territory provided it first offers the other Party the opportunity to assume such activities at its own expense. All expenses incurred by the Responsible Trademark Party with respect to the preparation, filing, prosecution, maintenance and enforcement of the Product Trademarks for the Profit Sharing Territory shall be included in Other Out-of-Pocket Costs and solely for the Royalty Territory shall be borne at the Independent Development Party's sole expense.

(d) Use of the Product Trademarks. To effectuate the purposes of this Agreement, the Responsible Trademark Party shall grant to the other Party, a non-exclusive, non-royalty bearing license (with the right to grant sublicenses) pursuant to a separate agreement, to use each Product Trademark solely in connection with the Commercialization of Products under this Agreement. The Party that is not the Responsible Trademark Party, its Affiliates and its sublicensees will comply with the Responsible Trademark Party's then-current trademark and trade dress guidelines for trademarks and trade dress and shall have the right to monitor the quality of the Products on which a Product Trademark appears or which incorporates a Product Trademark in the form of trade dress in accordance with reasonable procedures to be agreed by the Parties. The Party that is not the Responsible Trademark Party, its Affiliates and sublicensees shall use the Product Trademarks only in connection with the Commercialization of Products under this Agreement in the Territory in accordance with the licenses to be granted herein. The Responsible Trademark Party, or the Party commercializing an Independent Product or Royalty Product as the case may be, shall provide all materials (including without limitation advertising or promotional materials) that incorporate the Product Trademarks or a Party's house marks to the Responsible Trademark Party for prior review and approval, not to be unreasonably withheld.

(e) House Marks. In the event that the Parties mutually agree to permit a Party to use the house marks of the other Party in connection with the Commercialization and/or Co-Promotion of Products under this Agreement, the Parties will establish mutually acceptable terms for the usage of such house marks.

(f) Acknowledgement of Ownership Rights. Each Party acknowledges the sole ownership by the other Party and validity of all trademarks, trade dress, logos and slogans owned by the other Party and used or intended to be used on or in connection with the Commercialization of a Product under this Agreement. Each Party agrees that it will not at any time during or after the Term assert or claim any interest in or do anything which may adversely affect the validity or enforceability of any trademark, trade dress, logo or slogan owned by the other Party and used or intended to be used on or in connection with Commercialization of a Product under this Agreement. Neither Party will register, seek to register or cause to be registered any

trademarks, trade dress, logos or slogans owned by the other Party and used or intended to be used on or in connection with the Commercialization of a Product under this Agreement or any variation thereof, under any law providing for registration of trademarks, service marks, trade names, fictitious names or similar laws, as an Internet domain name, or in the name of a corporation, partnership, limited liability company or other entity, without the other Party's prior written consent.

(g) Use of Trademark Designations. The ™ designation may be used in conjunction with each Product Trademark within the Territory. Once registrations issue, the ® designation may be used in connection with the Product Trademarks. An appropriate statutory notice of trademark ownership shall be affixed to or imprinted on any material wherever a Party's house marks or Product Trademarks are used. The Responsible Trademark Party's ownership of the Product Trademarks 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.

(h) Infringement of Product Trademarks.

(i) Procedure. In the event that either Party becomes aware of (i) actual infringement of a Product Trademark in the Territory; (ii) a mark or name confusingly similar to a Product Trademark in the Territory; or (iii) any unfair trade practices, trade dress imitation, passing off, or like offenses, in the Territory that relate to the Product Trademarks, such Party shall promptly so notify the other Party in writing. The Responsible Trademark Party 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 Product Trademark against any Third Party. If the Responsible Trademark Party fails to

bring any such infringement action within a period of [****] after delivery of the notice set forth above, then the other Party 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 Product 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 and expense 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 Product 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.

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(ii) Costs. The costs associated with such defense for the Profit Sharing Territory shall be included in [****] as set forth in Exhibit C and the costs associated solely with the Royalty Territory shall be borne by the Independent Development Party. Any damages or monetary award recovered shall be allocated as follows: All cash amounts (plus the fair market value of all non-cash consideration) received by a Party or its Affiliates from a Third Party in connection with the final judgment, award or settlement of such action ("Recoveries") shall first be applied to reimbursement of the unreimbursed legal fees and expenses of the Parties in connection with such action, and then the remainder shall be [****].

12.14 Third Party Trademark Claims Based on Use of the Trademarks.

If a claim is brought by a Third Party that a Party's use of the Product Trademarks 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. The Responsible Trademark Party shall defend any such claim and any resulting suit brought in the Territory with respect to the use of the Product Trademark, provided the costs associated with such defense for the Profit Share Territory shall be included in [****] as set forth in Exhibit C and the costs associated solely with the Royalty Territory shall be borne by the [****]. Any damages or monetary award recovered shall be allocated as follows: All cash amounts (plus the fair market value of all non-cash consideration) received by a Party or its Affiliates from a Third Party in connection with the final judgment, award or settlement of such defense ("Recoveries") shall first be applied to reimbursement of the unreimbursed legal fees and expenses of the Parties in connection with such defense, and then the remainder shall be [****], except that [****]. The Responsible Trademark Party shall not settle any claim or suit in a manner that would adversely affect the other Party without obtaining the other Party's prior written consent, which shall not be unreasonably withheld.

ARTICLE 13

REPRESENTATIONS AND WARRANTIES

13.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of August 2, 2005:

(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;

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(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;

(d) Subject to Section 11.5(b)(iii) such Party has the right to grant the rights and licenses described in Article 11; and

(e) Such Party has and shall maintain the resources and capability to perform its obligations hereunder either alone or together with one or more of its Affiliates whose performance it can cause to be made available to perform obligations hereunder.

13.2 Representations by PDL. PDL hereby represents and warrants to Biogen Idec as of August 2, 2005:

(a) Prior to August 2, 2005, it has provided a complete copy of the [****] Agreements and of all Third Party Licenses in effect as of the Effective Date;

(b) [****];

(c) it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in PDL Technology in the Field;

(d) [****];

(e) [****];

(f) [****];

(g) [****];

(h) [****]; and

(i) [****].

As used and except as otherwise set forth herein, "PDL's knowledge" means the actual knowledge, after reasonable inquiry, as of the Effective Date, of any executive officer of PDL with operational responsibility for the subject matter of the applicable representation or warranty.

Without limiting the foregoing, the Parties agree and acknowledge that the representations made by PDL in this Section 13.2 shall not be deemed to be representations made by or on behalf of [****].

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13.3 Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTION 13.1 AND 13.2, EACH PARTY MAKES NO OTHER REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ARISING FROM A COURSE OR DEALING, USAGE OR TRADE PRACTICES, OR ANY WARRANTY AS TO THE VALIDITY OR ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTIES, IN ALL CASES WITH RESPECT THERETO.

13.4 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, EACH PARTY'S PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING LIMITATION SHALL NOT LIMIT EITHER PARTY'S OBLIGATION TO THE OTHER PARTY UNDER ARTICLES 14 AND 15.

13.5 Essential Basis. The Parties acknowledge and agree that the disclaimers, exclusions and limitations of liability set forth in this Article 13 form an essential basis of this Agreement, and that, absent any of such disclaimers, exclusions or limitations of liability, the terms of this Agreement, including the economic terms, would be substantially different.

ARTICLE 14

CONFIDENTIALITY

14.1 Generally. During and for five (5) years after the Term of this Agreement, each Party (i) shall maintain in confidence all Confidential Information of the other Party; (ii) shall not use such Confidential Information for any purpose except as permitted by this Agreement; and (iii) shall not disclose such Confidential Information to anyone other than those of its Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents or subcontractors who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this Article 14 and to whom such disclosure is necessary in connection with such Party's activities as contemplated in this Agreement. Each Party shall ensure that such Party's Affiliates, sublicensees, prospective sublicensees, employees, consultants, agents and subcontractors comply with these obligations. Each Party shall notify the other promptly on discovery of any unauthorized use or disclosure of the other's trade secrets or proprietary information.

14.2 Exceptions. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 14.1 shall not apply to the extent the receiving Party (the

"Recipient") can demonstrate that the disclosed information (i) was in the public domain at the time of disclosure to the Recipient by the other Party, or thereafter entered the public domain, in each case other than as a result of actions of the Recipient, its Affiliates, employees, licensees, agents or subcontractors, in breach of this Agreement; (ii) was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party; or (iii) was received by the Recipient or its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the other Party. Notwithstanding any other provision of this Agreement, Recipient's disclosure of Confidential Information shall not be prohibited if such disclosure: (a) is in response to a valid order of a court or other governmental body, provided that Recipient provides the other Party with prior written notice of such disclosure in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information; or (b) is otherwise required by applicable law or regulation, or rules of a nationally recognized securities exchange.

14.3 Publications.

(a) Prior to public disclosure or submission for publication of a proposed academic, scientific or other publication or presentation that contains or references the results of any scientific or clinical activity relating to any Development Program or Collaboration Product, or any Patents or Know-How related thereto, the Party disclosing or submitting such proposed publication (**"Submitting Party"**) shall send the other party (**"Responding Party"**) by expedited delivery a copy of the proposed publication to be submitted and shall allow the Responding Party a reasonable time period (but no less than forty-five (45) days from the date of confirmed receipt) in which to determine whether the proposed publication contains subject matter for which patent protection should be sought (prior to publication of such proposed publication) for the purpose of protecting an invention and/or whether the proposed publication

contains the Confidential Information of the Responding Party. Following the expiration of the forty-five (45) day review period, the Submitting Party shall be free to submit such proposed publication for publication and publish or otherwise disclose to the public such scientific or clinical results, subject to the procedures set forth in Section 14.3(b).

(b) If the Responding Party believes that the subject matter of the proposed publication contains Confidential Information or a patentable invention of the Responding Party, then prior to the expiration of the applicable time period for review, the Responding Party shall notify the Submitting Party in writing of its determination that such proposed publication contains such information or subject matter for which patent protection should be sought. On receipt of such written notice from the Responding Party, the Submitting Party shall delay public disclosure of such information or submission of the proposed publication for an additional period of ninety (90) days to permit preparation and filing of a patent application on the disclosed subject matter. The Submitting Party shall thereafter be free to publish or disclose such information, except that the Submitting Party may not disclose any Confidential Information of the Responding Party in violation of Sections 14.1 and 14.2 hereof.

14.4 Publicity. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of a mutually agreed press release. 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 unless such publication, news release or other public announcement contains information previously approved by the other Party for release hereunder; provided, however, that any disclosure which is required by law, or by the rules of a nationally recognized securities exchange, 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.

ARTICLE 15

INDEMNIFICATION

15.1 Indemnification by PDL.

(a) PDL agrees to indemnify, hold harmless and defend Biogen Idec and its Affiliates, directors, officers, employees and agents (the **"Biogen Idec Indemnitees"**) from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or losses (including attorneys' fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) (**"Losses"**) [****], but [****].

(b) PDL agrees to indemnify, hold harmless and defend the Biogen Idec Indemnitees from and against any and all Losses [****] (i) [****], or (ii) [****], except [****].

15.2 Indemnification by Biogen Idec.

(a) Biogen Idec shall indemnify, hold harmless and defend PDL and its Affiliates directors, officers, employees and agents (the **"PDL Indemnitees"**) from and against any and all Losses, [****], but [****], but not [****]. [****].

(b) Biogen Idec agrees to indemnify, hold harmless and defend the PDL Indemnitees from and against any and all Losses [****], except [****].

15.3 Procedure. In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified

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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.

15.4 Insurance. Each Party, 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. Each Party shall provide [****] prior written notice of any cancellation of its insurance program. Each Party shall provide the other Party with a certificate of insurance evidencing product liability coverage.

ARTICLE 16

TERM AND TERMINATION; EFFECTS OF TERMINATION

16.1 Term. The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article 16, will expire on the date on which neither Party has nor will have any additional payment obligations to the other Party under this Agreement (the **"Term"**).

16.2 Termination for Breach.

(a) **Breach**. If a Party materially breaches its obligations under this Agreement with respect to a Collaboration Product or Royalty Product, which breach is not cured within [****] after written notice thereof from the non-breaching Party (or if such breach is not capable of cure within such period, which breach the breaching Party is not making diligent good faith efforts to cure), then upon further express written notice from the non-breaching Party, the breaching Party automatically (and without further action on its part) shall be deemed to have [****] (a "Breaching Party"); provided however that the breaching Party shall be entitled to receive no more than [****] of the royalties due to a Non-Developing Party hereunder. This preceding sentence shall not, however, limit in any manner the non-breaching Party's other remedies for breach. The Parties acknowledge and agree that failure to exercise any right or option with respect

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to any Collaboration Product or to take any action expressly within the discretion of a Party shall not be deemed to be material breach hereunder.

(b) **Breaching Party Obligations**. A Breaching Party shall, with respect to the Collaboration Product or Royalty Product as to which it is the Breaching Party (i) notwithstanding the provisions of this Agreement to the contrary, the Breaching Party shall be [****], (ii) in addition to the obligations specified in [****] the Breaching Party shall [****], and (iii) the Breaching Party shall [****].

16.3 **Bankruptcy**. All rights and licenses granted under this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the **"Bankruptcy Code"**), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that a Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code in the event of a bankruptcy by the other Party. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against one Party under the Bankruptcy Code, the other Party shall be entitled to complete access to any such intellectual property pertaining to the rights granted in the licenses hereunder of the Party by or against whom a bankruptcy proceeding has been commenced and all embodiments of such intellectual property.

16.4 **Change of Control**.

(a) In the event a Party undergoes a Change of Control (the "Acquired Party"), the other Party (the "Non-Acquired Party") shall have the right, at any time within [****] following the closing of such Change of Control, and at its sole discretion, to elect none, some or all of the following. This Agreement shall otherwise remain in full force and effect.

(i) The provisions of this Agreement permitting the Acquired Party to vote in any Committee decision [****].

(ii) The Non-Acquired Party shall have the option [****].

(iii) The Non-Acquired Party shall have [****].

(iv) Upon [****] prior written notice, the Non-Acquired Party may [****]; and

(v) The Non-Acquired Party shall have the [****] to (A) [****] and (B) [****]. The purposes of such procedures shall be to strictly limit such disclosures to

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only those personnel having a need-to-know Sensitive Information in order for the Acquired Party to perform its remaining obligations under this Agreement and to prohibit the use of Sensitive Information for competitive reasons against the Non-Acquired Party and its Affiliates, including without limitation, the use of Sensitive Information for the development or commercialization of competing products.

(b) An Acquired Party shall have the one-time right, at any time within [****] following the election by the Non Acquired Party to exercise any of the rights specified in Section 16.4(a) to [****]. Upon written notice of the Acquired Party's intent to [****], the Acquired Party shall:

(i) Continue to participate in the equal funding of the Development and Commercialization of each Collaboration Product in the Profit Sharing Territory until the next applicable opt-out point specified in Exhibit 4.1(b)(iii) for such Collaboration Product.

(ii) Promptly comply with the provisions of Sections 4.3(c), 4.3(e), 4.3(f), 4.3(g) and 4.3 (h) with respect to each Collaboration Product as if it were a Non-Developing Party thereunder.

(iii) Following the termination of the Acquired Party's funding obligation as set forth in Section 16.4(b)(i) above, the Acquired Party shall thereafter be eligible to receive from the Non-Acquired Party, for the term specified below, incremental royalties on Net Sales of the relevant Collaboration Product at a royalty rate which is equal to the sum of (A) [****] (B) [****], as applicable. The term of the Non-Acquired Party's obligation to pay a royalty under this Section 16.4(b) shall expire on a country-by-country and Collaboration Product-by-Collaboration Product basis, at the dates specified in Section 9.5. Each Collaboration Product shall thereafter be deemed to be an Independent Product and all the applicable provisions of the Agreement shall remain in full force and effect.

16.5 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.

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ARTICLE 17

DISPUTE RESOLUTION; GOVERNING LAW

17.1 **Disputes**. Unless otherwise set forth in this Agreement, in the event of any dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the respective Executives, and such Executives shall attempt in good faith to resolve such dispute.

17.2 **Arbitration.** Subject to the provisions of Section 2.8(c), if the Parties are unable resolve a given dispute pursuant to Section 17.1 within [****] of referring such dispute to the Executives, 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 [****] 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 Los Angeles, California, or in such other venue as the Parties agree, 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 [****] 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 [****] of such failure. The award rendered by the arbitrator shall not include costs of arbitration, attorneys' fees or costs for expert and other witnesses. Within [****] of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures assuring that the arbitration will be concluded and the award rendered within no more than [****] from

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selection of the arbitrator. Failing such agreement, the AAA will design and the Parties will follow procedures that meet such a time schedule. The arbitrator (i) shall not have any power or authority to add to, alter, amend or modify the terms of this Agreement but shall specify rules sufficient to allow reasonable discovery by the Parties; (ii) shall establish and enforce appropriate rules to ensure that the proceedings, including the decision, be kept confidential and that all Confidential Information of the Parties be kept confidential and be used for no purpose other than the arbitration; (iii) shall have the power to enforce specifically this Agreement and the terms and conditions hereof in addition to any other remedies at law or in equity; and (iv) shall issue all decisions in writing. 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.

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

ARTICLE 18

MISCELLANEOUS

18.1 **Assignment.** Each Party, without the consent of the other Party, may assign this Agreement and its rights and obligations hereunder (i) [****], or (ii) [****]. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The assigning Party shall promptly notify the other Party of any such Change of Control and any such assignment and shall use all reasonable efforts to provide such notification at least [****] before the completion of the Change of Control and before the assignment. Except as specifically provided in this Section 18 or in Section 3.7, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party. Any attempted assignment not in accordance with this Section shall be void.

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

18.2 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 18.2 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.

18.3 Entire Agreement; Amendment. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter herein and, effective on the Effective Date, supersedes all previous agreements between the Parties with respect to the subject matter herein, whether written or oral, including the existing confidentiality agreement between PDL and Biogen Idec. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both Parties.

18.4 Severability. If any provision of this Agreement is declared invalid 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 if the provision so invalidated is essential to the Agreement as a whole, then 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 for resolution pursuant to Article 16.

18.5 Notices. Any notice or report required or permitted to be given under this Agreement shall be in writing and shall be mailed by nationally recognized overnight courier, or faxed and confirmed by mailing, as follows and shall be effective one (1) day after such mailing:

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

	Fremont, California U.S.A. 94555 Attention: General Counsel Facsimile:
If to Biogen Idec:	Biogen Idec Inc. 14 Cambridge Center Cambridge, Massachusetts U.S.A 02142 Attention: Chief Executive Officer Facsimile:
and	Biogen Idec Inc. 14 Cambridge Center Cambridge, Massachusetts U.S.A 02142 Attention: General Counsel Facsimile:

18.6 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.

18.7 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.

18.8 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.

18.9 No Strict Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

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

18.11 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

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

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties have executed this Collaboration Agreement through their duly authorized representatives to be effective as of the Effective Date.

PROTEIN DESIGN LABS, INC.	**BIOGEN IDEC MA INC.**
By: /s/ Mark McDade	By: /s/ James Mullen
Title: President and CEO	Title: President
Date: September 12, 2005	Date September 12, 2005

EXHIBIT A
PDL PATENT RIGHTS

I. Queen Patents

[****]

II. [****] Patent Rights

[****]

III. [****] Patent Rights

[****]

IV. [****] Patent Rights

[****]

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

THIRD PARTY LICENSES

[****]

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EXHIBIT C

FINANCIAL PLANNING, ACCOUNTING AND REPORTING PROCEDURES FOR COLLABORATION AGREEMENT

This Exhibit C to the Collaboration Agreement (the "**Agreement**") dated as of the Effective Date, between Protein Design Labs, Inc. ("**PDL**") and Biogen Idec MA, Inc. ("**Biogen Idec**") covers financial planning, accounting policies and procedures to be followed in determining Development Expenses, Ongoing Development Expenses, Other Out-of-Pocket Costs and Reimbursable Commercial Costs pursuant to the Agreement.

For such purpose, this Exhibit C sets forth the principles for reporting actual results and budgeted plans in the Territory, the frequency of reporting, the use of a single "**Functional Currency**" (as defined in A.3) and the methods of determining payments to the Parties, auditing of accounts and other matters.

This Exhibit C also provides agreed upon definitions of financial terms applicable to the Parties for purposes of the Agreement. All capitalized terms used herein without definition shall have the meanings ascribed thereto in the Agreement and, where applicable, the further definitions contained herein. References in this Exhibit C to a "**Party**" or "**Parties**" shall be construed to mean Biogen Idec or PDL, as the case may be, and in every case shall be deemed to include a Party's Affiliates or sublicensees under the Agreement.

The contents of this Exhibit C are hereby incorporated into the Agreement and are governed by the terms and conditions of the Agreement, including the confidentiality provisions set forth therein. Notwithstanding anything in the Agreement to the contrary, no cost, expense, amount or sum allocable or chargeable to the Parties' activities under the Agreement shall be allocated or charged more than once. Unless otherwise specifically authorized by the Parties or the Agreement, all costs, expenses, amounts or sums to be charged or allocated by one Party to the other Party under the Agreement shall not be so chargeable or allocable unless they are both directly related to the Agreement and the activities to be performed under the Agreement and are reasonable and customary with respect to the global biopharmaceutical industry considering the respective size and activities of the two Parties as collaborators under the Agreement.

A. Definitions, Reporting and Reconciliation

A.1. Definitions

A.1.1 "Combination Product" shall mean a product containing both the Collaboration Product and one or more other active ingredients in addition to the Collaboration Product where the other active ingredients have independent prophylactic or therapeutic effect when used alone to treat the disease or indication for which the Combination Product is labeled, whether the Collaboration Product and the other active

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ingredients are together in a physical mixture or packaged and priced together as a single product.

A.1.2 "Combination Product Amount" shall mean the following: in the event a Collaboration Product is sold in the form of a Combination Product, and provided that the JSC has approved the sale and marketing of such a Combination Product in a Commercialization Plan , Net Sales for such Combination Product for purposes of this Agreement will be determined by [****]. If, on a country-by-country basis, the other active component or components in the combination are not sold separately in such country, Net Sales shall be calculated by [****]. If, on a country-by-country basis, the Collaboration Product component of the Combination Product is not sold separately in such country, but the other active component or components are sold separately, Net Sales shall be calculated by [****]. If, on a country-by-country basis, neither the Collaboration Product nor the other active component or components of the Combination Product is sold separately in such country, [****].

A.1.3 "**Cost of Clinical Supplies**" shall mean a Party's costs to produce [****], to the extent that such costs would ordinarily be included [****] for a similar product, including without limitation labor and material cost, allocable depreciation and amortization, product quality assurance/control costs, allocable facilities costs (e.g., sewer, water, property taxes), Third Party Royalties, insurance, and other costs borne by the party for transport, customs and duty clearance and storage of Clinical Supplies of Collaboration Product. [****].

A.1.4 "Cost of Goods Manufactured for Sale" or "COGM" shall mean a Party's costs to produce [****] and/or [****] to the extent that such costs would ordinarily be included [****] for a similar product, including without limitation labor and material cost, allocable depreciation and amortization, product quality assurance/control costs, allocable facilities costs (e.g., sewer, water, property taxes), Third Party Royalties, insurance, and other costs borne by the party for transport, customs and duty clearance and storage of Commercial Supplies of Collaboration Product. [****].

A.1.5 "Cost of Sales" shall mean a Collaboration Product's Cost of Goods Manufactured for Sale [****], Third Party Royalties (i.e., any allocable intellectual property acquisition and licensing costs not included in COGM) and transport, customs and duty clearance on sales if borne by the seller.

A.1.6 "**Development Expenses**" shall mean the costs and expenses associated with Development activities actually for each Collaboration Product incurred by Biogen Idec or PDL or their Affiliates from August 2, 2005, provided that the provisions of Section 3.5(a)(ii) are complied with, and otherwise, from the Effective Date through the later of (a) [****], or (b) [****]. The costs and expenses associated with

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Development activities shall include those costs required to obtain, maintain and/or expand the authorization and/or ability to manufacture, formulate, fill, ship and/or sell Collaboration Product in commercial quantities to Third Parties in the Territory, including the costs of the Parties associated with the transfer of, and implementation of manufacturing technology necessary to qualify a manufacturing facility. Development Expenses shall also include, but are not limited to, costs of research or Development, including costs of studies on the toxicological, pharmacological, metabolical or clinical aspects of a Collaboration Product conducted internally or by individual investigators or consultants and necessary for the purpose of obtaining, maintaining and/or expanding marketing approval of a Collaboration Product, process development, process improvement and scale-up costs, validation costs, including qualification lots, the manufacture of Clinical Supplies of Collaboration Product, and costs for preparing, submitting, reviewing or developing data or information for the purpose of submission to a governmental authority to obtain, maintain and/or expand manufacturing and/or marketing approval of a Collaboration Product and costs of marketing studies related to Collaboration Product. Development Expenses shall include the previously incurred cost of any inventory of Collaboration Products held by PDL at the Effective Date, provided that the date at which the cost of any such inventory shall be deemed to be incurred by PDL as a Development Expense shall be the date such product is shipped for use in Clinical Trials for a Collaboration Product. Development Expenses shall also include expenses for data management, statistical designs and studies, document preparation, and other administration expenses associated with the clinical testing program. In determining Development Expenses chargeable under this Agreement, each Party will use its respective project accounting systems, and will review its respective project accounting systems and methodologies with the other Party. The Parties shall agree upon and consistently apply methodologies for calculating and allocating Development Expenses based on their respective internal accounting systems. The Parties hereby agree that efforts of the employees of a Party or its Affiliates in performing its activities hereunder shall be charged as Development Expenses at the applicable FTE Rate. Notwithstanding anything in this Section to the contrary, only those Development Expenses that are contemplated by the Development Plan and an Annual Workplan/Budget or were otherwise approved by the JSC shall be chargeable by a Party as Development Expenses with any cost overruns treated in the manner set forth in Section A.2.2 of this Exhibit C. All payments made by a Party to a Third Party in connection with the performance of its activities under the Development Plan and an Annual Workplan/Budget shall be charged as Development Expenses at such Party's actual out-of-pocket cost. The Cost of Clinical Supplies of Collaboration Product shall be charged as a Development Expense. Except to the extent included in Cost of Clinical Supplies of Collaboration Product, expenses incurred by each Party for equipment, materials and supplies utilized in performing its activities under the Development Plan and an Annual Workplan/Budget shall not be separately charged as Development Expenses, except for those expenses incurred by a Party, with the prior written consent of the JSC as set forth in the Development Plan and Annual Workplan/Budget, in the purchase or making of equipment, materials or supplies (other than common laboratory supplies, *e.g*., pipettes, test tubes, petri dishes, reagents, and the like) that are to be used exclusively in connection with the performance of such

Party's activities under a Development Plan and an Annual Workplan/Budget (*e.g*., laboratory animals, placebo supplies, etc.), which expenses shall be charged as Development Expenses at such Party's actual out-of-pocket expense incurred in purchasing or making such equipment, materials or supplies. Special purchases of capital equipment not related to Manufacturing that are used solely for purposes of the Collaboration shall be approved in advance by the JSC.

A.1.7 "**Distribution Costs**" shall mean the FTE costs and other costs specifically identifiable or allocable to the distribution of Collaboration Product by a Party and described in an Annual Commercialization Plan/Budget including warehousing, transportation, order entry, billing, shipping, credit and collection and other such activities as approved by the JSC. For purposes of this definition, FTE costs shall be charged at the applicable FTE Rate.

A.1.8 **"FTE Rate"** shall mean as defined in Section A.6 of this Exhibit C.

A.1.9 "**Gross Sales**" shall mean the gross amount invoiced by a Party or its Affiliates or sublicensees for sales of a Collaboration Product to Third Parties in the Territory, including sales to distributors. For clarity, Gross Sales will include a Party's revenue from distributors, and not revenue of the distributors themselves. A sale or transfer of a Collaboration Product by a Party to one of its Affiliates shall not be considered a sale to a Third Party for the purpose of this provision but the resale of such Collaboration Product by such Affiliate to a Third Party shall be a sale for such purposes. In the event the Collaboration Product is sold in the form of a Combination Product, Gross Sales will be the Combination Product Amount. Each Party shall communicate to the other Party any mandatory discounts to Gross Sales levied by any Third Party.

A.1.10 **"Marketing Costs"** shall mean the FTE costs and other direct costs of marketing, promotion and advertising, including, without limitation, costs for preparing and reproducing detailing aids, Collaboration Product promotional Materials and other promotional materials, costs of professional education, product related public relations, relationships with opinion leaders and professional societies, market research (before and after product approval), healthcare economics studies, Post-Approval Clinical Trials, and other similar activities directly related to the Collaboration Products, in each case as approved by the JSC as part of the Commercialization Plan and an Annual Commercialization Plan/Budget. Such costs may also include actual out-of-pocket costs for outside services and expenses (e.g., consultants, agency fees, meeting costs, etc.). "Marketing Costs" shall also include activities related to obtaining reimbursement from payers, costs of sales and marketing data, and costs not previously included as Sales Costs. For purposes of this definition, FTE costs shall be charged at the applicable FTE Rate, as set forth in Section A.1.16 of this Exhibit C.

A.1.11 **"Net Sales"** shall mean Gross Sales of a Collaboration Product less applicable Sales Returns and Allowances.

A.1.12 "**Ongoing Development Expense**" shall mean FTE costs and

other costs and expenses borne by either Party or its Affiliates with respect to Phase IV Clinical Trials approved by the JSC and other expenses approved by the JSC associated with market positioning of a Collaboration Product to the extent not otherwise included within Development Expenses or Marketing Costs or Sales Costs under any other written agreement between the Parties or their Affiliates relating to Collaboration Product. For purposes of this definition, FTE costs shall be charged at the applicable FTE Rate.

A.1.13 "**Operating Expenses"** shall mean Cost of Sales, Marketing Costs, Sales Costs, Ongoing Development Expenses, Other Out-of-Pocket Costs and Distribution Costs

A.1.14 "**Other Out-of-Pocket Costs**" shall mean other operating expenses paid by the Parties or their Affiliates to Third Parties which are not part of Development Expenses, but are considered and approved by the JSC as expenses for purposes of the cost sharing arrangements under the Agreement. Other Out-of-Pocket Costs shall be limited to the following:

- Third Party License Fees (other than those related to the manufacture of Collaboration Product to the extent covered under any other written agreement between the Parties or their Affiliates related to Collaboration Product)
- Patent Costs and trademark costs (as limited by Article 12 of the Agreement)
- product liability insurance to the extent the Parties obtain a joint policy
- costs pursuant to joint ownership of intellectual property as outlined in Article 12 of this Agreement
- costs incurred in the defense of infringement suits pursuant to Section 12.8 of the Agreement
- other expenses approved by the JSC

A.1.15 "**Post-Approval Clinical Trial**" shall mean any clinical trial in an indication, other than a Phase 3 Clinical Trial or Phase 4 Clinical Trial, to be conducted after a Regulatory Approval for such indication.

A.1.16 "Sales Costs" shall mean FTE costs and other direct costs approved by the JCC as part of the Commercialization Plan and an Annual Commercialization Plan/Budget and specifically identifiable to sales of Collaboration Products in the Territory. Sales Costs shall include costs associated with Sales Representatives and training of the Sales Representatives, sales meetings, details, sales call reporting, work on managed care accounts, costs related to customer service and other sales and customer service-related expenses. Sales Costs will not include start-up costs associated with either Party's sales force, including recruiting, relocation

and other similar costs. The annual FTE cost shall be determined based on the actual FTE cost from the prior budget year for the respective Sales, Marketing, Customer Service, Managed Markets, Decision Support and Medical Affairs functions of each Party, with one collaboration FTE rate established each year for all sales and marketing functions.

A.1.17 "Sales Returns & Allowances" shall mean the sum of (a) and (b), where: (a) [****]; and (b) [****].

It is the intention of the Parties that the interpretation of these definitions in this Exhibit C will be in accordance with U.S. GAAP consistently applied in accordance with Biogen Idec then current practices. A Party will promptly make the appropriate adjustments to the financial information it supplies under the Agreement to reflect changes to the provisions, including reasonable detail underlying the adjustment, in reporting results of operation.

A.2.1. Reporting. Each Party shall report to the other Party forecasts, budgets and actual results of operations related to the following:

- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Reporting by each Party will be performed as follows:

Reporting Event	Frequency	Timing of Submission
[****]	[****]	[****]

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

The financial representatives from the Parties will review financial information [****] and meet as appropriate but shall in any event meet in person at least quarterly to review and approve the following:

- [****]
- [****]
- [****]
- [****]
- [****]

Costs included in Cost of Clinical Supplies are not subject to JSC approval as long as they are consistent with the definitions and within the JSC approved budget.

A.2.2 Reconciliation Statements. Within [****] following the end of a Calendar Quarter, each Party shall submit to the other Party its report of actual results as outlined above (including a summary of charges and credits allocated to its Development Expense Project Account). Expenses charged by either Party as Ongoing Development Expenses, Other Out-of-Pocket Costs and Development Expenses shall not exceed [****] of the amount included for the total expenditure in the then current Development Plan or Annual Workplan/Budget, as the case may be, unless the JFC recommends, and the JSC approves such excess expense. If actual costs of any expense line item in implementing an Annual Work Plan/Budget or the Development Plan is expected to vary by more than [****], then the Party incurring the variance(s) has

the obligation to inform the other Party of such variance(s) in a timely manner and to discuss with such Party the causes of the variance(s). Any such discussion as to the cause of the variances shall occur at the JFC. If the actual costs of implementing an Annual Work Plan/Budget or the Development Plan are expected to vary by more than [****] from the amounts budgeted for expenditure during the calendar year, the Responsible Development Party will promptly revise, as applicable, the Annual Workplan/Budget or Development Plan and submit it in writing, with an explanation of the variance and the reasons therefore, for approval to the JSC. If the JSC does not approve the variance, the amount by which the actual costs exceed [****] of the budgeted costs shall be borne by the Party that incurred the costs.

The financial representatives from each Party on the JFC shall be responsible for, within [****] days following the end of a Calendar Quarter, preparing a statement ("**Reconciliation Statement**") in a format agreed to by the Parties showing each Party's results, the calculations of Ongoing Development Expenses, Other Out-of-Pocket Costs, Cost of Clinical Supplies, COGM and Development Expenses sharing under Section 3.6 of the Agreement and any cash settlement required. The Reconciliation Statement and reports of actual results compared to budget will be sent to the JFC, within [****] following the end of a Calendar Quarter for approval. After approval by the JFC, the JFC will forward the Reconciliation Statement to the JSC for its information or approval in the case of a dispute. The Reconciliation Statement shall be provided to the JSC [****] prior to the date upon which the JSC shall meet to approve the Reconciliation Statement, if approval is being sought. Reconciliation Statements shall be made by PDL or Biogen Idec in the manner set forth in Section A.5 of this Exhibit C.

A.3 Foreign Exchange. The "**Functional Currency**" for accounting for Ongoing Development Expenses, Other Out-of-Pocket Costs and Development Expenses will be U.S. dollars. Except as the Parties otherwise mutually agree, for billing and reporting, the statement of operations will be translated into U.S. dollars using the [****] listed in *The Wall Street Journal* for the [****]. If, due to restrictions or prohibitions imposed by national or international authority, payments cannot be made as provided in this Section, the Parties shall consult with each other with a view towards finding a prompt and acceptable solution, and the paying Party will transfer funds as the other Party may lawfully direct at no additional out-of-pocket expense to the paying Party.

A.4 Audits and Interim Reviews. Either Party shall have the right to request that a nationally recognized, independent accounting firm to be mutually agreed upon by the Parties and that is not either Party's independent accounting firm perform an audit or interim review of the other Party's books and records as they relate to

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activities under this Agreement in order to express an opinion regarding such Party's accounting for revenues, costs and expenses under this Agreement. Such audits or review will be conducted at the expense of the requesting Party. Either Party shall have the right to request that a nationally recognized, independent accounting firm to be mutually agreed upon by the Parties and that is not either Party's independent accounting firm perform an audit of the other Party's books of accounts for the sole purpose of verifying compliance with the Agreement and the Transaction Agreements. Upon [****] prior written notice from a Party (the "**Auditing Party**"), the other Party (the "**Audited Party**") shall permit the mutually agreed upon independent accounting firm to examine the

relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the reports and information submitted by the Audited Party and the accuracy of any Reconciliation Statement. An examination by a Party under this Section shall occur not more than [****] and shall be limited to the pertinent books and records for any calendar year ending not more than [****] before the date of the request. The accounting firm shall be provided access to such books and records at the Audited Party's facility(ies) and/or the facilities of its Affiliates or sublicensees where such books and records are normally kept and such examination shall be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement with terms that are not inconsistent with the terms of the Agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm shall provide both Biogen Idec and PDL a written report disclosing whether the reports submitted by the Audited Party are correct or incorrect and the specific details and supporting analysis for any discrepancies. No other information shall be provided to the Auditing Party. If the accounting firm determines that, based on errors in the reports so submitted, any report prepared in accordance with the Agreement is incorrect, the Parties shall promptly revise the report and the associated Reconciliation Statement and any additional amount owed by one Party to the other shall be paid within [****] after receipt of the accountant's report, along with interest at the lesser of (i) the [****] or (ii) the highest rate permitted by applicable law from the date that such additional amount should have first been paid; *provided*, *however*, that no such interest shall be payable if the errors leading to the Reconciliation Statement being incorrect were in the reports provided by the Party to receive such additional amount. Additionally, if the accountant determines that the reports submitted by the Audited Party overstate the Audited Party's share by more than [****], the Audited Party shall reimburse the Auditing Party for the expenses incurred by the Auditing Party in conducting the audit. Notwithstanding anything to the contrary herein, the Parties shall coordinate with their Affiliates such that not more than [****] audit of a Party and its Affiliates as a whole, shall be performed in any given calendar year with respect to the

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development, manufacturing, commercialization or other use of the Collaboration Product under any written agreement between the Parties and/or their Affiliates relating to the Collaboration Product. In the event of any sublicense or transfer of rights with respect to Collaboration Products by a Party under this Agreement, the sublicensor or transferor shall provide for audit rights by the other Party to this Agreement in accordance with this Section A.4 of this Exhibit C.

A.5 Payments Between the Parties. Based upon the Reconciliation Statement, as approved by the JFC or the JSC, as applicable, there shall be a cash settlement between the Parties no later than [****] after the end of each Calendar Quarter. In the event any payment is made after the date specified in the preceding sentence and provided that such payment is not otherwise subject to good faith dispute, the paying Party shall increase the amount otherwise due and payable by adding interest at the lesser of (i) [****] or (ii) the highest rate permitted by applicable law from the date that such additional amount should have first been paid. Except where the actual expenses for the Daclizumab development exceeds the annualized budget/plan by more than [****], and such variances were approved by the JSC, then the Parties shall get a payment deferral of [****] for cash settlement of the amount in excess of [****] of the annualized budget/plan. If a Party elects to defer payments during this time, interest will accrue [****] and through settlement.

Any other amount owed by one Party to the other Party under this Agreement, except for amounts pursuant to Reconciliation Statements, that is not paid within the applicable time period set forth herein shall bear simple interest [****], as reported in the *Wall Street* Journal, Eastern Edition, on the due date (or, if the due date is not a business day, on the last business day prior to such due date).

A.6 FTE Methodology

A.6.1 Accounting for Development Expenses. All Development Expenses, Ongoing Development Expenses and Other Out-of-Pocket Costs will be based on the appropriate costs definition stated in the Agreement or Section A.1 of this Exhibit C.

Each Party shall report Development Expenses and Ongoing Development Expenses based on its project cost system (which shall in any event track FTEs by functional area and by month) or using such other system as such Party applies with respect to its internal programs and which system has been reviewed with the JFC. In general, these project cost systems shall report actual and/or allocable time spent on specific projects, apply the FTE Rates, determined in the manner specified below, capture actual and/or allocable costs of specific projects and allocate other expenses to

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projects. For Other Out-of-Pocket Costs the Parties will allocate costs based on spending in the relevant departments or applying such other allocation methodology as such Party uses with respect to all other products taken as a whole, and which shall be approved by the JSC.

A.6.2 Research and Development FTE Rate. For the [****], the FTE rate will be set at [****] per year. FTE Rates will increase annually to reflect the change over the preceding [****] for which data is then available in the [****], All Items (as published by the [****]). FTE Rates shall be set in a manner, which fairly reflects the direct costs of each Party for the direct functional groups specified below:

Direct Functional Groups. Research & Development shall include the following: Research, Project Management, Preclinical, Product Development/QA, Medical Research/Medical Operations/Clinical, Biometry (biostatistics and data management), Medical Writing, Regulatory Affairs/Drug Safety, Manufacturing (not including production of Clinical Supplies and commercial supplies, which will be stated in the Clinical Supply Plan for Clinical Supplies and in the Commercial Supply Agreement for Commercial Supplies).

Total budgeted expenses incorporated in the FTE Rate shall include and be limited to: [****].

A.7 Principles of Reporting

The results of operations of the Collaboration will be presented in the following format (on a per Collaboration Product basis), with the categories as defined in Section A.1 below:

A.7.1 Income Statement

Gross Sales
Less: Sales Returns and Allowances
= Net Sales
Less: Cost of Sales
= Gross Profits
Less: Marketing Costs
Less: Sales Costs
Less: Ongoing Development Expenses
Less: Other Out-of-Pocket Costs
= Contribution
Less: Distribution Costs
= Collaboration Product Profit (Loss)

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Separately reported will also be:

Other Development Costs

Development Expenses

Cost of Clinical Supplies

Ongoing Development Expense

It is the intention of the Parties that the interpretation of these definitions will be in accordance with U.S. GAAP consistently applied consistent with a Party's report in its financial statements filed in accordance with the Securities Exchange Act of 1934, as amended.

A.7.2 Subcomponent Reporting

For reporting purposes only, expenses will be identified for the budget, forecast, and quarterly actual amounts within this Section A.7. by the following detail sub-components within the aggregate Income Statement expense components specified under Section A.7.1.

- Cost of Sales – cost of goods manufactured for sale, third party royalties, freight & other
- Marketing – marketing promotion, market research, marketing headcount
- Sales – sales headcount, sales promotion & sales operations
- Development – by indication label-enabling activities & trials, by indication post marketing activities & trials, cost of goods manufactured for clinical supply, medical education.

A.8 Budget and Long Range Plan

Responsibility for the Budget and Long Range Plan with regard to Collaboration Products, prior to the First New Product FDA Approval, will be as specified in Articles 2 and 3 of the Agreement

Budgets will be prepared annually for the following full calendar year containing monthly details/numbers.

Budgets will be supplemented with high level business plans and costs for clinical trials, registration applications, and plans for product introduction, sales efforts and promotion.

EXHIBIT D : OPT OUT ROYALTIES AND ROW ROYALTIES

I. OPT-OUT ROYALTIES FOR COLLABORATION PRODUCTS

	Existing Products Payable to Biogen Idec	Existing Products Payable to PDL	Future Products Payable to Biogen Idec/ PDL
Preclinical			
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
Phase I			

[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
Phase II			
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
Phase III			
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
After Approval			
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]

*Royalties in %

II. ROW ROYALTIES OWED FOR ROYALTY PRODUCTS

	ROW Royalty payable to PDL	Royalty on Termination** payable to Biogen Idec
[****]	[****]	[****]
[****]	[****]	[****]
[****]	[****]	[****]

*Royalties in %

**Note: The royalty in table applies provided that diligent efforts were underway in the territory, and that such termination was Phase III or later in the US and EU territories. In the event that this is not the case, Phase II royalties should apply for Biogen Idec in the ROW territory:

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

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 1.41

Daclizumab PRODUCT

[****]

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.54

Fontolizumab PRODUCT

[****]

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.135

Volociximab PRODUCT

[****]

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 2.1

Joint Operating Principles

The following Principles are intended as guidelines for the operation of the Committees and Collaboration, but the specific terms of the Agreement shall be controlling in the case of any conflict between a provision of the Agreement and these guidelines.

Guiding Principles

- Engage in development activities with the goal of obtaining regulatory approval for each collaborative product as soon as reasonably practicable in major market countries where it makes commercial sense to do so given the economic profile and the safety and efficacy profile of such collaborative product
- Utilize the then-prevailing infrastructure, expertise and experience of each party with respect to specific development activities for collaborative products in specific indications
- Create reasonable flexibility to allow each party to build infrastructure for development and commercialization activities if it reasonably elects, provided that the cost associated with building such infrastructure are not charged to the reimbursable activities under this agreement
- Avoid unnecessary duplication of resources
- Maximize information flow between parties
- Allow each party to have input into the content and scope of Registrations for collaborative products and, through their Joint Steering Committee representatives, the right to approve substantive portions of any registrations
- Allow each party to participate in substantive interactions with Regulatory Authorities related to collaborative products

1. Development: Joint Development Plan

Each joint development plan shall be in the form agreed upon by the Joint Strategy Committee, but shall address, at a minimum, the following:

- Goals for the development of the collaborative products
- Critical decision points criterion
- Scope of research and clinical work, including regulatory strategy
- Timeline for performing research and clinical work
- Anticipated indications, including the desired product profile and formulation
- Competitive market issues
- High level cost and other financial estimates
- Manufacturing, product supply and cell-line development activities
- General commercialization framework

- Operational responsibilities for each party
- Key technical and commercial assumptions

2. Development: Annual Work Plan

- A reasonable detailed description of the development activities to be performed during the next full calendar year or to the next key decision point
- The estimated budget for such activities for at least the next full calendar year
- A designation of which party is responsible for each task
- Estimated staffing levels
- Any expected use of Third Party contractors required to carry out the applicable development activities and the party that shall manage such third party contractor
- Estimated timelines for completion of such activities
- Estimated product requirements for each activity

Exhibit 3.3

Initial Development Plans And Initial Development Program Budget For Existing Products

Neither Party shall be obligated to incur costs for any activities, except for those set forth herein, unless and until (a) such study/activity is approved by the JSC, or (b) is included in a Development Plan approved by the JSC pursuant to Section 3.3(b) of the Agreement.

All costs submitted for reimbursement by the Parties must be demonstrably related to the activities specified in this draft Development Plan.

I. Development Plan for Daclizumab in [****]

2.1 <u>A. Daclizumab in [****]: Clinical Program Rationale and Strategy</u>

[****].

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*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

<u>B. Daclizumab in [****]: Clinical Development Studies</u>

Study	N [Active; Placebo] (Inv. Centers)	Purpose	First Patient Dosed	Last Patient Visit	Status	Projected Cost ****
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]				[****]

Notes:* – Pivotal studies; ** TBD – to be determined; *** dac – Daclizumab; **** [****].

<u>C. Daclizumab in [****]: Timetable of Development Milestones</u>

Milestone	Date	Comments
[****]	[****]	[****]
[****]	[****]	[****]
[****]	[****]	
[****]	[****]	
[****]	[****]	[****]
[****]	[****]	

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II. Development Plan for Volociximab in [****]

<u>A. Volociximab in [****]: Clinical Program Rationale and Strategy</u>

[****]

<u>B. Volociximab in [****]: Clinical Development Studies</u>

Study	Est. # Pts (# of Centers)	Purpose of study	Est. Start Date	Est. Last Patient visit	Status	Projected Cost*
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]

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

* [****].

C. Volociximab in [****]: Major Project Milestones

Milestone	Date	Comments
[****]	[****]	[****]
[****]	[****]	[****]
[****]	[****]	
[****]	[****]	
[****]	[****]	
[****]	[****]	
[****]	[****]	
[****]	[****]	
[****]	[****]	

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

III. Development Plan for Volociximab in [****]

A. Volociximab in [****]: Clinical Development Rationale and Strategy

[****]

B. Volociximab in [****]: Clinical Development Studies

Study	Est. # Pts (# of Centers)	Purpose of study	Est. Start Date	Est. Last Patient visit (safety)	Status	Projected Cost*
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]

* [****].

C. Volociximab in [****]: Major Project Milestones

Milestone	Date	Comments
[****]	[****]	[****]
[****]	[****]	[****]
[****]	[****]	[****]
[****]	[****]	
[****]	[****]	
[****]	[****]	
[****]	[****]	

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

IV. Development Plan for Fontolizumab in [****]

A. Fontolizumab in [****]: Clinical Development Rationale and Strategy

[****]

B. Fontolizumab in [****]: Clinical Development Studies

Study	Est. # Pts (# of Centers)	Purpose of study	Est. Start Date	Est. Last Patient visit	Status	Projected Cost*
[****]	[****]	[****]	[****]	[****]	[****]	[****]

* [****].

C. Fontolizumab in [****]: Major Project Milestones

Milestone	Date	Comments
[****]	[****]	[****]
[****]	[****]	
[****]	[****]	
[****]	[****]	

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V. Initial Program Budget for Existing Products

2005 FTE and External Cost ($ in thousands)

Function	Type	[****]	[****]	[****]	[****]	Program Totals
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]						
[****]		[****]	[****]	[****]	[****]	[****]
[****]		[****]	[****]	[****]	[****]	[****]
[****]						
[****]		[****]	[****]	[****]	[****]	[****]
[****]		[****]	[****]	[****]	[****]	[****]
[****]		[****]	[****]	[****]	[****]	[****]

* An additional [****] in [****] expense will be incurred if the [****] trial enrolls on plan.

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 4.1(b)(ii)
OPT OUT POINTS FOR EXISTING COLLABORATION PRODUCTS

2.1 Daclizumab

- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]

- [****]

2.2 Fontolizumab

- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

2.3 Volociximab

- [****]
- [****]
- [****]
- [****]
- [****]
- [****]
- [****]

Opt out points for New Collaboration Products or Indications shall be decided by the JSC.

*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 8.3

A Commercial Supply Agreement between the Parties for Collaboration Products or Royalty Products shall contain, in addition to customary manufacturing terms and conditions, the following obligations:

a. The Responsible Commercialization Party shall purchase [****] of its, its Affiliates and its sublicensees' commercial requirements of Collaboration Product from the Manufacturing Party.

b. The Parties will agree to reasonable forecasting mechanisms in the Commercial Supply Agreement. The Manufacturing Party will provide the other Party with notice not less than [****] in advance of any anticipated change in annual production that would impact such party's ability to meet forecasted demand.

c. Collaboration Product shall be Manufactured in accordance with all requirements of applicable laws and regulations and all GMP, as prescribed from time to time by the FDA and other applicable worldwide regulatory authorities, using the product specifications, manufacturing methods and formulae as agreed upon by the Parties.

d. If either Party believes that any Regulatory Approval, GMP, or other applicable law, or any other notice from a regulatory authority, shall require a change to the particular product specifications, the Parties shall consult prior to the implementation of such change in order to mutually determine whether such change is, in fact, required by such Regulatory Approval, GMP, other applicable law or notice. Any such change in product specifications will be effected upon mutual agreement of the Parties.

e. In the event either Party is unable to obtain Regulatory Approval for a Collaboration Product and such lack of approval is related to the CMC Section, then the other Party shall have the right to become, and assume all of the responsibilities of, the Manufacturing Party for such product.

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f. The non-Manufacturing Party shall have the right to conduct (upon reasonable notice during reasonable business hours) reasonable quality assurance audits with respect to all facilities, operations and laboratories (and any records related thereto) of the Manufacturing Party or, if applicable, the Third Party contract manufacturer used by such Party, where applicable Manufacturing activities are conducted, as is reasonably necessary to verify the compliance with GMP and other regulatory requirements. The results of any such audit shall be provided to the other Party.

g. The Manufacturing Party may not utilize a Third Party contract manufacturer without the consent of the non-Manufacturing Party.

h. The Manufacturing Party shall be responsible for release of product from its and its Third Party CMO's facilities. The non Manufacturing Party shall have access to, and the right to review, all release documentation for any evidence of product nonconformance.

i. If the Manufacturing Party desires to use a Third Party to perform any part of the Manufacture and supply or if the Manufacturing Party plans to undertake capacity expansion, significant facility improvements, or the purchase of capital equipment for the Manufacture of Collaboration Product, the JSC shall first consider whether the other Party has the ability, capability, and desire to perform such Manufacture and supply and, if so, the Parties shall amend the Commercial Manufacturing Agreement to cover the part of the Manufacture and supply to be performed by such other Party.

j. In the event that the non Manufacturing Party consents to use of a Third Party contract manufacturer, the Manufacturing Party shall enter into a supply agreement and quality agreement and shall ensure that the non Manufacturing Party shall either be a party to such agreements (in addition to the Responsible Manufacturing Party), or a third party beneficiary of such agreements. To the extent the non Manufacturing Party is not a party to such agreements, it shall be a permitted assignee or sublicensee under such agreement.

k. The non Manufacturing Party shall have the right to review and comment upon the Third Party supply agreement and quality agreement.

l. If the Manufacturing Party utilizes a Third Party contract manufacturer, such supply agreement shall require the Third Party supplier to transfer sufficient information (including information contained in the CMC section of any applicable Regulatory Filings, the results of any stability studies performed on Product and copies of any direct communications between the Third Party supplier and regulatory authorities in relation to Product) to

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Biogen Idec or PDL (as appropriate), in each case as is required to implement the then-most current versions of such Manufacturing process, upon termination of such agreement or otherwise upon request.

m. If the Manufacturing Party is unwilling or unable to meet [****] of the Responsible Commercialization Party's requirements for Collaboration Product on the timelines set forth in the Commercialization Plan for such Collaboration Product or if the Collaboration Product Manufactured consistently does not meet the requisite Product specifications and other quality requirements set forth herein, then the Manufacturing Party shall, at the election of the other party, conduct a transfer of the necessary Manufacturing Technology to the non Manufacturing Party so as to enable it to Manufacture or have Manufactured such Product by a Third Party contract manufacturer of its choice. The non Manufacturing Party, upon such transfer, shall become the Manufacturing Party for purposes of the Collaboration Product.

n. The Parties shall enter into a Technology Transfer Agreement containing the FTE Plans and costs related to CMC/filing activities for the Collaboration Products. In addition, the Parties shall enter into a Quality Agreement related to the Manufacture of the Collaboration Products. Such Quality Agreement shall specify the designated Qualified Person for release of finished Collaboration Products.

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*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 11.5

Required Attachment of Certain Provisions of the [****]

[****]

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*Certain information on this page has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 31.1

CERTIFICATIONS

I, Mark McDade, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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 8, 2005

/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 10-Q 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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 8, 2005

/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 8, 2005

By:

/s/ Mark McDade
Mark McDade
Chief Executive Officer

/s/ Glen Sato
Glen Sato
Chief Financial Officer