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 March 31, 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 Act). Yes ☒ No o

As of May 6, 2005, there were 106,019,129 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 March 31,	
	2005	2004
Revenues:		
Product sales, net	$ 948	$ —
Royalties	33,164	22,010
License and other	4,703	5,618
Total revenues	38,815	27,628
Costs and expenses:		
Cost of product sales	1,137	—
Research and development	35,261	33,029
Selling, general and administrative	7,666	8,068
Acquired in-process research and development	79,417	—
Total costs and expenses	123,481	41,097
Operating loss	(84,666)	(13,469)
Interest and other income, net	2,935	2,284
Interest expense	(2,142)	(1,385)
Loss before income taxes	(83,873)	(12,570)
Provision for income taxes	22	48
Net loss	$ (83,895)	$ (12,618)
Net loss per basic and diluted share	$ (0.87)	$ (0.13)
Shares used in computation of net loss per basic and diluted share	96,754	94,000

See accompanying notes.

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

	March 31, 2005	December 31, 2004 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,077	$ 91,395
Marketable securities, including $6.8 million and $6.9 million of restricted investments at March 31, 2005 and December 31, 2004, respectively	165,234	298,969
Inventories	19,837	—
Other current assets	18,702	9,750
Total current assets	218,850	400,114
Land, property and equipment, net	251,990	238,077
Goodwill	67,359	—

Other intangible assets, net	462,286	31,309
Restricted investments	3,355	6,716
Other assets	14,937	7,516
Convertible note receivable	30,000	30,000
Total assets	**$ 1,048,777**	**$ 713,732**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,175	$ 4,921
Accrued compensation	9,101	6,977
Accrued clinical trial costs	2,320	1,324
Accrued interest	1,499	2,593
Royalties payable	5,482	—
Taxes payable	2,333	—
Other accrued liabilities	24,523	9,327
Deferred revenue	16,317	17,389
Current portion of long-term obligations	825	923
Total current liabilities	70,575	43,454
Convertible subordinated notes	499,998	249,998
Other long-term debt	7,289	7,469
Other long-term liabilities	372	301
Total liabilities	578,234	301,222
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value $0.01 per share, 250,000 shares authorized; 105,931 and 95,857 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	1,059	959
Additional paid-in capital	829,402	686,302
Accumulated deficit	(357,427)	(273,532)
Accumulated other comprehensive loss	(2,491)	(1,219)
Total stockholders' equity	470,543	412,510
Total liabilities and stockholders' equity	**$ 1,048,777**	**$ 713,732**

See accompanying notes.

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

	Three months ended March 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	$ (83,895)	$ (12,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,230	2,611
Acquired in-process research and development	79,417	
Amortization of convertible notes offering costs	444	304
Stock-based compensation expense	148	45
Amortization of intangible assets	1,723	588
Loss on disposal of fixed assets	—	397
Changes in assets and liabilities:		
Inventories	(125)	—
Interest receivable	(311)	768
Other current assets	(7,048)	4,056
Other assets	304	(895)
Accounts payable	1,418	1,629
Accrued liabilities	(2,832)	(2,833)
Deferred revenue	(1,072)	(161)
Total adjustments	75,296	6,509
Net cash used in operating activities	(8,599)	(6,109)
Cash flows from investing activities:		
Net cash paid for ESP and *Retavase* acquisitions	(432,577)	—
Maturities and sales of marketable securities	132,736	50,000
Maturities of restricted investments	3,438	4,049
Purchases of land, property and equipment	(14,975)	(33,222)
Net cash provided by (used in) investing activities	(311,378)	20,827
Cash flows from financing activities:		
Proceeds from issuance of capital stock	2,105	2,493
Proceeds from issuance of convertible subordinated notes	241,831	—

Payments on other long-term obligations	(277)	(386)
Net cash provided by financing activities	243,659	2,107
Net increase (decrease) in cash and cash equivalents	(76,318)	16,825
Cash and cash equivalents at beginning of period	91,395	341,768
Cash and cash equivalents at end of period	$ 15,077	$ 358,593

See accompanying notes.

PROTEIN DESIGN LABS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
March 31, 2005
(unaudited)

1. Summary of Significant Accounting Policies

Organization and Business

Protein Design Labs, Inc. (we, us, our, PDL or the Company) is a fully-integrated biopharmaceutical company focused on the development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. 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.

Basis of Presentation and Responsibility for Quarterly Financial Statements

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

The information included in this quarterly report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2004. The Consolidated Condensed Balance Sheet as of December 31, 2004 included herein is derived from our audited consolidated financial statements.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim consolidated condensed financial statements may not be indicative of results for any other interim period or for the entire year. For example, we receive a substantial portion of our royalty revenues on sales of the product *Synagis*® marketed by MedImmune. This product has significantly higher sales in the fall and winter, which to date have resulted in much higher royalties recognized by us in our first and second quarters than in other quarters. In addition, as a result of the closing of our acquisition of ESP Pharma Holding Company, Inc. (ESP) on March 23, 2005, the results of operations of ESP from March 24, 2005 through March 31, 2005 are included in our first quarter 2005 consolidated condensed financial statements (see Note 6).

Principles of Consolidation

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

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, and raw materials (active pharmaceutical ingredients). As a result of the ESP Pharma and *Retavase*® acquisitions (see Notes 6 and 7), we acquired and recorded certain inventories at 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, the licensing and use of our technology and from services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." 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, 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, product returns, bad debts and rebates.

Royalties

Under some 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 partners, such as product licenses. Under these agreements, our partners may make milestone payments to us when they or we achieve certain levels of development with respect to the licensed technology.

Reimbursement of Development Costs

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

Accounts Receivable, Sales Allowances and Rebate Accruals

Accounts receivable are recorded net of allowances for cash discounts for prompt payment, doubtful accounts, government chargebacks and sales returns. Estimates for cash discounts, government chargebacks and sales returns are based on contractual terms, historical trends experienced by ESP and expectations regarding the utilization rates for these programs and are recorded as an offset to product sales in the same period the related revenue is recognized. Estimates for our allowance for doubtful accounts is determined based on existing contractual obligations, historical payment patterns of our customers experienced by ESP and individual customer circumstances and are included in selling, general and administrative expenses.

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 of ESP. Medicaid rebate accruals are evaluated based on historical rebate payments by product as a percentage of historical sales, product pricing and current contracts.

At March 31, 2005, our estimated sales returns allowance exceeded our trade accounts receivable balance by approximately $1.5 million, which relates to products sold by ESP prior to our acquisition of ESP on March 23, 2005. We have included this net balance in other accrued liabilities on our Consolidated Condensed Balance Sheet as of March 31, 2005.

Product sales receivable allowances and rebate accruals require substantial judgement. 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.

Advertising and Promotion

The Company engages in promotional activities, which typically take the form of detail aids, industry publications, journal ads, hospital grants, 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 months ended March 31, 2005 was not material.

Stock-Based Compensation

As of March 31, 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. During the three months ended March 31, 2005 and 2004, no stock-based employee compensation cost is reflected in net loss as all options granted under our plans had exercise prices equal to the market value of the underlying common stock on the date of grant. 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 March 31,	
	2005	2004
Net loss, as reported	$ (83,895)	$ (12,618)
Deduct: Stock-based employee compensation expense determined under the fair-value-based method for all awards, net of taxes	(3,925)	(5,755)
Pro forma net loss	$ (87,820)	$ (18,373)
Basic and diluted net loss per share:		
As reported	$ (0.87)	$ (0.13)
Pro forma	$ (0.91)	$ (0.20)

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

	Three Months Ended March 31,	
	2005	2004
Expected life, in years	2.7	2.7
Risk-free interest rate	3.4%	3.0%

Volatility	66%	69%
Dividend yield	0	0

In December 2004, the FASB issued Statement No. 123R "Share Based Payment," (FAS 123R) which will require all equity-based awards to employees to be recognized in the statement of operations based on their fair values. We are evaluating the requirements of FAS 123R and we expect that the adoption of FAS 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 FAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under FAS 123. Under the current regulations, we will be required to adopt the final standard 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 $148,000 and $45,000 for the quarters ended March 31, 2005 and 2004, respectively.

Segments and Concentrations

In accordance with FASB Statement No. 131, "Disclosure About Segments of an Enterprise and Related Information" (FAS 131), 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.

Royalty, license and other revenues from Genentech in the first quarters of 2005 and 2004 accounted for 49% and 33% of total revenues, respectively, and royalty, license and other revenues from MedImmune in the first quarters of 2005 and 2004 accounted for 34% and 42% of total revenues, respectively. Revenues from Roche accounted for 13% of total revenues during the first quarter of 2005, and revenues from Seattle Genetics, Inc. accounted for 11% of total revenues in the first quarter of 2004. No other revenue from any other source exceeded 10% of total revenues for either period 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 Roche, product rights obtained through the acquisition of ESP and licensed research technology. In accordance with FASB Statement No. 142, "Goodwill and Other Intangible Assets" (FAS 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 Statement of Operations.

On March 23, 2005, we recorded goodwill in connection with our acquisition of ESP (see Note 6). In accordance with FAS 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 reportig 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. No such impairments have been identified with respect to our long-lived assets, which consist primarily of property and equipment and the intangible assets discussed above.

2. Net Loss Per Share

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

The total number of shares excluded from the calculations of diluted net loss per share for outstanding convertible notes was 22,968,327 and 12,415,450 for the quarters ended March 31, 2005 and 2004, respectively. The total number of shares excluded from the calculation of diluted net loss per share for stock options was 2,433,634 and 4,289,000 for the quarters ended March 31, 2005 and 2004, respectively.

3. Comprehensive Loss

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

	Three Months Ended March 31,	
(In thousands)	**2005**	**2004**
Net loss	$ (83,895)	$ (12,618)
Other comprehensive loss:		
Change in unrealized gains and losses on marketable securities	(1,272)	(182)
Total comprehensive loss	$ (85,167)	$ (12,800)

4. Inventory

Inventories consisted of the following:

(In thousands)	March 31, 2005	December 31, 2004
Raw materials	$ 1,866	$ —
Finished goods	17,971	—
	$ 19,837	$ —

5. Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(In thousands)	March 31, 2005	December 31, 2004
Construction-in-process	$ 652	$ 3,810
Consulting and services	10,662	5,229
Sales rebates	4,817	—
Other	8,392	288
	$ 24,523	$ 9,327

6. ESP Pharma Acquisition

In January 2005, we entered into a definitive agreement with ESP Pharma Holding Company, Inc. (ESP), a privately held, hospital-focused pharmaceutical company, under which PDL would acquire ESP 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's agreement to acquire from Centocor, Inc. (Centocor), a biopharmaceutical operating company of Johnson & Johnson, rights to manufacture, develop, market and distribute *Retavase*® (reteplase) in the United States and Canada, including an increase in the purchase price by $25 million in cash payable to the ESP stockholders at the closing of the ESP acquisition. The acquisition price paid to Centocor for the rights to *Retavase* was $110 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.

By adding ESP's sales and distribution capabilities to our antibody development and humanization technology platform, the ESP and *Retavase* acquisitions established PDL as a fully integrated, commercial biopharmaceutical company with proprietary marketed products, a growing and diverse high-margin operating revenue base and a broad, proprietary pipeline. We believe that providing a sales capability for our proprietary pipeline products, such as ularitide, terlipressin, daclizumab and Nuvion, once approved by the Federal Drug Admininistration, to ESP's approved products will create the potential for exceptional sales growth and an accelerated path to positive cash flow, which is one of the key factors contributing to the goodwill recorded as a result of this acquistion.

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP. The aggregate preliminary purchase price was approximately $471.3 million, including the cash paid to ESP stockholders of $325.0 million, the fair value of 9,853,770 shares of PDL's common stock issued to ESP stockholders totaling approximately $140.9 million, and estimated direct transaction costs of approximately $5.4 million. The value assigned to our common stock issued to ESP shareholders 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 became fixed at 9,835,770 (March 4, 2005). The ESP acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The results of operations of ESP from March 24, 2005 have been included in our first quarter condensed consolidated financial statements.

Of the 9,853,770 shares of PDL common stock issued to ESP shareholders, 2,523,588 shares will 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. We expect to issue all shares to the former ESP shareholders at the end of this contingency period, and as such, we have included the value for all shares issued in the purchase price of ESP.

As part of the purchase and included in the $325 million paid to ESP shareholders, ESP 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 1 year. ESP shareholders were obligated to pay such termination costs from the acquisition proceeds of $325 million. At March 31, 2005, approximately $1.0 million of these ESP 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:

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, and this value will be amortized over periods between 4 and 12 years, or a weighted-average period of approximately 10.0 years, the estimated useful lives of these assets.

As part of the allocation of the purchase price, $79.4 million was allocated to acquired in-process research and development related to ESP'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 holds the IND and is conducting a Phase III trial in patients with type I HRS in the United States and Europe	23,765
Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	Our third-party licensor, 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'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 ranged from 2006 to 2009.

Pro Forma Results

The unaudited pro forma results of operations for the quarters ended March 31, 2005 and 2004 for PDL are set forth below (in thousands, except per share amounts). This presentation assumes that the ESP 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 and $9.2 million for the amortization of intangible assets for each period presented.

	Three Months Ended March 31,	
	2005	2004
Revenue	$ 59,103	$ 54,162
Net loss	98,873	93,886
Basic and diluted net loss per share	$ 0.96	$ 0.93

The unaudited pro forma information is not 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 completed its acquisition of rights to manufacture, develop, market and distribute *Retavase* in the United States and Canada. The aggregate purchase price was approximately $110.0 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 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
	$ 110,000

The $93.5 million value assigned to the intangible assets will be 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 (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.

9. 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 represented less than 2% of the Company's total workforce at the time of the reduction, and the abandonment of our New Jersey leased facility. As a result of the restructuring plan, in 2004 we incurred charges of approximately $305,000, including adjustments in the fourth quarter of 2004 related to the extension of a sublease of the facilities, included in research and development expense in the Consolidated Statement of Operations. The restructuring charge included approximately $164,000 of severance-related amounts, $119,000 of committed cost for our New Jersey leased facility, primarily related to rent expenses for the remaining term of the lease, and $22,000 related to the net book value of assets that we abandoned. 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 during October 2004. The workforce reductions were completed by June 30, 2004. We expect to pay the balance of the accrued facility-related costs of approximately $37,000 at March 31, 2005 through October 2005.

10. Postretirement Benefit Plan

In June 2003, we established a postretirement health care plan, which covers medical, dental and vision coverage for certain of our former officers and their dependents. During the quarters ended March 31, 2005 and 2004, we recognized net periodic benefit cost of approximately $71,000 and $62,000, respectively. This expense includes service cost, interest cost, and amortization of prior service cost.

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

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

OVERVIEW

We are a fully-integrated biopharmaceutical company focused on the development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. 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. During the quarter ended March 31, 2005, we received royalties on eight marketed products, with approximately 87% of our royalty revenues derived from the *Herceptin*® and *Avastin*™ antibody products marketed by Genentech and the *Synagis* antibody product marketed by MedImmune.

On March 23, 2005, we completed the acquisition of all of the outstanding stock of ESP Pharma Holding Company, Inc. (ESP), a privately held, hospital-focused pharmaceutical company. The aggregate preliminary purchase price was approximately $471.3 million, including the cash paid to ESP stockholders

of $325.0 million, the fair value of 9,853,770 shares of PDL's common stock issued to ESP stockholders totaling approximately $140.9 million, and estimated direct transaction costs of approximately $5.4 million. The ESP acquisition has been accounted for as a business combination in accordance with FASB Statement No. 141, "Business Combinations." The results of operations of ESP from March 23, 2005 have been included in our first quarter consolidated condensed financial statements.

Also on March 23, 2005, ESP 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 estimated direct transaction costs of approximately $0.5 million.

By adding marketed products and sales and distribution capabilities to our antibody development and humanization technology platform, the ESP acquisition is intended to establish PDL as a fully integrated, commercial, biopharmaceutical company with novel marketed products, a growing and diverse revenue base and a broad, proprietary pipeline. We believe that we will achieve positive cash flow from operations on a quarterly basis beginning in the second half of 2006 based upon revenues consisting of royalties, license and other income and product sales.

In order to partially fund the acquisition of ESP, 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 March 31, 2005, we had an accumulated deficit of approximately $357.4 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 will be a complex, time consuming and expensive process 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 into our organization could have a material adverse effect on our operating results after the merger and could result in our not achieving the anticipated benefits of the merger.

In order to reach our goal to be cash flow positive on a quarterly basis beginning in the second half of 2006, we will have to continue to increase sales from historical levels for *Cardene* IV, *Retavase* and IV *Busulfex*. Accordingly, we will need to effectively transition existing relationships with distributors, third-party vendors, manufacturers and customers of ESP. Although we plan to retain 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 such capabilities from ESP necessary to continue to successfully promote the ESP 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 March 31, 2005 we have approximately $500 million in convertible notes outstanding, approximately $250 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.

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, we recognize revenues from product sales, net of estimated allowances for cash discounts, product returns 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 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 Collaboration Agreement as services are provided.

In addition, we enter into nonmonetary transactions in connection with our patent licensing arrangements, and management must use estimates and judgments when considering the fair value of the technology rights acquired and the patent licenses granted under these arrangements. When available, the fair value of the nonmonetary transaction is based on vendor-specific objective evidence of fair value of each significant element of the patent license agreement. Otherwise, management uses other methods of 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 expired products, 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 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. This includes monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, reviewing inventory data available to us through our U.S. wholesaler inventory management agreements to assist 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 other long shelf life products we have sold through the same or similar channels. 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.

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 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.

RESULTS OF OPERATIONS

Three months ended March 31, 2005 and 2004

Revenues

(In thousands)	Three Months Ended March 31, 2005	2004	% Change
Product sales, net	$ 948	$ —	—%
Royalties	33,164	22,010	50%
License and other	4,703	5,618	(16)%
Total revenues	$ 38,815	$ 27,628	40%

Product sales, net

Product sales recognized for the period March 24 through March 31, 2005 were from six products obtained through the acquisition of ESP. The majority of product sales relate to *Cardene* IV and IV *Busulfex* for the period from March 24, 2005 to March 31, 2005.

Royalties

Royalty revenues increased during the first quarter of 2005 compared to the first quarter of 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 55% of total royalty revenues in the first quarter of 2005, up from 36% in the comparable period of 2004, while sales of MedImmune's product accounted for 39% of total royalty revenues, down from 53% in the first quarter of 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 quarter of 2005 as compared to the first quarter 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 31%, 17% and 39% of our royalty revenues for the three months ended March 31, 2005 as compared to 33%, 0% and 53% 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 quarter of 2005 and 2004 primarily consisted of upfront licensing and patent rights fees and license maintenance fees. Also included in license and other revenues for the first quarter of 2005 is revenue recognized under our asthma collaboration with Roche, which we entered into in September 2004.

License and other revenues decreased in the first quarter of 2005 compared to the first quarter of 2004 primarily due to the recognition in the first quarter of 2004 of an upfront license fee from Genentech for its *Avastin* antibody product following approval by the U.S. Food and Drug Administration and an upfront license fee of $3.0 million, in connection with certain agreements signed with Seattle Genetics, Inc., with no such revenue during theh 2005 period. Offsetting these decreases when compared to the first quarter of 2004 was revenue recognized under our asthma collaboration with Roche during the first quarter of 2005 of approximately $3.5 million.

Costs and Expenses

(In thousands)	Three Months Ended March 31, 2005	2004	% Change
Cost of product sales	$ 1,137	$ —	—%
Research and development	35,261	33,029	6%
Selling, general and administrative	7,666	8,068	(4)%
Acquired in-process research and development	79,417	—	—%
Total costs and expenses	$ 123,481	$ 41,097	200%

Cost of Product Sales

Cost of product sales includes the costs to purchase inventory for our product sales and the amortization of intangible assets related to product rights obtained in connection with our acquistion of ESP. We expect the amortization expense for such intangible assets to be approximately $12 million on a quarterly basis during the remainder of 2005.

Research and Development

Research and development costs include costs of personnel to support our research and development activities, costs of preclinical studies, costs of conducting our clinical trials, such as clinical investigator fees, monitoring costs, data management and drug supply costs, research and development funding provided to third parties and an allocation of facility costs. The increase in the first quarter of 2005 compared to the first quarter of 2004 was primarily due to an increase in research and development personnel headcount of approximately 83 employees from March 31, 2004 to March 31, 2005 and associated costs of approximately $5.2 million, an increase in direct clinical trial expenses of $0.6 million due to the start of three new clinical trials, and an increase in facility-related costs of $1.2 million, partially offset by a decrease of approximately $1.0 million of contract manufacturing services due to the timing of lot runs. 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 related stages of development for each product in clinical development, including the research and development expenses recognized in connection with each product.

Product	Principal Indication	Phase of Development	Collaborator	Estimated Completion of Phase	Research and Development Expenses for the three months ended March 31, 2005	2004
Current Product Candidates						
Daclizumab					$ 7,402	$ 6,323
	Asthma	Phase II	Roche	Completed		
	Multiple Sclerosis(1)	Phase II	—	2007		
HuZAF	Crohn's disease	Phase II	—	2005	859	3,497
Nuvion	Severe steroid-refractory ulcerative colitis	Phase I/II	—	2005	6,731	4,602
M200	Solid tumors	Phase II	—	2006	3,826	5,297
Other (2)			—		16,443	13,310
	Total Research and Development Expenses				**$ 35,261**	**$ 33,029**

(1) Enrollment to begin in the second quarter of 2005.
(2) No single potential clinical product included in "other" constitutes more than 5% of the total research and development expenses for the period 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 sections of our Risk Factors entitled "Clinical development is inherently uncertain and expense levels may fluctuate unexpectedly because we can not accurately predict the timing and level of such expenses," "If we cannot successfully complete our clinical trials, we will be unable to obtain regulatory approvals required to market our products," "Our clinical trial strategy may increase the risk of clinical trial difficulties," "If we do not attract and retain key employees, our business could be impaired," and "We may be unable to obtain or maintain regulatory approval for our products."

Selling, General and Administrative Expenses

Selling, general and administrative costs include costs of personnel, professional services, consulting and other expenses related to selling efforts for our product sales, our administrative functions and an allocation of facility costs. Selling, general and administrative expenses for the three months ended March 31, 2005 decreased slightly from the comparable period in 2004 primarily due to decreased outside services expenses of $0.3 million and lower facility-related costs of $0.6 million, partially offset by higher legal costs related to our intellectual property, licensing and other matters of $0.1 million.

Acquired In-Process Research and Development

In connection with the March 2005 acquisition of ESP, we recorded charges for acquired in-process research and development of $79.4 million due to ESP'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 first quarter of 2005 follows:

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 and Europe	$ 23,765

Ularitide	A synthetic form of the natriuretic peptide for the treatment of decompensated congestive heart failure	Our third-party licensor, 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'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 ranged from 2006 to 2009.

In connection with the April 2003 acquisition of Eos, we recorded charges for acquired in-process research and development of $37.8 million due to Eos' incomplete research and development programs that had not yet reached technological feasibility as of April 4, 2003 and had no alternative future use as of that date. There have been no significant changes to the acquired in-process research and development projects as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2004.

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 and Interest Expense

(In thousands)	Three Months Ended March 31, 2005	2004	% Change
Interest and other income, net	$ 2,935	$ 2,284	28%
Interest expense	(2,142)	(1,385)	54%

Interest and Other Income, Net

Interest income for the three months ended March 31, 2005 increased from the comparable period in 2004 primarily as a result of higher invested balances prior to the closing of the ESP and *Retavase* acquisitions in late March 2005.

Interest Expense

Interest expense for the three months ended March 31, 2005 increased from the comparable period in 2004 primarily due to both our 2.00%, $250 million Convertible Senior Notes and our 2.75%, $250 million Convertible Subordinated Notes being outstanding during the first quarter of 2005, compared to only our 2.75%, $250 million Convertible Subordinated Notes being outstanding in the first quarter of 2004.

Income Taxes

We have recorded a tax provision of approximately $22,000 for the three months ended March 31, 2005, compared to $48,000 for the comparable period in 2004. Taxes during both periods primarily related to income earned in our foreign operations and foreign withholding tax in connection with a license maintenance fee.

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 March 31, 2005, we had cash, cash equivalents, marketable securities and restricted investments in the aggregate of $184 million, compared to $397.1 million at December 31, 2004.

Net cash used in operating activities for the three months ended March 31, 2005 was approximately $8.6 million, compared to net cash used in operating activities of $6.1 million in the comparable 2004 period. The change from the 2004 period was primarily due to higher research and development expenses in the 2005 period as compared to the 2004 period, which was primarily the result of higher spending to support our ongoing preclinical and clinical efforts, including an approximate 15% increase in research and development personnel from March 31, 2004 to March 31, 2005.

Net cash used in investing activities was $311.4 million for the three months ended March 31, 2005, compared to net cash provided by investing activities of $20.8 million in the comparable period in 2004. The change from the 2004 period was primarily the result of approximately $432.6 million in cash payments (net of cash received) related to the ESP and *Retavase* acquisitions in March 2005 and the timing of the maturities of our marketable securities.

Net cash provided by financing activities for the three months ended March 31, 2005 was $243.7 million compared to $2.1 million in the comparable period in 2004. In February 2005, we issued our 2.00%, $250 million Convertible Senior Notes. In both periods, other financing activities related to the exercise of employee stock options offset by payments on our long-term debt obligations.

We estimate that our existing capital resources, including the cash proceeds from the 2005 Notes, will be sufficient to fund our current and future level of operations. Our future capital requirements will depend on numerous factors, including, among others, royalties from sales of products by third-party licensees, including *Synagis*, *Herceptin*, *Xolair, Raptiva, Zenapax, Mylotarg*, and *Avastin*; product sales from products acquired in our acquisition of ESP; 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 March 31, 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	$ 3,281	$ 4,749	$ 1,083	$ 294	$ 9,407
Long-term debt	1,447	2,343	2,278	5,220	11,288
Convertible debentures	11,875	23,750	263,438	257,500	556,563
Construction contracts	11,141	1,660	—	—	12,801
Contract manufacturing and other	5,048	—	—	—	5,048
Total contractual obligations	$ 32,792	$ 32,502	$ 266,799	$ 263,014	$ 595,107

(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.

RISKS RELATED TO OUR BUSINESS

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

In general, our expenses have exceeded revenues. As of March 31, 2005, we had an accumulated deficit of approximately $357.4 million. We expect our expenses to increase because of the extensive resource commitments required to achieve regulatory approval and commercial success for any individual product. For example, over the next several years, we will incur substantial additional expenses as we continue to develop and manufacture our potential products, invest in research and improve and expand our manufacturing, marketing and sales capabilities. Since we or our partners or licensees may not be able to successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost and with appropriate quality, or successfully market such products with desired margins, we may never achieve sustained profitable operations. The amount of net losses and the time required to reach sustained profitability are highly uncertain.

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

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

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

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

At March 31, 2005, we had approximately $508.1 million of outstanding debt, including without limitation approximately $250 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 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.

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

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

- the seasonality of sales of licensed products;
- the existence of competing products;
- the market launch of recently licensed products;
- the continued safety of approved products;
- the marketing efforts of our licensees;

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

We receive royalty revenues on sales of the product Synagis, which product is marketed by MedImmune, Inc. (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 expect to recognize expense for employee stock options beginning in the third quarter of 2005, and as a result, we will incur significantly higher losses. In addition, we hold a $30 million five-year convertible note receivable we purchased from Exelixis, Inc. in May 2001. Accounting rules require the conversion feature of some convertible notes to be separated from the debt agreement in which the conversion feature is contained and accounted for as a derivative instrument, and therefore reflected in the note purchaser's financial statements based upon the fair market value of the stock into which the note is convertible. Due in part to the number of shares into which this note receivable would currently convert and the average daily trading volume of Exelixis stock, the Exelixis note is not currently considered a derivative instrument and, therefore, changes in the market value of Exelixis stock are not required to be recorded in our financial statements. However, a significant increase in the average daily trading volume of Exelixis stock, or new accounting pronouncements or regulatory rulings could require us to report the change in the value of the Exelixis stock in our financial statements such that changes in the Exelixis stock price contribute to fluctuations of our operating results from quarter to quarter.

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

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

At an oral hearing in March 2000, the Opposition Division of the European Patent Office decided to revoke the broad claims of our first European 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 plan to appeal the decision to the Technical Board of Appeal at the European Patent Office. 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 IL-2 receptor and the composition of matter directed to Zenapax (daclizumab). 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, Inc. (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, 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 a notice of 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. We recently negotiated an extension that has extended the term of the current agreement to December 2014. Notwithstanding this agreement, if our humanized antibodies were covered by Celltech's European or U.S. patents and if we need more than the three licenses under those patents currently available to us under the agreement, we would be required to negotiate additional licenses under those patents or to significantly alter our processes or products. We might not be able to successfully alter our processes or products to avoid conflict with these patents or to obtain the required additional licenses on commercially reasonable terms, if at all.

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

We do not have a license to an issued U.S. patent assigned to Stanford University and Columbia University, which may cover a process we use to produce our potential products. We have been advised that an exclusive license has been previously granted to a third party, Centocor, 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 efficiently and economically integrate the research, development and commercialization of these products.

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 pharmaceutical products. 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 new drugs and biologics 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 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, 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 spend significant amounts of money, 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. Neither the FDA nor any other regulatory agency has approved any of our product candidates for sale in the United States or any foreign market. 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. Most recently, in May 2004, we announced that daclizumab, our humanized antibody that binds to the interleukin-2 (IL-2) receptor, did not meet the primary endpoint in a Phase II clinical trial in patients with moderate-to-severe ulcerative colitis. As a result, we terminated further development of daclizumab in this indication.

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 materials where a change in materials 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 United States in 2007 depended upon regulatory approval to initiate Phase II/III studies in 2005. We are in the process of revising that original timeline to reflect recent discussions with the FDA. 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, Inc. and Elan Corp. 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 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, to conduct clinical trials, to compile and analyze the data received from these trials, to obtain regulatory approvals and, if approved, to market these licensed products. As a result, we may have little or no control over the manufacturing, development and marketing of these potential products and little or no opportunity to review the clinical data prior to or following public announcement.

We do not currently have the ability to independently conduct pre-clinical and clinical trials for any of our product candidates, and we must rely on third parties, such as medical institutions and clinical investigators, including physician sponsors, to conduct 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 preclinical or clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, and need to be replaced, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by medical institutions and clinical investigators, including physician sponsors, 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 development, manufacturing and marketing 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 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 considerations. Such 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.

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

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

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

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

Our own ability to manufacture our 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 Zenapax, we may 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. Our ability to successfully market and develop Zenapax, in particular in transplantation, depends upon our success in manufacturing Zenapax at commercial scale. There can be no assurance that we will successfully and in a timely manner be capable of manufacturing Zenapax following the transfer of Zenapax to us by Roche.

We 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. Our collaborative partners may also independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues under our agreements with these partners.

Any product that our collaborative partners or we succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborative partners can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. For example, Novartis, which has a significant marketing and sales force directed to the transplantation market, markets Simulect® (basiliximab), a product competitive with Zenapax, in the United States and Europe. Novartis has acquired a significant interest in Roche. 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.

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 current good manufacturing practice (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. In addition, when we assume responsibility for manufacturing Zenapax, we will be required to demonstrate that the material manufactured by Roche is comparable to the material we produce at our manufacturing facilities. New regulations resulting from the transfer of regulatory responsibility from CBER to CDER could make it more difficult for us to show comparability which could delay development and regulatory approval of Zenapax in new indications or reduce or interrupt commercial sales of Zenapax for the prevention of acute kidney transplant rejection.

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

Both before and after approval is obtained, a biologic pharmaceutical product, its manufacturer and the holder of the 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 payors 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 payors; 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 the use of products during research and development efforts or after commercialization results in adverse effects. This risk will exist even with respect to any products that receive regulatory approval for commercial sale. While we have obtained liability insurance for our products, it may not be sufficient to satisfy any liability that may arise. Also, adequate insurance coverage may not be available in the future at acceptable cost, if at all.

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

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

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

The U.S. and international health care industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. 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 payors may challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales can commence. As a result, significant uncertainty exists as to the reimbursement status of approved health care products.

We may not be able to obtain or maintain our desired price for our products. Our products may not be considered cost effective relative to alternative therapies. As a result, adequate third-party reimbursement may not be available to enable us to maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborative partners. 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, 2004 to March 31, 2005, our common stock closed as high as $27.14 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 different method of determining the compensation expense of our employee stock options. SFAS 123R will have a significant adverse effect on our reported financial conditions 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.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and beginning with our annual report on Form 10-K for the year ended December 31, 2004, our management is required to report on, and our independent auditors to attest to, the effectiveness of our internal controls over financial reporting as of the end of 2004. The rules governing the standards that must be met for management to assess the effectiveness of our internal controls over financial reporting are new and complex and require significant documentation, testing and possible remediation. We reviewed, documented and tested our internal controls over financial reporting. This process has resulted, and may continue to result, in increased expenses and the devotion of significant management resources. If we cannot continue to favorably assess the effectiveness of our internal controls over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment in the future, investor confidence and our stock price could be adversely affected.

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 a 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.

RISKS RELATED TO THE ACQUISITION OF ESP PHARMA

The following risks may arise as a result of the completion of our acquisition of ESP Pharma.

PDL and ESP Pharma may not successfully integrate their businesses 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' technologies, 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 now have to operate as a combined organization and begin utilizing common business, information and communication systems, operating procedures, financial controls and human resource practices, including benefits, training and professional development programs. PDL and ESP Pharma will face significant challenges in integrating their 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 technologies;
- preserving important relationships of both PDL and ESP Pharma and resolving potential conflicts that may arise;
- 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, IT and administrative infrastructures;
- 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 successful integration of the two companies.

In addition, the integration of PDL and ESP Pharma will be a complex, time consuming and expensive process 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. It is not certain that PDL and ESP Pharma can be successfully integrated in a timely manner or at all or that any 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 merger substantially reduces 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 therefor converted into the right to receive up to $325 million in cash and 9,853,770 shares of PDL common stock. Based on this number of PDL shares issued in the acquisition of ESP Pharma, former ESP Pharma stockholders owned approximately 9% of the combined company's outstanding common stock at the time of the completion of the merger. We have granted registration rights covering the PDL shares issued in the acquisition of ESP Pharma, and we have registered such shares, 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. The issuance of these shares in connection with the merger also caused a significant reduction in the relative percentage interests in earnings, voting power, liquidation value and book and market value of all holders of common stock and securities convertible into common stock, including without limitation the 2003 Notes, the 2005 Notes and the PDL common stock issuable thereunder.

The market price of PDL common stock has historically been highly volatile and may continue to be so in the future. In addition to conditions that affect the market for stocks of biotechnology companies generally, factors such as new product announcements by PDL or its competitors, quarterly fluctuations in PDL's operating results and challenges associated with the integration of ESP Pharma's business may have a significant impact on the market price of PDL shares. These conditions could cause the price of PDL shares to fluctuate substantially over short periods.

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 in the merger.

We intend to continue to market and sell aggressively the products acquired as part of the ESP Pharma merger, including in particular Cardene IV, *Retavase* and IV Busulfex. In order to successfully achieve the planned results from the merger, we will need to transition existing relationships with distributors, third party vendors, manufacturers and customers of ESP Pharma. Although we plan to retain 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 such capabilities from ESP Pharma necessary to continue to successfully promote the ESP Pharma products.

To be successful, the combined company must retain and motivate key employees, which will be more difficult in light of uncertainty regarding the merger, and failure to do so could seriously harm the combined company.

To be successful, the combined company must retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing and information technology support positions. Employees of PDL or ESP Pharma may experience uncertainty about their future role with the combined company until or after strategies with regard to the combined company are announced or executed. This potential uncertainty may adversely affect the combined company's ability to attract and retain key personnel. The combined company must also continue to motivate employees and keep them focused on the strategies and goals of the combined company, which may be particularly difficult due to the potential distractions of the merger or the loss of key employees due to such uncertainties.

If customers delay or defer purchasing decisions as a result of the merger, the operating results and prospects of the combined company could be adversely affected.

We cannot assure you that our customers will continue their current buying patterns; our customers may delay or defer purchasing decisions in response to the merger. 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.

As a result of the 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.

Following the merger, the combined company has approximately 800 full-time employees. As a result, 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 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.

Charges to earnings resulting from the merger may adversely affect the market value of PDL's common stock following the merger.

In accordance with U.S. generally accepted accounting principles, the combined company will account for the merger using the purchase method of accounting, which will result in charges to earnings that could have a material adverse effect on the market value of PDL's common stock. Under the purchase method of accounting, the combined company will allocate 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 record the excess of the purchase price over those fair values as goodwill. The portion of the estimated purchase price allocated to in-process research and development has been expensed by the combined company in the first quarter of 2005. The combined company 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 merger. In addition, to the extent the value of goodwill becomes impaired, the combined company 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.

PDL incurred significant costs associated with the merger which could adversely affect future liquidity and operating results.

PDL estimates that it incurred transaction costs of approximately $5.3 million associated with the merger, which will be included as a part of the total purchase costs for accounting purposes. These amounts are estimates and could increase. In addition, we believe that the combined entity may incur charges to operations, in amounts that are not currently reasonably estimable, in the quarter in which the merger is completed or in subsequent quarters, to reflect costs associated with integrating the two companies. The combined company may incur additional material charges in subsequent quarters to reflect additional costs associated with the merger. These significant costs associated with the merger could adversely affect the future liquidity and operating results of the combined company.

RISKS RELATED TO THE BUSINESS OF ESP PHARMA

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

Cardene IV accounts for a significant portion of the operating income and growth in sales for ESP Pharma. Cardene IV faces a competitive marketplace with branded and generic intravenous anti-hypertensive products being marketed in the United States and it may be harder to continue to penetrate this market at the current rate of growth. While we expect to maintain and increase committed sales and marketing presence 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 has achieved. Some of our competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing hypertensive 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 marketed 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 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 TNKaseÔ and Activase from Genentech, a biotechnology company with significantly more resources and sales and marketing capabilities than we currently have available. While we believe our planned investment in additional sales and 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 is marketed on behalf of Centocor by Scios, Inc. (Scios), a Johnson & Johnson company. We will require the cooperation of Centocor and Scios to successfully transfer

the product to us and there can be no assurance that our sales and marketing efforts will be implemented in a timely manner or that we will be successful in achieving 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*.

As part of the acquisition of *Retavase*, we are required to manufacture this product 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 Biotechnology and Roche. While ESP Pharma's agreement to purchase the rights to *Retavase* includes the acquisition of approximately 24 months of inventory, the manufacturing of this product for use as therapeutics in compliance with regulatory requirements will be complex, time-consuming and expensive. 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.

ESP Pharma relies on third-party suppliers to provide for each of 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. ESP Pharma has existing long-term agreements with various third parties to supply its products. If there are supply problems with the third party manufacturers for the ESP Pharma products, in particular Cardene IV, there may not be sufficient supplies of Cardene IV 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, or 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.

Our profitability will depend in significant part upon ESP Pharma's continued successful operations.

ESP Pharma was founded in April 2002. While ESP Pharma was profitable in 2003 and 2004, it has a short operating history and there can be no assurance that it will continue to achieve profitable results as part of the combined companies. PDL has incurred losses since inception and expects to continue to incur losses until, at the earliest, 2008, the currently anticipated date in which PDL could complete its first full year of sales of its antibody products. In order for the combined companies to achieve a cash flow positive rate by 2007, ESP Pharma's products must continue to grow in accordance with the internal projections of the companies.

ESP Pharma 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 patterns of these wholesalers and distribution partners.

ESP Pharma sells its products primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. 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 revenues. ESP Pharma's reliance on a small number of wholesalers and distribution partners could cause its revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers and distribution partners. In addition, as of December 31, 2004, these three U.S. wholesalers represented approximately 91% of ESP Pharma's outstanding accounts receivable. If any of these wholesalers or international partners fails to pay ESP Pharma on a timely basis or at all, ESP Pharma's financial position and results of operations could be materially adversely affected.

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 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 PDL's and ESP Pharma's 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 our research and development activities related to our clinical trials, in particular with respect to daclizumab, Nuvion 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.

ESP Pharma faces 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 PDL's and ESP Pharma's products. Potential competitors of PDL and ESP Pharma in the U.S. and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. For example, we are aware that The Medicines Company has a product currently in Phase III development, CleveloxÔ, 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. While The Medicines Company has recently terminated its Phase III studies of Clevelox, 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, ESP Pharma product sales face significant competition from both brand-name and generic manufacturers that could adversely affect the future sales of its products. ESP Pharma has several marketed products that are generic versions of brand-name products. Additionally, ESP Pharma has brand-name products that are subject to competition from generic products. ESP Pharma faces competition in its 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 the ESP Pharma products, or that would render the ESP Pharma products obsolete or noncompetitive.

ESP Pharma's 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, ESP Pharma 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 ESP Pharma's products, and may not be able to obtain a satisfactory financial return on ESP Pharma's 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 products that ESP Pharma sells. 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 by PDL or ESP Pharma and approved by regulators. 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 the ESP Pharma business.

A significant portion of ESP Pharma product sales result from off-patent products. If we are unable to maintain the cash flow returns from these products, our ability to achieve a cash flow positive position would be impacted.

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 have accounted for a majority of the cash flow from operations of ESP Pharma. If sales of Cardene IV do not perform as planned and we are unable to maintain the cash flow returns from these off-patent products, our ability to achieve positive cash flow from operations by 2007 could be delayed.

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

Our market risks at March 31, 2005 have not changed significantly from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2004 on file with the Securities and Exchange Commission.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation as of March 31, 2005, our chief executive officer and chief financial officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q.

Changes in internal controls. There were no changes in our internal controls over financial reporting during the quarter ended March 31, 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 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 Amended Certificate of Incorporation. (Incorporated by reference to Exhibit 3.3 to Annual Report on Form 10-K filed March 14, 2002.)

3.2 Amended and Restated Bylaws. (Incorporated by reference to Exhibit 3.4 to Annual Report on Form 10-K filed March 31, 2003.)

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 Registration Rights Agreement for the Company's 2.75% Convertible Subordinated Notes due 2023, between the Company and the Initial Purchasers dated July 14, 2003. (Incorporated by reference to Exhibit 4.2 to Registration Statement on Form S-3 filed September 11, 2003.)

4.3 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.)

4.4 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 Sublicense and Supply Agreement between Syntex (U.S.A.) LLC and American Home Products Corporation dated September 1, 1993, re: Nicardipine IV and related letter assigning such agreement to ESP Pharma, Inc. dated October 30, 2003 (with certain confidential portions deleted and marked by notation indicating such deletion).

10.2 Letter dated September 5, 2003 between Roche Palo Alto LLC and ESP Pharma, Inc., amending Sublicense and Supply Agreement (with

certain confidential portions deleted and marked by notation indicating such deletion).

31.1 Certification required by Rule 13a-14(a) or Rule 15d-14(a).

31.2 Certification required by Rule 13a-14(a) or Rule 15d-14(a).

32.1 Certification by the Chief Executive Officer and the Chief Financial Officer of Protein Design Labs, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

SIGNATURES

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

Dated: May 9, 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
(Principal Accounting Officer)

Exhibit 10.1

CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SYNTEX (U.S.A.) INC. - AMERICAN HOME PRODUCTS CORPORATION
SUBLICENSE AND SUPPLY AGREEMENT
DATED SEPTEMBER 1, 1993 RE: NICARDIPINE IV

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SUBLICENSE AND SUPPLY AGREEMENT

This AGREEMENT is made to be effective as of September 1, 1993 (the “effective date”), by and between American Home Products Corporation (“AMPC”), a corporation organized and existing under the laws of the State of Delaware, acting by the through its Wyeth-Ayerst Laboratories Division (“Wyeth-Ayerst”), having a mailing address at P.O. Box 8299, Philadelphia, Pennsylvania 19101, and syntex (U.S.A.) Inc., a corporation organized and existing under the laws of the State of Delaware, having a business address at 3401 Hillview Avenue, Palo Alto, California 94304 (“Syntex”).

RECITALS

WHEREAS, Syntex, a wholly-owned subsidiary of Syntex Corporation, is the assignee of the rights of Syntex Corporation granted by Yamanouchi International Limited (“Yamanouchi”) pursuant to an Agreement dated December, 16, 1977 (the “License Agreement”) to make, have made, use and sell the compound nicardipine hydrochloride (USAN), which has the full chemical name 2, 6-dimethyl-4-(3-nitrophenyl)-1, 4-dinydro-pyridine-3, 5-dicarboxylic acid 3-[2-(N-benzyl-N-methylamino] ethyl ester 5-methyl ester hydrochloride, which is also known as YC-93 and RS-69216-003 (the “Agreement Compound”), in certain countries;

WHEREAS, Syntex and American Hospital Supply Corporation ("AHSC"), acting through its American Critical Care Division ("ACC"), entered into an Agreement (the "Agreement") providing for the marketing by ACC of the intravenous form of the Agreement

Compound in the United States;

WHEREAS, E.I. du Pont de Nemours & Company ("du Pont"), a Delaware corporation, acquired certain assets relating to the critical care business of AHSC, and received an assignment, with the consent of Syntex, whereby du Pont succeeded to all of the rights and obligations of AHSC under the Agreement;

WHEREAS, Syntex and du Pont entered into an Amendment to the Agreement to substitute "du Pont" for "ACC" throughout the Agreement and to include Canada as part of the Territory covered by the Agreement;

WHEREAS, du Pont and Calgon Corporation, a Delaware corporation and a wholly-owned subsidiary of Merck & Co., a New Jersey corporation, entered into a partnership agreement establishing The Du Pont Merck Pharmaceutical Company ("Du Pont Merck"), a Delaware partnership;

WHEREAS, du Pont assigned, with the consent of Syntex, its rights under the Agreement (as amended) to Du Pont Merck;

WHEREAS, Du Pont Merck desired to be relieved of its obligation to market the Covered Product (as defined below) in the Territory and, in furtherance thereof, has assigned its rights under the Agreement (as amended) to Syntex in contemplation, and with the knowledge, that such rights might be granted to AHPC, acting through Wyeth-Ayerst;

WHEREAS, AHPC desires to market, and is capable of marketing

through Wyeth-Ayerst, the intravenous form of the Agreement Compound in the United States;

WHEREAS, Syntex desires that AHPC through Wyeth-Ayerst market the intravenous form of the Agreement Compound in the United States and, in furtherance thereof, is willing to sell the Agreement Compound to AHPC in bulk form to be processed by or on behalf of AHPC into the finished intravenous form(s) of the Agreement Compound for distribution and marketing by Wyeth-Ayerst in the United States; and

WHEREAS, AHPC is willing to purchase the Agreement Compound from Syntex in bulk form to be processed by or on behalf of AHPC into the finished intravenous form(s) of the Agreement Compound and to have Wyeth-Ayerst distribute and market such finished intravenous form(s) in the United States.

NOW, THEREFORE in consideration of the foregoing and of the mutual promises herein contained, AHPC and Syntex do hereby agree as follows:

1. Definitions

1.1 "Affiliate" of a party shall mean any corporation or any other business entity controlling, controlled by or under common control with such party. "Control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the voting or income interest in such corporation or other business entity. Any reference to Syntex or AHPC shall, unless otherwise expressly

indicated, include reference to Syntex's or AHPC's affiliates (as the case may be), as defined in this Section.

1.2 "Average Net Selling Price" shall mean (a) the aggregate proceeds invoiced by Wyeth-Ayerst for sales of Covered Product (as herein defined) to non-Affiliated purchasers during the Quarter (as herein defined) in question, less (i) trade and cash discounts actually allowed and taken with respect to the Covered Product, (ii) credits or allowances actually allowed and taken for damaged, outdated, returned or recalled Covered Product, (iii) transportation or shipping charges invoiced to such purchasers, (iv) sales taxes imposed directly on such sales of the Covered Product by Wyeth-Ayerst, (v) volume or formulary or other positioning discount amounts paid or credited by AHPC to a wholesaler, purchaser, third party payor or other contractee as a result of a contractual arrangement specific to the Covered Product, (vi) rebates paid or credited by AHPC to any governmental agency (or branch thereof) or to any third party payor, administrator or contractee with respect to sales of the Covered Product, and (vii) discounts paid or credited by AHPC that are mandated by, or granted in response to, applicable federal or state law with respect to sales of the Covered Product, divided by (b) the aggregate number of grams of Agreement Compound contained in the quantities of Covered Product (according to package content as stated on the Covered Product label) invoiced during such Quarter.

1.3 "Bulk Product" shall mean the Agreement Compound in unfinished form, having the specifications set forth in Schedule A to this Agreement.

1.4 "Covered Product" shall mean the Agreement Compound packaged (in other than oral dosage form) for use as an intravenous solution, the specifications of which shall be consistent with and shall conform to the requirements of the United States Food and Drug Administration ("FDA").

1.5 “Indications” shall mean use of the Covered Product in the (a) short-term treatment of hypertension when oral therapy is not feasible or not desirable (b) such other indications for the Covered Product as may be approved by the FDA, and (c) use of the Covered Product in such other indications supported by clinical data.

1.6 “Licensed Patents” shall mean United States Patents Nos. 3,985,758, 4,880,823 and 5,164,405.

1.7 “Quarter” shall mean each calendar quarter, which shall begin each January 1st, April 1st, July 1st and October 1st during the term of this Agreement, or the portion of a calendar quarter just prior to termination or expiration hereof (as the case may be)

1.8 “Trademark” shall mean the product mark or marks, whether registered or not, designated by Syntex and owned by Syntex in the Territory for the Covered Product, and shall be the same product

mark or marks used by Syntex in the Territory for its oral dosage forms of the Agreement Compound, which currently is “CARDENE”®.

1.9 “Territory” shall mean the United States of America and any of its territories or possessions, including the Commonwealth of Puerto Rico.

2. Grant of Licenses

2.1 The grant of licenses are as follows:

(a) Syntex grants to AHPC an exclusive sublicense under the License Agreement, including United States Patents Nos. 3,985,758 and 4,880,823, to (i) carry out the processing (including pharmaceutical formulation) and packaging of the Bulk Product into the Covered Product on its own or by a third party manufacturer approved by Syntex in accordance herewith and (ii) have Wyeth-Ayerst market, distribute, promote and sell the Covered Product in the Territory for use in the treatment of the Indications. Syntex represents and warrants that it has the right to grant such a sublicense under the License Agreement and the Licensed Patents listed above in this Section 2.1(a) and that such sublicense will not violate the rights of any party not a party hereto, including, without limitation, Yamanouchi, AHSC, du Pont and Du Pont Merck. In the event Syntex loses that right, this Agreement shall be terminated forthwith, but Syntex shall attempt, in good faith, to secure from Yamanouchi AHPC’s right to continue to manufacture, market, distribute, promote and sell the Covered Product in the

Territory for use in the treatment of the Indications upon terms and conditions comparable to those set forth herein.

(b) Syntex grants to AHPC an exclusive license under United States Patent No. 5,164,405 to (i) carry out the processing (including pharmaceutical formulation) and packaging of the Bulk Product into the Covered Product and (ii) have Wyeth-Ayerst market, distribute, promote and sell the Covered Product in the Territory for use in the treatment of the Indications. Syntex represents and warrants that it has the right to grant such a license under United States Patent No. 5,164,405.

(c) Subject to Syntex’s right to detail and promote the Covered Product as set forth in Section 6.6 below, the licenses granted to AHPC in Sections 2.1(a) and 2.1(b) above are exclusive even as against Syntex.

(d) Syntex grants to Wyeth-Ayerst a license to use the Trademark only with respect to the marketing, distribution, promotion and sale of the Covered Product in the Territory during the term of this Agreement, subject to the terms and conditions set forth herein.

2.2 (a) AHPC, on behalf of itself and Wyeth-Ayerst, hereby accepts the rights granted in Section 2.1 above and agrees to endeavor in good faith to process (including pharmaceutical formulation), package, market, distribute, promote and sell the Covered Product in the Territory at its own expense under the

Trademark for any and all of the Indications, using generally the same channels and methods, exercising the same diligence and adhering to the same standards that Wyeth-Ayerst employs in processing (including pharmaceutical formulation), packaging, marketing, distributing, promoting and selling its own pharmaceutical products in the Territory. Wyeth-Ayerst shall, in its sole discretion, determine its prices and other terms and conditions for sales of the Covered Product to third parties.

2.2 (b) In view of the fact that the FDA has approved the marketing of the Covered Product in the United States for the treatment of hypertension, AHPC and Syntex agree that it would be to the benefit of both parties, and the consuming public, if the Covered Product is launched in the Territory for that Indication as soon as is possible. Accordingly, the parties agree that:

(i) AHPC and Wyeth-Ayerst shall endeavor in good faith to have One Hundred Thousand ampoules of non-shortdated, saleable (i.e., released) Covered Product in inventory by November 1, 1993; and

(ii) AHPC, Wyeth-Ayerst and Syntex shall work together and endeavor in good faith to (x) review and submit promotional launch materials to the FDA as soon as possible and (y) assist the FDA in its review of such materials, including meeting with the FDA to seek and obtain FDA approval of such materials by November 1, 1993.

If both (i) and (ii) above occur, then Wyeth-Ayerst shall launch the Covered Product in the Territory for that Indication by November 1, 1993. If (i) above is not achieved, after good faith pharmaceutical manufacturing efforts by AHPC and Wyeth-Ayerst (in conjunction with Berk (U.K.) to do so, launch may be delayed by Wyeth-Ayerst until December 1, 1993, but not beyond that date without the prior written approval of Syntax, which shall not unreasonably be withheld. If the FDA approval contemplated by (ii) above has not been obtained, after good faith efforts to obtain such approval, then launch may be delayed until such materials have been approved by the FDA.

2.3 Only Wyeth-Ayerst and not any Affiliate (s) thereof, shall market, distribute, promote (subject to Syntex's right to detail and co-promote as set forth in Section 6.6 below) and sell the Covered Product in the Territory, unless Syntex agrees in writing to such activities being conducted by an Affiliate of Wyeth-Ayerst, such agreement by Syntex not to be unreasonably withheld.

3. Supply of Bulk Product

3.1 Syntex shall supply, and AHPC shall purchase, all quantities of Bulk Product that AHPC requires to process, package, market, distribute, promote and sell the Covered Product in Territory, such supply and purchase to be in accordance with the following provisions of this Agreement. AHPC shall use all Bulk

Product supplied by Syntex only to manufacture Covered Product for use or sale in the Territory for the Indications or for research purposes in support of such use or sale.

3.2 (a) Syntex agrees that all quantities of Bulk Product supplied hereunder shall meet the specifications set forth in Schedule A attached hereto and made a part hereof, which shall conform to or be amended to conform to all applicable governmental requirements (whether or not contained in governmental regulatory approvals) in the Territory. In addition, Schedule A may be amended from time to time by written agreement of the parties. Syntex, with each quantity of Bulk Product supplied hereunder, shall provide AHPC with a Certificate of Analysis documenting that such Bulk Product complies with the specifications therefor as set forth in Schedule A hereto as determined according to the methods of analysis referenced in such specifications.

3.3 (b) All Bulk product received by AHPC shall be deemed accepted, unless AHPC shall give written notice to Syntex within thirty (30) days after receipt of such Bulk Product specifying the manner in which the Bulk Product does not conform to the specifications therefor. Such notice shall be accompanied by written reports of any testing performed by AHPC on the Bulk Product. Upon receipt of such notice, Syntex may request AHPC to return the non-accepted Bulk Product, or samples thereof, for further testing by Syntex. AHPC's test results shall be conclusive

unless Syntex notifies AHPC within thirty (30) days after receipt by Syntex of the non-accepted Bulk Product, or samples thereof, that it disagrees with such test results. In the event of such notice of Syntex, (i) AHPC, to the extent necessary or required, shall conduct an investigation to determine if there are legally sufficient grounds upon which to invalidate its test results that suggested non-conformance of such Bulk Product with the specifications therefor, and (ii) the Bulk Product, or samples thereof, shall be submitted to a mutually acceptable independent laboratory for analysis. The results of the independent testing laboratory shall be binding upon AHPC and Syntex for the purposes of acceptance of, and the obligation to pay for, such Bulk Product. The costs of the independent testing laboratory shall be paid by the party against whom the discrepancy is resolved. In the event any Bulk Product not accepted by AHPC does not meet the specifications therefor as determined in accordance with this Section 3.2, Syntex will give AHPC full credit for such Bulk Product at the price invoiced by Syntex or paid by AHPC and will replace such Bulk Product with conforming Bulk Product to be invoiced at the original invoice price per gram. All transportation, shipping and insurance cost, and other fees incident to the shipping of such replacement (to the extent previously paid by AHPC with respect to the non-conforming Bulk Product) will be paid for by Syntex. Such replacement shall be

made immediately upon written request by AHPC (so as to be able to maintain scheduled pharmaceutical manufacturing dates) or, if no such request is made, then within sixty (60) days after it is determined by the independent laboratory or agreed by both parties hereto that the Bulk Product was non-conforming unless the parties agree in writing to another delivery date.

3.2 (c) Wyeth-Ayerst and Syntex agree that Syntex shall prepare and file, with the assistance and cooperation of Wyeth-Ayerst, the necessary documentation with the FDA to substitute Syntex's Quality Control Method-QC-1203 (Limulus Amebocyte Lysate (LAL) gel clot test for bacterial endotoxins) as the NDA specification for pyrogens in place of the USP (151) rabbit test, which is less preferable to both parties.

3.2 (d) Wyeth-Ayerst and Syntex agree that Syntex shall prepare, with the assistance and cooperation of Wyeth-Ayerst, and file with the FDA a U.S.P. monograph referencing the best analytical methods for the Covered Product (selected from the USP methods referenced in the attachment to Schedule A hereto, Syntex's Quality Control methods for the Bulk Product, and the LAL method referred to in Section 3.2(c)), such filing being done for the purpose of establishing new methods of analysis (acceptable to the FDA) for the Bulk Product to be supplied by Syntex, and purchased by AHPC or Wyeth-Ayerst, hereunder.

3.3 (a) In connection with AHPC's first purchase of Bulk Product, AHPC shall give Syntex written notice of the amount of such initial order prior to the execution and delivery hereof by the parties hereto. In connection with each subsequent order, AHPC shall provide Syntex with a written estimate during the first month of each Quarter as to the amount that it desires for delivery during the next succeeding Quarter. AHPC agrees to submit its

firm order for the Bulk Product at least sixty (60) days prior to the desired delivery date and Syntex agrees to ship the Bulk Product to AHPC within sixty (60) days after receipt of AHPC's firm order. Syntex will fill AHPC's firm orders up to twice the amount specified in the Quarterly estimate applicable thereto (in five (5) kilogram pack increments, unless otherwise agreed to in writing by the parties), and will, in good faith, attempt to fill the balance (if any) as soon as possible, due consideration being given to Syntex's own needs and the needs of the other parties to which it supplies the Bulk Product.

3.3 (b) With respect to Covered Product that is pharmaceutically formulated outside the Territory, title to any quantities of Bulk Product sold by Syntex to AHPC for use in such formulation shall pass to AHPC upon delivery by Syntex to AHPC at Syntex's European depot (currently Antwerp, Belgium) or such other Syntex facility as may be agreed to in writing by the parties. With respect to Covered Product that is pharmaceutically formulated

in the Territory, title to any quantities of Bulk Product sold by Syntex to AHPC for use in such formulation shall pass to AHPC upon delivery by Syntex to AHPC at any Syntex warehouse in the United States (currently Columbus, Ohio). AHPC shall select the common carrier and determine the method of transportation and routing for all shipments of Bulk Product and shall pay (and be responsible for) all freight and insurance costs therefor.

3.4 (a) The price of Bulk Product shall be, on a per gram basis for Bulk Product supplied by Syntex hereunder, [*] percent ([*]%) of the Average Net Selling Price (as defined in Section 1.2 above) in the Territory during the Quarter in which such Bulk Product is shipped times the number of grams of Bulk Product so shipped by Syntex.

3.4 (b) An initial price per gram shall be invoiced by Syntex and paid by AHPC, which shall be equal to the actual price per gram calculated as above for the most recently reported Quarter (due to inherent time lag in the filing of Quarterly reports hereunder, the actual price for any given Quarter will become the estimated or invoice price for the second quarter thereafter, subject, or course, to the retroactive adjustment set forth in Section 3.4(c) below). The initial price per gram for orders for commercial quantities shipped to AHPC during the Quarter or Quarters immediately prior to commercial launch of the Covered Product in the Territory shall be [*] percent ([*]%) of

Wyeth-Ayerst's estimated initial ex-factory price of Covered Product, set by Wyeth-Ayerst in good faith.

3.4 (c) Within sixty (60) days after the end of each Quarter, AHPC shall calculate the actual price due Syntex hereunder and shall give Syntex written notice thereof. Such notice shall specify all information on which the calculation is based as well as stating the actual price due. If the initial price paid by AHPC was less than the price actually due Syntex, AHPC shall remit to Syntex the difference together with its notice. If the initial price was greater than the price actually due Syntex, Syntex shall apply such difference as a credit against future purchases of Bulk Product hereunder, and upon termination or expiration of this Agreement, Syntex shall remit to AHPC within forty-five (45) days after receipt to such notice any credit(s) that have not been exhausted by subsequent purchases of Bulk product.

3.4 (d) In the event there is a verifiable rejection of all or a substantial portion of a batch of Covered Product during the manufacture thereof and the loss associated with such rejection is not covered by insurance, Syntex shall replace the quantity of Bulk Product included within the rejected Covered Product for an additional price, on a per gram basis for each gram of Bulk Product supplied under this Section 3.4(d), of [*] percent ([*]%) of the price paid or to be paid by AHPC with respect thereto pursuant to Sections 3.4(a) or 3.4(b) above (i.e., [*] percent ([*]%) of

[*] percent ([*]%), which is equal to [*] percent ([*]%) of the Average Net Selling Price, on a per gram basis).

3.4 (e) Payment for each purchase of Bulk Product hereunder plus any other charges due Syntex shall be paid by AHPC forty-five (45) days after the date of Syntex's invoice for each such purchase and shall be paid by AHPC in United States Dollars.

3.4 (f) AHPC shall be responsible for and pay any and all customs duties, brokerage fees, excise, sales or use taxes, and other governmentally-imposed taxes (if any) incurred directly with respect to the shipment of Bulk Product supplied by Syntex hereunder of Covered Product shipped by AHPC of Wyeth-Ayerst hereunder, and shall pay or reimburse Syntex upon demand for customs duties, brokerage fees, excise, sales or use taxes or other governmentally-imposed taxes (if any) imposed directly by any taxing authority with respect to the sale of the Covered Product.

3.5 (a) For each [*] grams of Bulk Product purchased by AHPC at the [*] percent ([*]%) price set forth in Section 3.4 above through June 30, 1995, Syntex shall provide [*] grams of Bulk Product free of any charge under Section 3.4(a) above (AHPC shall, however, be responsible for all freight, insurance, customs duties, brokerage fees, excise, sales or use taxes and other governmentally-imposed taxes (if any) referred to in Section 3.3(b) and 3.4(f) above). This material is

provided by Syntex to assist AHPC with estimated yield losses of [*] percent ([*]%) during pharmaceutical formulation of the Bulk Product into the Covered Product.

3.5 (b) Syntex will also provide such assistance to AHPC for the first six (6) months of pharmaceutical formulation of the Bulk Product into the Covered Product by AHPC (or Wyeth-Ayerst) in its own facilities even if such assistance extends beyond June 30, 1995, but such assistance by Syntex for all or any portion of such six (6)-month period after June 30, 1995 will only be applicable to that Bulk Product purchased by AHPC for pharmaceutical formulation in its (or Wyeth-Ayerst's) facilities, unless otherwise agreed to in writing by Syntex.

3.5 (c) During the Quarter ending June 30, 1995, and after completion of six (6) months in-house production experience by AHPC (or Wyeth-Ayerst) (if later), AHPC (or Wyeth-Ayerst) and Syntex shall meet to discuss what level of yield loss assistance Syntex, in its sole discretion, considers appropriate under the circumstances (given the formulating experience by or on behalf of AHPC to that time) and will thereafter make available to AHPC (or Wyeth-Ayerst).

3.6 (a) For each [*] grams of Bulk Product purchased by AHPC at the [*] percent ([*]%) price set forth in Section 3.4 above, Syntex shall provide [*] grams of Bulk Product free of any charge under Section 3.4(a) above (AHPC

shall, however, be responsible for all freight, insurance, customs duties, brokerage fees, excise, sales or use taxes and other governmentally-imposed taxes (if any) referred to in Sections 3.3(b) and 3.4(f) above), which free material shall be in support of AHPC's (or Wyeth-Ayerst's) importation, packaging, marketing, distributing, promoting (including sampling) and selling of the Covered Product. This support shall only apply for that period of time when the Covered Product is pharmaceutically formulated outside the United States and a duty on the formulated Covered Product must be paid upon importation thereof into the United States. Thereafter, the support of Syntex under this Section 3.6 shall be limited to [*] grams per each [*] grams of Bulk Product purchased by AHPC at the [*] percent ([*]%) price set forth in Section 3.4 above

3.6 (b) AHPC shall provide written documentation showing duties paid by AHPC upon important of the Covered Product into the United States for so long as the Covered Product is pharmaceutically formulated outside the United States, duties are paid upon the importation thereof into the United States, and support is sought by AHPC under Section 3.6(a) above for such duties.

4. Development Work and Regulatory Approvals

4.1 Upon execution of this Agreement and periodically thereafter, Syntex shall provide AHPC, subject to the provisions of

Section 11 below, relevant information and data developed by it with respect to the agreement Compound, the Bulk Product and/or the Covered Product. Syntex shall continue to provide such information and data that is relevant to additional development work to be undertaken by AHPC with respect to the Covered Product during the term of this agreement. Syntex shall provide written consent directly to the FDA to permit AHPC to refer to Syntex's Notice of Claimed Investigational Exemption for New Drug and New Drug Application ("NDA") for the Agreement Compound, and all information relating to the manufacture and control of the Bulk Product, with respect to development work that is conducted by AHPC in accordance with this agreement.

4.2 (a) Syntex shall make available to AHPC all information received from Du Pont Merck that Du Pont Merck has developed for a subarachnoid hemorrhage indication for the Covered Product (the "SAH Indication"). AHPC shall promptly review such information and determine, in good faith, if in AHPC's judgment the development of the SAH Indication is appropriate or desirable.

4.2 (b) If the development of the SAH Indication is considered appropriate or desirable by AHPC, then AHPC shall conduct all clinical tests and develop all technical data reasonably necessary to seek FDA approval for the SAH Indication. The NDA for the SAH Indication to be submitted to the FDA shall be reviewed and approved by Syntex in writing in advance of submission

to the FDA. In addition, AHPC shall provide Syntex fifteen (15) working days to review all data, including all technical and clinical data (including summaries thereof), to be submitted by Syntex to the FDA. All such data, and the back-up data pertaining thereto, shall be available for inspection and review by Syntex at any reasonable time, and copies thereof shall be promptly provided to Syntex upon Syntex's written request therefor. AHPC shall use reasonable efforts to complete the SAH studies (but may terminate its efforts at any time in its sole discretion) and shall file, in Syntex's name, NDA or a supplemental NDA for the SAH Indication. All technical and clinical data developed by AHPC in support of the SAH Indication shall be and remain the property of AHPC. Syntex shall, however, own any resulting registration and AHPC shall ensure that any such registration (including all right, title and interest thereto) is issued in Syntex's name.

4.2 (c) At least semi-annually, AHPC shall provide to Syntex a written report on any development undertaken by AHPC of the SAH Indication.

4.2 (d) In addition to any reports provided to Syntex by AHPC under Section 4.2(c) above, SAH Indication review meetings shall be held at least annually at locations to be agreed on until the NDA or supplemental NDA for the SAH Indication is approved. At such meetings, AHPC shall report on its progress in the development of the SAH Indication for the Covered Product. Each party hereby

designates the person listed in Schedule B as its clinical co-ordinator to receive and respond to inquiries during the regulatory phase concerning the SAH Indication and to make arrangements for the joint review meetings.

4.3 (a) Syntex shall have and retain ownership of the NDA for the Covered Product. Syntex shall inform the FDA in writing that AHPC, acting through Wyeth-Ayerst, has become Syntex's exclusive sub-licensee of the Covered Product in the Territory and will have the right, in conjunction with Syntex, to interact with the FDA with respect to the NDA pertaining thereto, subject to the terms and conditions hereof.

4.3 (b) Each party shall promptly provide to the other copies of all correspondence received from the FDA concerning the Covered Product, and shall advise each other within ten (10) working days of any oral communications that it receives from the FDA concerning the Covered Product.

4.3 (c) Unless otherwise required by law, or required by the FDA in written correspondence with Wyeth-Ayerst, or by this agreement, Wyeth-Ayerst shall provide Syntex fifteen (15) working days to review and approve correspondence to the submitted by Wyeth-Ayerst to the FDA with respect to the Covered Product (if the FDA requires that the correspondence be submitted to the FDA in less than fifteen (15) days, then Wyeth-Ayerst shall provide Syntex at least two (2) full working days to review and approve such

correspondence). Wyeth-Ayerst shall not submit any such correspondence that is objected to by Syntex in good faith, unless required by law or the FDA in writing. Syntax agrees to make all necessary filings to the FDA with respect to the NDA for the Agreement Compound, including Annual Reports (21 C.F.R. 314.80(c) (2)) and promotional submissions (21 C.F.R. 314.81(b) (3) (i), as are (i) prepared by Wyeth-Ayerst, provided on a timely basis by Wyeth-Ayerst to Syntex, and reviewed and approved by Syntex in accordance with the provisions of this Agreement, or (ii) prepared by Syntex (e.g., periodic or increased frequency adverse drug event reports (21 C.F.R. 314.81(b) (2) and provided by Syntex to Wyeth-Ayerst for comment prior to any such filing.

4.3 (d) Each party shall inform the other party of any meetings scheduled with the FDA concerning the Covered Product and shall provide the other party the opportunity to review and approve any submissions (including promotional materials and labeling) to be sent to, reviewed by, or any presentations to be made to, the FDA with respect to the Covered Product and to have representatives present at any meetings pertaining to the Covered Product; provided, however, that Syntex, by virtue of its ownership of the NDA for the Covered Product, shall be the primary contact with the FDA, unless the parties agree otherwise in writing.

4.3 (e) Syntex's approval under this Section 4.3 shall not be unreasonably withheld, but may be withheld, in Syntex's sole

discretion, if Syntex considers, in good faith, that any Wyeth-Ayerst correspondence or presentation will have an adverse impact on the other dosage forms of the Agreement Compound that are being marketed in, or being developed for, the Territory by or on behalf of Syntex.

4.3 (f) Syntex agrees, subject to the review and approval procedures set forth in this Agreement, to submit to the FDA Supplementary data supplied to Syntex by AHPC or Wyeth-Ayerst to permit AHPC or Wyeth-Ayerst to manufacture and test the Covered Product in its facilities, and to substitute supplementary or alternative packaging designs or Covered Product presentations that Wyeth-Ayerst desires. Subject to the terms and conditions of this agreement, all data developed by AHPC or Wyeth-Ayerst in support of such submissions to the FDA shall be and remain the property of AHPC or Wyeth-Ayerst.

4.4 All data developed by AHPC or Wyeth-Ayerst for the United States NDA or supplemental NDA may be used by Syntex for filing applications for government registration in countries outside the Territory and in supporting FDA filings for other products containing the Agreement Compound. AHPC and Wyeth-Ayerst shall provide to Syntex without charge all data requested by Syntex for this purpose and hereby consents to Syntex's use of such data for the sole purposes of obtaining foreign registrations in any and all countries outside the Territory and formulating, packaging,

distributing, marketing, promoting and selling the products covered by such registrations pursuant thereto. Syntex agrees to keep all such data confidential in accordance with Article 11 hereof, and shall not use such data except as provided for herein. Neither AHPC nor Wyeth-Ayerst shall be required to develop data to be used solely for Syntex's needs or desires outside the Territory, unless AHPC or Wyeth-Ayerst is willing to do so upon terms and conditions to be agreed upon in writing by the parties.

4.5 As an inducement for Syntex to continue to furnish information and data pertaining to the Agreement Compound and the Bulk Product, to cooperate in filing and obtaining approval of any NDA for the SAH Indication, to provide subsequent information (including trade secrets and other confidential information relating to the marketing of products containing the Agreement Compound), and to grant to AHPC the exclusive rights to the Covered Product in the Territory (as set forth herein), including with respect to the currently approved NDA for certain indications for the Covered Products, AHPC, on behalf of itself and Wyeth-Ayerst, agrees that it shall not manufacture or sell in the Territory, or apply for FDA approval to manufacture or sell in the Territory, any product containing the Agreement Compound except the Covered Product during the term of this agreement. This provision shall not preclude AHPC from manufacturing

Covered Product (a) in the Territory with Bulk Product purchased

from Syntex hereunder for sale by Wyeth-Ayerst in accordance with this agreement or (b) for Syntex for countries outside the Territory pursuant to separate written agreements between the parties.

5. Trademarks and Quality Control

5.1 The use of the Trademark by Wyeth-Ayerst shall be governed by the following provisions:

(a) Syntex shall have equitable and legal ownership of the entire right, title and interest in and to the Trademark.

(b) Syntex shall file and maintain registration of the Trademark in the Territory, and neither AHPC, Wyeth-Ayerst nor any of their respective Affiliates shall obtain any right, title of interest in the Trademark, except the right to use the Trademark on the Covered Product pursuant to this Agreement.

(c) If AHPC or Wyeth-Ayerst becomes aware that a third party is infringing any of Syntex's rights with respect to the use of the Trademark on the Covered Product, AHPC or Wyeth-Ayerst shall give notice to Syntex of such infringement. Syntex may, at its sole discretion, bring legal action to restrain such infringement and for damages, and AHPC and Wyeth-Ayerst agree to cooperate at their own expense in any such action involving the Covered Product. If within six (6) months after receipt of such notice, Syntex does not effect a cessation of such infringement or institute a legal action for infringement, then AHPC or Wyeth-Ayerst shall have the right,

at their own expense, to bring suit against any such infringing party. If such a suit by AHPC or Wyeth-Ayerst is successful, AHPC or Wyeth-Ayerst shall be entitled to any monetary recovery obtained. If AHPC or Wyeth-Ayerst elects to bring such action, it agrees to fully indemnify Syntex for any costs, expenses or losses incurred by Syntex as a result of any such action. Syntex reserves the right to intervene in any such action at its own expense. AHPC or Wyeth-Ayerst shall only have the right to bring a trademark infringement or related action in the Territory against a third party who uses the precise Trademark on the precise Covered Product, and nothing herein shall grant AHPC or Wyeth-Ayerst the right to otherwise enforce the Trademark. AHPC or Wyeth-Ayerst shall not settle any such suit without the prior written approval of Syntex.

(d) Each Covered Product processed and distributed by Wyeth-Ayerst shall bear a Trademark and a label approved by Syntex featuring the Wyeth-Ayerst name and the Syntex name in a manner acceptable to the FDA and to both parties. Neither party, by virtue of this agreement, obtains any rights whatsoever in the trade name of the other party. Wyeth-Ayerst shall use the same format/font and style for the Trademark and Syntex's name on such labeling (and on all other promotional material) as Syntex then-currently uses with respect to the oral dosage form of the Agreement Compound in the Territory.

(e) Syntex may, for the purpose of avoiding trademark infringement, change the Trademark, and Wyeth-Ayerst will, when requested by Syntex to do so, case further sue of the earlier designated Trademark and use only the newly designated Trademark. This provision may be invoked by Syntex only if Syntex is itself ceasing the further use of the Trademark on the oral dosage form of the Agreement Compound (which is currently contemplated to be unlikely in view of the marketing by Syntex of such oral dosage form under the Trademark in the Territory since March, 1989). In the case of any such redesignation, Syntex shall reimburse Wyeth-Ayerst for any new packaging and package inserts required by Syntex's request to convert to the newly designated Trademark, but shall not otherwise be liable to Wyeth-Ayerst (and, in this regard, shall not be obligated to reimburse Wyeth-Ayerst for the printing of any new promotional materials that are required).

5.2 The parties recognize that Syntex has a proper concern in maintaining and controlling the quality of products containing the Agreement Compound (e.g., the Covered Product) marketed under a Trademark owned by Syntex, which products are publicly associated with Syntex research and are or will be marketed by Syntex and its Affiliates, sublicensees and distributors both inside and outside the Territory. The parties accordingly agree as follows:

(a) AHPC and Wyeth-Ayerst warrant that the Covered Product will meet the quality standards specified by Syntex in this

Agreement and as required by the FDA.

(b) To ensure that the quality standards for the Covered Product are met, AHPC shall purchase from Syntex all quantities of the Bulk Product to be used in the manufacture of Covered Product by or on behalf of AHPC. If for any reason Syntex is unable to deliver Bulk Product of its own manufacture within sixty (60) days after receipt of any order placed by AHPC, Syntex shall arrange for delivery of Bulk Product from another source; provided, however, that such source has been approved by the FDA as a supplier of Bulk Product.

(c) AHPC shall not include any Agreement Compound as an ingredient or component part of a composition containing one or more other active medicinal, therapeutic or prophylactic agents without the prior written approval of Syntex.

(d) All dosage forms of the Agreement Compound suitable for intravenous administration to be manufactured by AHPC or marketed by Wyeth-Ayerst must have the prior written approval of Syntex, and each Covered Product shall be distributed only in dosage forms suitable for intravenous administration as approved in writing by Syntex and the FDA. If Syntex does not indicate approval or disapproval within sixty (60) days after receipt of a complete package of information from AHPC (or Wyeth-Ayerst) for the development and distribution of a new dosage from of the Agreement Compound suitable for intravenous administration, such package will

be deemed approved.

(e) AHPC may employ a third party manufacturer for any portion of the pharmaceutical manufacturing, processing or packaging process of the Covered Product, but only with the prior written approval of Syntex, which shall not be unreasonably withheld, and the FDA.

5.3 Subject to Section 5.2(e) above, AHPC shall perform such pharmaceutical manufacturing, processing and packaging necessary to convert the Bulk Product purchased from Syntex into finished pharmaceutical dosage form packaged for resale to the ultimate consumer. AHPC shall have full responsibility for maintaining, at its own expense, suitable manufacturing procedures and quality controls, which shall comply with all federal and local laws and regulations, with Good Manufacturing Practices (GMPs) for the manufacture of pharmaceutical products in the Territory, and with Syntex quality

standards set forth in the NDA for the Covered Product. In addition to, and without in any way limiting the foregoing, the following procedures shall be observed:

(a) Syntex shall provide to AHPC such documents as it has developed pertaining to pharmaceutical manufacture, package and control procedures for the Covered Product. Based on such information and on its own procedures pertaining to the manufacture of sterile intravenous products, AHPC shall develop manufacturing, packaging and control procedures for the Covered Product, which it

shall submit to Syntex for Syntex's prior review and written approval. If Syntex does not indicate disapproval within sixty (60) days after receipt from AHPC of AHPC's pharmaceutical manufacturing, packaging and control procedures for the Covered Product, such procedures as are received by Syntex shall be deemed approved.

(b) AHPC warrants that it shall strictly follow such procedures as required to comply with GMPs; however, minor infractions by themselves will not be the basis for termination of this Agreement.

(c) AHPC shall promptly forward to Syntex a reasonable number of samples and copies of analytical reports with respect to the first three (3) commercial batches of the Covered Product that are produced by AHPC (or by subsequent manufacturer approved by Syntex pursuant to this Agreement), and such additional reports as may be reasonably requested by Syntex from time to time. None of these commercial batches shall be distributed by or on behalf of Wyeth-Ayerst prior to receipt of Syntex's written approval thereof.

(d) AHPC shall, whenever requested by Syntex, send a reasonable number of random samples (and copies of the corresponding batch sheets) to Syntex to be re-checked for quality control purposes by Syntex. The cost of such random samples shall be borne by AHPC, and the cost of all re-checking shall be borne by Syntex. Syntex shall promptly send a copy of the results of such

re-checking to AHPC.

(e) Syntex shall have the right, upon reasonable notice to AHPC and during regular business hours, to visit and inspect AHPC's (or Wyeth-Ayerst's premises or the premises of any third party manufacturer employed by AHPC) where the Bulk Product is stored and the Covered Product is pharmaceutically manufactured from such Bulk Product, processed, packaged and/or stored.

6. Promotion

6.1 Wyeth-Ayerst shall meet with, present and submit to Syntex a marketing plan for the Covered Product as soon as possible, and in any event not later than thirty (30) days after the effective date hereof. Such plan shall cover in detail the period beginning with the effective date hereof and ending at the end of the then-current calendar year. The marketing plan for calendar year 1994 (the "Initial Plan Year") shall also contain estimates for the three (3) -year period starting with that Initial Plan Year. Each calendar year during the term hereof, after the Initial Plan Year, shall be referred to as a "Plan Year". The marketing plan shall include at least the following:

(a) market analysis, including review of competitive products, presentations, dosages and dosage forms, and if possible, sales volume;

(b) estimated sales (in number of units) of the Covered Product by dosage form for the Initial Plan Year and the three

(3) -year period starting with the Initial Plan Year (only the estimates for the Initial Plan Year or for any subsequent Plan Years shall be used to measure performance pursuant to Section 10.5 below);

(c) proposed labeling (including label, package and carton, package insert, introductory folder and advertising), recognizing that such materials may be subject to FDA modification and approval (modifications or revisions to the labeling approved by Wyeth-Ayerst and Syntex shall be permitted without resubmission of the marketing plan);

(d) selected strategic option;

(e) proposed literature and mailing plan;

(f) media advertising plan;

(g) amount, percent of and bonus weighting for, detail effort by the sales force to be dedicated on an annual basis to the Covered Product;

(h) sampling (package sizes and number to be distributed); and

(i) other marketing activities.

5.2 Syntex shall, not later than thirty (30) days after receipt of the marketing plan, send Wyeth-Ayerst a notification containing its approval, disapproval or any suggested modifications. If Syntex does not notify Wyeth-Ayerst of its disapproval of the marketing plan within such period of time, it

will be deemed approved. If Syntex does not approve the plan, or if any of its suggested modifications are not acceptable to Wyeth-Ayerst, representatives of the parties shall meet and confer, and a mutually acceptable plan shall be developed within the next thirty (30) days. Wyeth-Ayerst will endeavor in good faith to achieve a consistent brand image for the Covered Product with the oral dosage forms of the Agreement Compound. The parties recognize that situations may exist in which promotional strategies for the Covered Product may necessarily be different than for the oral dosage forms of the Agreement Compound. Use of such different promotional strategies shall not be reason for Syntex to refuse approval of Wyeth-Ayerst's promotional plan, unless Syntex believes, in good faith, that Wyeth-Ayerst's strategy would be damaging to the image or medical acceptance of the oral dosage forms of the Agreement Compound or inconsistent, in significant respect, with Syntex's promotional strategy for the oral dosage forms of the Agreement Compound.

6.3 For each succeeding Plan Year (or portion thereof) during the term of this Agreement, Wyeth-Ayerst shall prepare and submit to Syntex a marketing plan containing the information specified in Section 6.1 above for the ensuing twelve (12)-month and any three (3)-year or lesser periods remaining during the term of this Agreement. The plan shall be submitted to Syntex ninety (90) days prior to the beginning of Plan Year or period to which it pertains,

and any objections by Syntex shall be handled as set forth in Section 6.2 above.

6.4 (a) Wyeth-Ayerst shall submit for prior medical, regulatory and marketing (review only) review and approval by Syntex all advertising materials that it prepares or has prepared concerning the Covered Product prior to publication thereof. For purposes of this provision, advertising/promotional material includes, without limitation, copy and art work for magazine and journal publications, sales aids, television and radio advertising, leaflets, brochures, medical services related materials, press releases, and any other printed, audio or visual materials pertaining to the Covered Product. Syntex may request modifications to such materials to ensure medical and regulatory consistency with its advertising of other products containing the Agreement Compound and with the approved marketing plans. Wyeth-Ayerst shall not publish, broadcast, announce, exhibit or distribute any advertising materials for the Covered Product that have not been approved in writing by Syntex. Such approval shall not be unreasonably withheld, and Syntex shall advise of approval or disapproval within fifteen (15) working days after receipt thereof. If Syntex does not indicate disapproval within fifteen (15) working days after receipt from Wyeth-Ayerst of such materials, such materials as are received by Syntex shall be deemed approved.

6.4 (b) Wyeth-Ayerst and Syntex shall endeavor in good faith to establish procedures whereby Syntex is involved in the review and approval of the advertising materials referred to in Section 6.4(a) above as such materials are being prepared by Wyeth-Ayerst, so as to minimize the potential for "last minute" disapproval thereof by Syntex under Section 6.4(a) above.

6.4 (c) Wyeth-Ayerst shall have the right, with respect to such advertising and promotional materials, to communicate directly with the FDA's Division of Drug Advertising, Marketing and Communications, subject to Syntex's right of review, approval and participation as set forth in this Agreement.

6.5 If Wyeth-Ayerst and Syntex disagree on specific aspects of the marketing plan or the advertising/promotional material to be used in marketing and promoting the Covered Product in the Territory, the parties agree to promptly meet and attempt to resolve such differences of opinion. If after good faith attempt to resolve such differences the parties still cannot agree, the position to be followed shall be decided by Syntex as holder of the regulatory approval for the marketing of the Covered Product in the Territory.

6.6 (a) Syntex may engage in its own detailing and promotional activities for the Covered Product during the term of this Agreement, and it shall inform Wyeth-Ayerst of all such activities that it undertakes. Wyeth-Ayerst shall provide to

Syntex reasonable quantities of advertising/promotional materials prepared by Wyeth-Ayerst to be used for informational and promotional purposes by Syntex professional medical representatives. The cost of the advertising/promotional materials provided by Wyeth-Ayerst to Syntex shall be reimbursed by Syntex at Wyeth-Ayerst's cost within thirty (30) days after receipt of Wyeth-Ayerst's invoice therefor.

6.6 (b) Syntex shall submit to Wyeth-Ayerst for review all advertising/promotional materials that it may develop for the Covered Product prior to publication, and Wyeth-Ayerst shall confer with Syntex if it objects to any such materials. Syntex shall also provide to Wyeth-Ayerst, for its information, copies of all published advertising for other products containing the Agreement Compound. To permit appropriate coordination of activities, Syntex shall keep Wyeth-Ayerst advised of its marketing plans with respect to the Agreement Compound on an annual basis and shall endeavor in good faith to provide such plans prior to Wyeth-Ayerst's submission of its marketing plans for each plan Year.

6.6 (c) Wyeth-Ayerst shall, upon written request from Syntex, provide Syntex with a reasonable number of samples of the Covered Product for (a) sampling by Syntex and (b) conducting by Syntex of any Phase IV studies. The cost of the samples provided by Wyeth-Ayerst to Syntex shall be reimbursed by Syntex at Wyeth-Ayerst's cost (exclusive of any Bulk Product cost).

6.7 If either party distributes samples of the Covered Product to its sales force, such party shall maintain records concerning such sample distribution as required by the Prescription Drug Marketing Act of 1987 (the "Act") and relevant state laws. Each party shall take such steps as are necessary to ensure that its sales force representatives comply with all requirements of the Act, including but not limited to obtaining requests and receipts signed by

licensed prescribers for all samples delivered. Each party shall have access, upon reasonable notice to the other party, to such records of the other party so as to be able to meet its obligations under the Act. Wyeth-Ayerst and Syntex each indemnify and hold the other party harmless from any liability that the other party may incur, whether civil, criminal or otherwise, by reason of a violation of the Act by Wyeth-Ayerst or Syntex (as the case may be) or by any member of their respective sales forces.

6.8 Subject to the applicable review and approval provisions set forth in this Agreement, Wyeth-Ayerst shall prepare on a timely-basis and provide to Syntex for filing with the FDA a form FDA-2253, or its replacement, for the purpose of submitting copies of advertising and promotional labeling to the FDA at the time of initial dissemination of such labeling and at the time of initial publication of any such advertising material. Such form and advertising and promotional labeling shall be provided to Syntex in accordance with 21 C.F.R. 314.81(b) (3) (i).

7. Operating Procedures

7.1 Wyeth-Ayerst and Syntex shall exchange information concerning technical and scientific data and therapeutic claims to be used in advertising materials, sales literature, professional journals and the like with respect to the Covered Product and the Agreement Compound and shall confer concerning any inconsistencies or objections noted by either party.

7.2 Wyeth-Ayerst shall as promptly as practicable submit written reports to Syntex as follows:

(a) semi-annual clinical and other Covered Product development progress reports;

(b) semi-annual reports showing the status of any application for FDA approval to market the Covered Product for the SAH Indication and any further indication to be developed for the Covered Product as may be agreed upon in writing by the parties hereto;

(c) Quarterly reports showing cumulative sales of each ampoule size and concentration of the Covered Product (in terms of units and dollars) for the Quarter; and

(d) Quarterly reports showing the amount of inventory on hand of the Bulk Product and the Covered Product, including work in progress.

7.3 The Quarterly reports referred to in Sections 7.2 above shall be submitted by Wyeth-Ayerst to Syntex along with the notice

given by Wyeth-Ayerst to Syntex pursuant to Section 3.4(c).

7.4 During the clinical testing (if any) of the Covered Product for the SAH Indication, Wyeth-Ayerst shall, in accordance with federal regulations, report to the FDA any information that it receives concerning an adverse drug event associated therewith. At the same time that it submits such report to the FDA, Wyeth-Ayerst shall notify Syntex by facsimile letter or message (Manager, Central Drug Experience Reporting Group; facsimile number 415-852-3013) that it is submitting a report and shall transmit a copy of the report to Syntex (Attention: Manager, Central Drug Experience Reporting Group, Corporate Regulatory Affairs, Syntex (U.S.A.) Inc., 3401 Hillview Avenue, Palo Alto, California 94304) by express delivery service.

7.5 (a) Wyeth-Ayerst shall promptly (i.e., within seven (7) business days) report to Syntex in accordance with FDA regulations any information that Wyeth-Ayerst receives concerning an adverse drug event associated with the Covered Product that is serious, as defined in the applicable federal regulations, including, without limitation, 21 C.F.R. 314.80, or such other definition of serious as the parties may agree upon to take into consideration, and satisfy, international reporting requirements (“Serious”), which report shall include a completed Form 1639 (or any successor form) prepared by Wyeth-Ayerst for subsequent filing by Syntex with the FDA in accordance with the applicable regulations.

7.5 (b) Syntex shall attempt to immediately refer any telephone call received by Syntex regarding an adverse drug event associated with use in the Territory of the Covered Product that is Serious, to Wyeth-Ayerst for direct handling. However, if that can not be done, Syntex shall promptly (i.e., within two (2) business days) refer (by telephone call or facsimile transmission) to Wyeth-Ayerst any information that Syntex receives concerning such adverse drug event. Wyeth-Ayerst shall follow-up with the person or persons making the initial adverse drug event report to Syntex and shall report back to Syntex within five (5) business days after the date of Syntex’s telephone call or facsimile transmission, which report back to Syntex shall include a completed Form 1639 (or any successor form) prepared by Wyeth-Ayerst for subsequent filing by Syntex with the FDA in accordance with the applicable regulations.

7.5 (c) Syntex shall also inform Wyeth-Ayerst of any Serious adverse drug event associated with the use outside the Territory of a Covered Product that was manufactured with Bulk Product supplied by Syntex. This information shall be reported to Wyeth-Ayerst by Syntex sending a copy of any report or form filed with the FDA with respect to such use or promptly by Syntex if not reportable to the FDA (i.e., is Serious labelled, foreign origin).

7.5 (d) Information concerning adverse drug events that are non-serious that Wyeth-Ayerst receives for the Covered Product shall be provided to Syntex in sufficient time for reporting to the

FDA by Syntex in accordance with the FDA’s required reporting schedule. Syntex shall also keep Wyeth-Ayerst advised of any information that Syntex receives concerning a non-Serious adverse drug event associated with the use (either inside or outside the Territory) of a Covered Product that was

manufactured with Bulk Product supplied by Syntex.

7.5 (e) In addition, each party shall transmit to the other, in accordance with the above, any report requested by or submitted to the FDA concerning safety of the Agreement Compound and/or the Covered Product.

7.5 (f) Syntex shall, utilizing the information contained in Wyeth-Ayerst's reports to Syntex and other adverse event information available to it, prepare those formal (i.e., periodic and increased frequency) reports required to be provided to the FDA in accordance with 21 C.F.R. 314.80 and shall transmit such reports on a timely-basis to Wyeth-Ayerst for Wyeth-Ayerst's comments. Wyeth-Ayerst shall return such draft reports to Syntex along with its comments in time for Syntex to file such reports with the FDA in accordance with the applicable reporting schedule(s). Syntex shall submit such reports to the FDA and shall also send to Wyeth-Ayerst (Attention: Wyeth-Ayerst Laboratories, Executive Director, Worldwide Safety Surveillance Division (555-3), 555 E. Lancaster Avenue, St. Davids, Pennsylvania 19087 by express delivery service a copy of any such report eventually submitted to

the FDA.

7.6 If either party receives any information concerning an adverse drug event caused by a form of the Agreement Compound other than the Covered Product, then such party shall promptly report such information in writing to the other party but if the adverse drug event is Serious and unexpected (as defined by the applicable federal regulations), such report shall be given by (a) Wyeth-Ayerst to Syntex within two (2) working days (by telephone call or facsimile transmission) after it is received by Wyeth-Ayerst and (b) concurrently by Syntex with the submission of its report thereon to the FDA.

7.7 Although Sections 7.5 and 7.6 refer solely to the FDA, the parties agree to cooperate with each other in good faith to timely satisfy any adverse drug event reporting obligations outside the Territory concerning the Agreement Compound and the Covered Product.

7.8 Each party shall keep all supporting documentation regarding adverse drug events concerning the Agreement Compound and the Covered Product as are required by the FDA and regulatory agencies outside the Territory for the maximum period for which such documentation is required to be kept.

7.9 If either party learns of any hazard concerning the Covered Product that may be of a severity that requires action in order to protect the public interest, it shall immediately notify

the other party, and the parties shall promptly consult concerning such hazard. If after consultation the parties agree that distribution of the Covered Product should be discontinued and/or that Covered Product previously distributed should be recalled, one of the parties shall be designated to notify the FDA to determine the nature and extent of the recall.

7.10 In the event of a recall pursuant to Section 7.9 above or otherwise, Wyeth-Ayerst shall provide services to recover Covered Product distributed by it, but the costs of such recall, including the value of lost Covered Product and Bulk Product, shall be borne by the party responsible, as provided in Article 9 below.

8. Technology and Patents

8.1 AHPC and Wyeth-Ayerst shall promptly advise Syntex of any developments and/or improvements made by AHPC or Wyeth-Ayerst with regard to the Agreement Compound and/or the Covered Product (the "Sublicensee Technology"), particularly with regard to any developments and/or improvements made by AHPC or Wyeth-Ayerst with respect to pharmaceutical compositions and/or formulations of the Agreement Compound, including, without limitation, compositions and/or formulations in other that oral dosage form for use with regard to an intravenous solution of the Agreement Compound.

8.2 (a) AHPC and Wyeth-Ayerst agree to grant, and do hereby grant, to Syntex and exclusive, but for AHPC and Wyeth-Ayerst, royalty-free, fully paid-up license in the Territory under the

Sublicensee Technology developed by AHPC or Wyeth-Ayerst during the term hereof, and any patent applications and patents pertaining thereto.

8.2 (b) AHPC and Wyeth-Ayerst agree to grant, and do hereby grant, to Syntex an exclusive, but for AHPC and Wyeth-Ayerst, royalty-free, fully paid-up license in all countries outside the Territory under the Sublicensee Technology, developed by AHPC or Wyeth-Ayerst during the term hereof, and any patent applications and patents pertaining thereto.

8.3 If AHPC or Wyeth-Ayerst develop a significant new patentable use of the Agreement Compound outside the scope of the Licensed Patents, and the foreign counterparts thereof, AHPC and Wyeth-Ayerst hereby grant to Syntex a right of first refusal to obtain an exclusive, but for AHPC and Wyeth-Ayerst, license under such development and any patents pertaining thereto upon reasonable terms and conditions to be determined by good faith negotiations between the parties. Such right shall be exercised by Syntex, in writing, within sixty (60) days after receipt by Syntex from AHPC or Wyeth-Ayerst of a package of information (including any patent application(s) or patent(s) pertaining thereto) describing any such development in sufficient detail to enable Syntex to make an informed decision as to whether or not it wishes to obtain rights thereto as set forth herein.

8.4 If AHPC or Wyeth-Ayerst elect not to file for patent

protection within thirty (30) days after being requested to do so by Syntex, or does not file a priority patent application within ninety (90) days after Syntex's request, Syntex may do so. AHPC and Wyeth-Ayerst agree to make, execute and deliver, without compensation from Syntex, any and all instruments and documents necessary to obtain patents on the Sublicensee Technology in any and all countries throughout the world.

8.5 (a) In the event that either party learns of or suspects a third party infringement of the Licensed Patents in the Territory pertaining to the Covered Product by manufacture, use or sale of a product conforming to the definition of Covered Product herein, it shall promptly inform the other in writing.

8.5 (b) If AHPC or Wyeth-Ayerst becomes aware that a third party is infringing Syntex's U.S. Patent No. 5,164,405, AHPC or Wyeth-Ayerst shall give written notice to Syntex of such infringement. Syntex may, at its sole discretion, bring legal action to restrain such infringement and for damages, and AHPC and Wyeth-Ayerst agree to cooperate at their own expense in any such action. If within six (6) months after receipt of such notice, Syntex does not effect a cessation of such infringement or institute a legal action for infringement, then AHPC or Wyeth-Ayerst shall have the right, at their own expense, to bring suit against any such infringing party. If such a suit by AHPC or Wyeth-Ayerst is successful, AHPC or Wyeth-Ayerst shall be entitled

to any monetary recovery obtained. If AHPC or Wyeth-Ayerst elects to bring such an action, it agrees to fully indemnify Syntex for any costs, expenses or losses incurred by Syntex as a result of any such action. Syntex reserves the right to intervene in any such action at its own expense. AHPC any Wyeth-Ayerst shall not settle any such suit without the prior written approval of Syntex. AHPC and Wyeth-Ayerst shall only have the right to enforce the aforesaid Syntex patent under the conditions set forth above, and nothing herein shall grant AHPC or Wyeth-Ayerst the right to otherwise enforce such Syntex patent.

8.5 (c) If AHPC or Wyeth-Ayerst becomes aware that a third party is infringing Yamanouchi's U.S. Patent No. 4,880,823, AHPC or Wyeth-Ayerst shall give written notice to Syntex of such infringement. Either Syntex or Yamanouchi may, at their individual discretion, bring legal action to restrain such infringement and for damages, and AHPC and Wyeth-Ayerst agree to cooperate at their own expense in any such action. If neither Yamanouchi nor Syntex bring legal action to restrain such infringement within six (6) months after the date of such notice, Syntex will attempt, in good faith, to obtain from Yamanouchi the right for AHPC or Wyeth-Ayerst, at their own expense, to bring suit against any such infringing party, upon terms and conditions to be agreed upon at that time by Yamanouchi, Syntex, and AHPC or Wyeth-Ayerst.

8.6 (a) In the event that a third party claims that AHPC's

or Wyeth-Ayerst's manufacture, use or sale of the Agreement Compound and/or the Covered Product in the Territory infringes the patent of such third party, AHPC or Wyeth-Ayerst shall promptly notify Syntex of such claim.

8.6 (b) If the claim of patent infringement pertains to the Agreement Compound per se or any formulation of the Covered Product developed by Syntex, Syntex shall be responsible for the handling, prosecution and/or settlement of any such claim, and the decisions of the counsel for Syntex shall be controlling (although AHPC and Wyeth-Ayerst may, at their own expense, retain their own counsel; counsel for Syntex shall, however, give due consideration to the advice and recommendations of the counsel for AHPC and Wyeth-Ayerst). If AHPC or Wyeth-Ayerst becomes obligated to pay royalties to any non-Affiliated third party in order to make, have made, use or sell Covered Product in the Territory, by reason of a patent of such third party, such royalties shall be creditable against the price for Bulk Product otherwise payable to Syntex hereunder, provided that (a) the obligation to pay such royalties arises out of use of the formulation developed by Syntex for the Covered Product and not out of any modification to the Covered Product made by AHPC or Wyeth-Ayerst, (b) Syntex has the right to participate in the negotiations with such third party and to approve of the royalties to be paid to such third party, and (c) such credit shall not reduce the price otherwise payable to Syntex

by more than ([*]%) of the price set forth in Section 3.4(a) above (that is, [*] ([*]%) of [*] percent ([*]%), which is equal to a maximum reduction of [*] percent ([*]%) of the Average Net Selling Price).

8.6 (c) If the claim of patent infringement pertains to any formulation of the Covered Product developed by AHPC or Wyeth-Ayerst or initially developed by Syntex and modified by AHPC or Wyeth-Ayerst where such modification is the basis for the claim of infringement, AHPC and Wyeth-Ayerst shall be responsible for the handling, prosecution and/or settlement of any such claim, and the decisions of the counsel for AHPC or Wyeth-Ayerst shall be controlling (although Syntex may, at its own expense, retain its own counsel; counsel for AHPC or Wyeth-Ayerst shall, however, give due consideration to the advice and recommendations of the counsel for Syntex).

8.7 Syntex represents that, to the best of its current knowledge, there are no third party patents (other than Yamanouchi's U.S. Patents Nos. 3,985,758 and 4,880,823 referred to in Section 2.1(a) above) that would be infringed by the making, using and selling the Covered Product in the Territory.

9. Indemnification

9.1 Subject to Section 9.2 below, Syntex shall be responsible for, and shall defend, indemnify and hold AHPC and Wyeth-Ayerst harmless from and against, any and all loss, claims, suits,

proceedings, expenses (including reasonable attorneys' fees and other litigation costs, regardless of outcome), recoveries and damages, including costs and expenses of a total or partial product recall, arising out of, based on, or caused by any claim of third parties relating to the manufacture or formulation of Bulk Product furnished by Syntex and used for the manufacture of Covered Products sold in the Territory; provided, however, that Syntex shall incur no obligation to defend, indemnify or hold AHPC and Wyeth-Ayerst harmless from any liability, loss or expense resulting from AHPC's or Wyeth-Ayerst's clinical testing, storage (including storage of the Bulk Product), manufacture, processing, packaging, registration for the SAH Indication, distribution, promotion, use or sale of the Covered Product or from the negligence or other wrongdoing of AHPC, Wyeth-Ayerst or any third party manufacturer, distributor, purchaser or user of the Covered Product.

9.2 AHPC and Wyeth-Ayerst shall defend, indemnify and hold Syntex harmless from and against any and all loss, claims, suits, proceedings, expenses (including reasonable attorneys' fees and other litigation costs, regardless of outcome), recoveries and damages, including costs and expenses of a total or partial recall, arising out of, based on, or caused by any claim relating to the clinical testing, storage (including storage of the Bulk Product), manufacture, processing, packaging, registration for the SAH Indication, distribution, promotion, use or sale of the Covered

product in the Territory, except any such claim for which Syntex is responsible under Section 9.1 above.

9.3 Subject to Sections 9.1 and 9.2 above, each party warrants that, in the performance of their respective obligations hereunder, such party and their representatives shall, at all times, comply with all applicable laws, rules and regulations promulgated by any governmental authority having jurisdiction over the activities contemplated hereby, including, without limitation, the applicability of such laws, rules and regulations to the Agreement Compound NDA for the Indications, the manufacture of the Covered Product, and the marketing, distribution and sale of the Covered Product in the Territory.

10. Term and Termination

10.1 The initial term of this Agreement shall begin as of the effective date hereof and shall extend for the life of the last to expire of the Licensed Patents and any extension(s) thereof.

10.2 The Agreement shall be automatically renewed for successive renewal terms of four (4) years each, unless either party notifies the other at least one (1) year prior to the renewal date of its intention not to renew, in which event this Agreement shall terminate upon expiration of the initial or renewal term (as the case may be) without further notice.

10.3 Either party shall have the right to terminate this Agreement if the other party commits a material breach of a

material obligation under this Agreement and continues in default for more than ninety (90) days after receiving written notice of such default from the non-defaulting party. Such termination shall be effective upon further written notice to the defaulting party after its failure to cure the default.

10.4 Either party shall also have the right to terminate this Agreement in the event the other party is declared insolvent or bankrupt by a court of competent jurisdiction, or a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party, or the other party shall make or execute an assignment for the benefit of the creditors, in which case termination shall be effective upon written notice to that effect.

10.5 In order to ensure that Wyeth-Ayerst endeavors in good faith to market the Covered Product in the Territory as required by Section 2.2 above, Syntex may also terminate this Agreement after the end of any Plan Year, except the Initial Plan Year and the next succeeding Plan Year, in which Wyeth-Ayerst's unit sales of Covered Product fall short of its estimates to be submitted under Sections 6.1 and 6.3, and approved by Syntex under Section 6.2, by more than [*] percent ([*]%), or in which Wyeth-Ayerst's unit sales of Covered Product are less than [*] percent ([*]%) of its unit sales for the prior Plan Year, or less than [*] percent ([*]%) of its highest unit sales for any Plan Year. Since it is not

the parties' intention to terminate for depressed sales due to competitive market pressures, this Section 10.5 shall not be applicable to any Plan Year during which a non-Affiliated third party enters the market in the Territory with a new product not previously used or sold by anyone in the intravenous market for indications that are the same as the approved Indications. If Syntex elects to terminate pursuant to this Section 10.5, it must give notice of such election to Wyeth-Ayerst within ninety (90) days after receipt of
Wyeth-Ayerst's last Quarterly report for such Plan Year pursuant to Section 7.2(c) above. Prior to giving such notice or upon giving such notice, Syntex agrees, at the request of Wyeth-Ayerst, to meet with Wyeth-Ayerst and discuss whether this Agreement should be terminated as proposed or desired by Syntex. If Syntex elects, in its sole discretion after any such meeting, to continue with its desire to terminate this Agreement, termination under this provision shall be effective six (6) months after the date of any such notice by Syntex or three (3) years after initial launch of the Covered Product by Wyeth-Ayerst, whichever is later.

10.6 (a) Upon the termination or expiration of this Agreement, Syntex shall have the obligation to purchase all of AHPC's or Wyeth-Ayerst's existing (at time of termination) finished inventory of Covered Product, except any such Covered Product that (a) does not meet the then-current specifications therefor, or (b) has less than eighteen (18) months of shelf-life remaining if the

Covered Product has not been launched in the Territory by Wyeth-Ayerst, or (c) has less than twelve (12)-months of shelf-life remaining if the Covered Products has previously been launched in the Territory by Wyeth-Ayerst, for AHPC's or Wyeth-Ayerst's acquisition cost from Syntex of the Bulk Product plus (i) shipping costs (including customs duties, brokerage fees, excise, sales or use taxes and other governmentally-imposed taxes (if any) paid by AHPC or Wyeth-Ayerst with respect to the shipment of such Bulk Product from Syntex's delivery site of AHPC's or Wyeth-Ayerst's storage or pharmaceutical manufacturing facility (as the case may be), (ii) AHPC's or Wyeth-Ayerst's direct cost of production of the Covered Product (not to exceed [*] percent ([*]%) of Average Net Selling Price), excluding production yield losses if Syntex is providing free goods in support thereof under Section 3.5(a) above, (ii) shipping costs (including customs duties, brokerage fees, excise, sales or use taxes or other governmentally-imposed taxes (if any) paid by AHPC or Wyeth-Ayerst with respect to the shipment of the Covered Product from AHPC's or Wyeth-Ayerst's pharmaceutical manufacturing facility (if outside the Territory) to the Territory, but excluding customs duties, brokerage fees, excise, sales or use taxes and other governmentally-imposed taxes (if any) under subsections (i) and (iii) above if Syntex is providing free goods in support thereof under Section 3.5(b) above. For the purposes of this Section 10.6 (a) "direct cost" shall mean direct labor, direct

materials other than Bulk Product, and direct labor applicable to the production of the Covered Product.

10.6 (b) Syntex shall also be obliged to purchase all of AHPC's or Wyeth-Ayerst's inventory of Bulk Product for AHPC's or Wyeth-Ayerst's acquisition cost thereof from Syntex plus (a) shipping costs paid by AHPC or Wyeth-Ayerst with respect to the shipment of such Bulk Product from Syntex's delivery site to AHPC's or Wyeth-Ayerst's storage or pharmaceutical manufacturing facility (as the case may be), and customs duties, brokerage fees, excise, sales or use taxes and other
governmentally-imposed taxes (if any) paid with respect to shipment of the Bulk Product into the Territory, but excluding customs duties, brokerage fees, excise, sales or use taxes and other governmentally-imposed taxes (if any) if Syntex is providing free goods in support thereof under Section 3.5(b) above.

10.6 (c) Syntex shall pay for such goods as meet the applicable specifications therefor within sixty (60) days after the receipt thereof by Syntex at Syntex's designated receiving facility.

10.6 (d) Wyeth-Ayerst shall be permitted to continue to sell the Covered Product until the date of termination or expiration hereof (as the case may be). As to Covered Product that is not purchased by Syntex, Wyeth-Ayerst shall have the right to dispose thereof by any lawful means, whether by sale, donation, destruction

or otherwise, but shall not significantly undermine Syntex's ability to profitably market the Covered Product in the Territory after such termination or expiration.

11. Confidentiality, Non-Use and Public Statements

11.1 (a) Both AHPC and Syntex recognize that information disclosed by Syntex to AHPC or Wyeth-Ayerst pursuant to the Confidentiality Agreement effective February 18, 1993, between the parties, as well as technical, business and financial information of either party exchanged pursuant to this Agreement, are of proprietary value and are to be considered confidential ("Confidential Information"). Each party agrees not be disclose or transfer the other party's Confidential Information to others (except to its employees who reasonably require the same for the purposes hereof and who are bound to it by a like obligation as to confidentiality) without the express written permission of the disclosing party, except that neither party shall be prevented from using or disclosing that portion of the Confidential Information received from the other that (i) the receiving party can demonstrate by written records to be known to the receiving party before the date of disclosure (from a source other than the disclosing party); or (ii) is now, or becomes in the future, publicly available other than by breach of this Agreement by either party; or (iii) is lawfully disclosed to the receiving party on a non-confidential basis by a third party who is not obligated to

retain such Confidential Information in confidence. Information that AHPC or Wyeth-Ayerst receives from Du Pont Merck or Berk (U.K.) shall be deemed received from Syntex hereunder and subject to the terms and conditions hereof as if received directly from Syntex.

11.1 (b) Each party's obligation of confidentiality set forth herein shall continue for a period ending five (5) years after termination or expiration (as the case may be) of this Agreement; except that either party's obligation with respect to information designated in writing by the other as highly proprietary shall continue indefinitely. Neither party shall, however, submit or disclose information that it considers highly proprietary to the other unless and until the disclosing party obtains the receiving party's written approval to receive such information on the "highly proprietary" basis.

11.2 All information developed by AHPC or Wyeth-Ayerst in the performance of services hereunder by the use of Syntex Confidential Information shall be considered Syntex Confidential Information and shall be treated as such by Wyeth-Ayerst pursuant to the provisions of Section 11.1 above. APHC and Wyeth-Ayerst shall not use any Syntex Confidential Information except for the purpose of carrying out its obligations under this Agreement.

11.3 Except as required to comply with federal and state securities laws or other laws, or any order of a court or

government agency, neither party shall publicly release information concerning this Agreement or the subject matter hereof without first sending the other party, by facsimile or express mail, a copy of the information to be disclosed, and allowing the other party a period of five (5) business days from the date of

receipt by the other party to comment on the information. If the other party objects to the information to be disclosed, then prior to the expiration of the five (5) day period, the other party shall so notify the disclosing party, who shall then delay public disclosure of the information and make reasonable efforts to accommodate any requests for revisions made by the other party. If no notification is received during the five (5) day period, the party proposing disclosure shall be free to disclose the information. In the event the parties disagree regarding disclosure of certain information pursuant to the review and approval procedure required by this Section 11.3, the parties agree to confer in good faith in an attempt to reach a mutually-satisfactory resolution with respect to the information that is the subject matter of the disagreement. The parties designate the following individuals to receive and approve releases under this provision: Syntex - Vice President, Public Affairs; Wyeth-Ayerst - Director of Public Affairs.

12. Accounting Procedures

12.1 AHPC and Wyeth-Ayerst shall keep complete and accurate records in connection with the payments provided for under this

Agreement. Syntex shall have the right to nominate an independent firm of certified public accountants acceptable to AHPC and Wyeth-Ayerst who, after giving reasonable notice, shall have access to the books and records of AHPC and Wyeth-Ayerst during regular business hours for the purpose of verifying any amounts payable under this Agreement. Such firm of certified public accountants shall not disclose to Syntex any information other than information relating to the accuracy of, or of the necessity for, any payment made or required to be made hereunder. The fees and expenses of the firm of certified public accountants performing such verification shall be borne by AHPC if such verification shows an underpayment by AHPC to Syntex of [*] percent ([*]%) or more; in any other event, the fees and expenses of the firm of certified public accountants performing such verification shall be borne by Syntex.

13. Governing Law

13.1 This Agreement shall be governed by and interpreted in accordance with the laws of the State of California (regardless of its, or any other jurisdiction's, choice of law principles).

14. Assignment and Delegation

14.1 Syntex shall have the right to:

(a) assign this Agreement or transfer any part of its interest under this Agreement to any Affiliate, or

(b) designate and cause any Affiliate to perform all or part of its activities hereunder, or to have the benefit of

all or part of its rights hereunder.

14.2 AHPC shall have the rights, with Syntex's prior written approval, which shall not unreasonably withheld, to:

(a) assign this Agreement or transfer any part of its interest under this Agreement to any Affiliate, or

(b) designate and cause any Affiliate to perform all or part of its activities hereunder, or to have the benefit of all or part of its rights hereunder,

provided that AHPC demonstrates, to Syntex's reasonable satisfaction, that such Affiliate has at least the interest in, and at least the capability with respect to, that interest or activity(ies) with respect to the Covered Product that are being assigned or delegated to such Affiliate as Wyeth-Ayerst had at the time this Agreement was entered into.

14.3 In addition to Section 14.2 above, AHPC shall have the right, without Syntex's prior written consent, to assign this Agreement, or transfer any part of its interest under this Agreement, in connection with a reorganization of AHPC to any Affiliate operating as a Wyeth-Ayerst activity with Wyeth-Ayerst employees, provided that such Affiliate has at least the interest in, and at least the capability with respect to, that interest or activity(ies) with respect to the Covered Product that are being assigned or delegated to such Affiliate as Wyeth-Ayerst had at the time this Agreement was entered into.

14.4 In the event of any assignment, transfer or designation permitted under Sections 14.1, 14.2 or 14.3 above, the respective Affiliate shall assume and be bound by the provisions of this Agreement and its performance under this Agreement shall be guaranteed by the transferring party.

14.5 This Agreement shall be binding upon and inure to the benefit of the successors or permitted or approved assigns of Syntex or AHPC, respectively, provided that any such successor or assign shall have acquired all or substantially all of the stock or assets of its predecessor by reorganization, incorporation, merger, consolidation, purchase or otherwise. Otherwise this Agreement shall be assignable, and the rights and obligations of the parties may be transferred or delegated (except to the limited extent provided in this Article 14) only with the consent in writing of the other party hereto.

14.6 Syntex shall promptly notify AHPC of any such assignment, transfer or designation permitted under Section 14.1 above and the effective date thereof.

15. Force Majeure

15.1 Neither party hereto shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control ("force majeure") including, but not

limited to, acts of

God; regulation or law or other action of any government or agency thereof; war or insurrection; civil commotion; destruction of production facilities or materials by earthquake, fire, flood or storm; labor disturbances; epidemic; or failure or suppliers, public utilities or common carriers.

15.2 In the event the performance of either party's obligations to the other party is affected by force majeure as provided for in Section 15.1 above, the party so affected shall treat its obligations under this Agreement no less favorably than such party treats any of its own operations or any third party.

15.3 Each party shall endeavor to resume its performance hereunder as soon as reasonably possible if such performance is delayed or interrupted by reason of force majeure.

16. Severability

16.1 Should any part of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provision shall be replaced with a provision that accomplishes, to the extent possible, the original business purpose of such part or provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the parties hereto.

17. Captions

17.1 The captions of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

18. Notices

18.1 Unless otherwise provided herein, any notices, payment, report or other correspondence (hereinafter collectively the "Correspondence") required or permitted to be given hereunder shall be sent by certified or registered mail, postage prepaid, or delivered by hand to the party to whom such Correspondence is required or permitted to be given hereunder. If mailed, any such Correspondence shall be deemed to have been given when mailed, as evidenced by the postmark at the point of mailing. If delivered by hand, any such Correspondence shall be deemed to have been given when received by the party to whom such Correspondence is given, as evidenced by written and dated receipt of the receiving party.

18.2 All Correspondence to Syntex shall be addressed as follows:

Syntex Laboratories, Inc.
3401 Hillview Avenue
Palo Alto, California 94304
Attention: President

With a copy to:

Syntex (U.S.A.) Inc.
3401 Hillview Avenue
Palo Alto, California 94304
Attention: Associate General Counsel and
Director, Commercial Contracts
and General Law Department

18.3 All Correspondence to AHPC shall be addressed as follows:

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, Pennsylvania 19101
Attention: Senior Vice President
Business Development

With a copy to:

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, Pennsylvania 19101
Attention: Assistant General Counsel &
Director, Legal Division

18.4 Either party may change the address to which any Correspondence to it is to be addressed by notification to the other party as provided herein.

19. Survival

19.1 Sections 5.2 (a), 5.3 (d), 6.7, 7.7, 7.8, 8.2(a), 8.2(b), 9.1, 9.2, 9.3, 11.1, 11.2, 13.1, 13.2, 13.3 and 14.4 shall survive expiration or termination (as the case may be) of this Agreement.

19.2 The provisions of this Agreement that do not survive expiration or termination (as the case may be) of this Agreement shall, nonetheless, be controlling on, and shall be used in construing and interpreting the rights and obligations of the parties hereto with respect to any dispute, controversy or claim

that may arise under, out of, in connection with, or relating to any act (or failure to act) that occurred during the term of this Agreement (including the initial term and any renewal thereof).

20. Independent Party

20.1 AHPC shall act solely as an independent party and nothing in this Agreement shall be construed to give either party the power or authority to act for, bind or commit the other party hereto in any way whatsoever. Accordingly, neither party shall use or refer to the name or business logo (if any) of the other party or its Affiliates or this Agreement without the prior written consent of the other party.

21. Waiver

21.1 The failure on the part of AHPC or Syntex to exercise or enforce any rights conferred upon it hereunder shall not be deemed to be a waiver of any such rights nor operate to bar the exercise or enforcement thereof at any time or times thereafter, unless specifically set forth in writing and executed and delivered by a duly authorized representative of each of the parties hereto.

22. Entire Agreement

22.1 This Agreement and the Schedules hereto constitutes the entire understanding as of the effective date hereof between the parties with respect to the subject matter hereof and supersedes all prior agreements, negotiations, understandings, representations, statements and writings relating thereto. No

modification, alteration, waiver or change in any of the terms of this Agreement shall be valid or binding upon the parties hereto unless made in writing and duly executed and delivered by each of the parties.

IN WITNESS WHEREOF, this Agreement has been executed and delivered by each party with the intent that it be binding upon the parties hereto in accordance with the terms and conditions hereof.

SYNTEX (U.S.A.) INC.	AMERICAN HOME PRODUCTS CORPORATION
By /s/ Richard Powers	By /s/ Fred Hassan
Print Name Richard Powers	Print Name FRED HASSAN
Title Vice President	Title SVP
Date September 14, 1993	Date 9/30/93

Schedule A

Specifications for the Bulk Product

Schedule B

Clinical Coordinators and Marketing Coordinators

Five Giralda Farms
Madison, NJ 07940

Wyeth

October 30, 2003

ESP Pharma, Inc.
2035 Lincoln Highway, Suite 2150
Edison, New Jersey 08817

Re: Cardene IV Sublicense and Supply Agreement
Acebutolol License Agreement

Gentlemen:

Reference is made to the agreements listed in I and II below (together referred to as the "Agreements"):

I. Sublicense and Supply Agreement, dated September 1, 1993 as amended January 8, 2001, between Wyeth (formerly American Home Products Corporation) acting through its Wyeth Pharmaceuticals Division (formerly Wyeth-Ayerst Laboratories Division) and Syntex (U.S.A) Inc.; and

II. Acebutolol License Agreement, dated November 9, 1977, by and between Aventis S.A. (as successor to Rhone-Poulenc Rorer S.A. and Rhone-Poulenc Sante, together "Aventis") and Wyeth (as successor to American Home Products Corporation).

Since ESP has repaid all amounts owed to Wyeth under the Senior Secured Promissory Note, dated May 22, 2002, in the principal amount of $9.5 million and all pertinent conditions have been met and all necessary consents have been obtained, Wyeth hereby assigns and ESP accepts assignment of each of the Agreements. It is agreed and understood that ESP shall have the responsibility to comply with all of the terms and conditions of each of the Agreements and Wyeth shall have no further responsibility under either of the Agreements as of the date of this letter.

Wyeth Pharmaceuticals
Wyeth Consumer Healthcare
Fort Dodge Animal Health

By signing below, you confirm your agreement with the above terms.

Sincerely,

/s/ Jeffrey S. Sherman
Jeffrey S. Sherman
Vice President and Associate General Counsel

Agreed and Accepted
ESP Pharma, Inc.

By: Anthony A. Rascio
Name: ANTHONY A. RASCIO
Title: SENIOR VICE PRESIDENT

Exhibit 10.2

CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Pharmaceuticals

David R. Austin
Sr. Vice President and CFO

September 5, 2003

Howard Weisman
President
ESP Pharma
2035 Lincoln Highway, Suite 2150
Edison, NJ 08817

Re: Sublicense and Supply Agreement

Dear Howard:

This letter, when signed for ESP and returned to me, will amend the Sublicense and Supply Agreement of September 1, 1993, (that is under agreement for assignment by American Home Products Corporation, now Wyeth, to ESP) (the Agreement) on the first day of a calendar quarter following the assignment of the Agreement to ESP and the fulfillment of all the conditions for license assignment enumerated in the letter agreement of April 18, 2002, among Wyeth, ESP and Roche (formerly Syntex (U.S.A.) LLC), provided that there be no disputes about payments due Roche and also provided that the Quality Agreement and side letter regarding quality, both dated June 2003, are signed by all applicable parties ("Amendment Date"). The licensor in this agreement is now Roche Palo Alto LLC, formerly Syntex (U.S.A.) Inc.

The parties hereby agree to the following amendments:

1. Section 1.2 shall be amended by deleting from that section all of subsection (b), beginning with "divided by" and continuing through the end of that section. And the defined term "Average Net Selling Price" shall be replaced throughout the Agreement with the term "Net Sales."

2. Section 3.4(a) shall be replaced in its entirety by the following:
3.4(a) The initial price of Bulk Product shipped to ESP, or its designated manufacturer, shall be [*] dollars ($[*]) per kilogram through December 31, 2004.

Roche Palo Alto LLC
5491 Hillview Ave.
Palo Alto,
California 94304-1497
Tel. 850-852-1140
Fax 850-254-7645
David.Austin@roche.com

Annually thereafter, beginning on January 1, 2005, and thereafter beginning on the first day of the calendar year, the price shall be increased or decreased by the percentage increase or decrease in the U.S. Producer Price Index for Chemicals and Allied Products (WPU006) for the immediately preceding calendar year. There shall be no decrease in price below [*] dollars ($[*]) per kilogram.

3. Section 3.4(b) shall be replaced in the entirety by the following:
3.4(b) From the Amendment Date until December 31, 2003, ESP shall pay to Roche a royalty of [*] percent ([*]%) of Net Sales. Beginning January 1, 2004, ESP shall pay Roche a royalty on its Net Sales as follows, calculated on an annual basis using a calendar year:

   1) On the first $[*] of Net Sales, a royalty equal to [*] percent ([*]%) of Net Sales;

   2) On the next $[*] of Net Sales, a royalty equal to [*] percent ([*]%) of Net Sales;

   3) On Net Sales in excess of $[*], a royalty equal to [*] percent ([*]%) of such excess;

4. Section 3.4(c) shall be replaced in its entirety by the following:
3.4(c) Within sixty (60) days after the end of each calendar Quarter, ESP shall calculate and report to Roche for such previous quarter the (i) gross sales of Covered Product made by ESP or its distributor, (ii) Net Sales (including those sales to a distributor) of Covered Products, (iii) cumulative annual Net Sales for the current calendar year, (iv) the amount of Bulk Product (at label strength) contained in the Covered Products sold by ESP during such covered Quarter, and (v) the calculation of payments due. With such report, ESP shall remit in U.S. dollars to Roche the payment due pursuant to Section 3.4(b).

5. Section 3.4(d) shall be deleted in its entirety and shall be replaced by the existing 3.4(e).

6. Section 3.4(f) shall be renumbered to become Section 3.4(e).

7. Sections 3.5(a), (b) and (c) and all of Section 3.6 shall be replaced in their entirety by the following:
3.5(a) Roche shall provide free Bulk Product to ESP on a quarterly basis at the rate of [*] percent ([*]%) of the number of grams at label strength contained in the Covered Product sold by ESP during the last Quarter for which ESP reported sales pursuant to Section 3.4(c). Such free Bulk

Product shall be added to shipments of Bulk Product ordered by ESP, and if no such shipment is made during any Quarter, the free Bulk Product shall be added to the next shipment made, if there is one. Such free Bulk Product shall be all the material supplied by Roche for samples, yield losses, overfill or other manufacturing issues; the only exception shall be replacement pursuant to Section 3.2 for Bulk Product that does not meet specifications set forth in Schedule A.

8. The transition from the old agreement pricing to the pricing above will be accomplished in the following manner, which is exemplified in the model attached as Exhibit A. Baxter (for inventory only) and ESP shall verify a calculation of the Transitional Royalty Credit (as defined below) substantially in the form of Exhibit A attached hereto which is provided as an example of how such calculation is made.

8.1 ESP and Baxter shall verify the amount of unsold inventory of Bulk Product, work in process ("W-I-P") and Covered Product on the day prior to the Amendment Date ("Audit Date") and determine the Total Grams of Bulk Product and Invoiced Grams of Bulk Product as described herein.

(a) The grams of Bulk Product contained in the W-I-P and Covered Product on the Audit Date shall be calculated by taking the number of individual ampoules in the W-I-P and Covered Product multiplied by 0.025 grams (the "Raw Material Equivalent").

The Raw Material Equivalent shall be added to the grams of Bulk Product on hand as of the Audit date to determine the "Total Grams of Bulk Product."

(b) ESP shall calculate a percentage (the "Invoiced Grams Percentage") by taking 100% minus (i) [*]% for Bulk Product acquired before September 1st, 2003, and (ii) [*]% for Bulk Product acquired after September 1st, 2003.

(c) ESP shall multiply the Total Grams of Bulk Product by the applicable Invoiced Grams Percentage to determine the total Invoiced Grams of Bulk Product.

These results shall be reported to Roche within ten (10) days after the Audit Date. ESP shall keep accurate records of such inventory and Roche shall have the option of auditing such records and corresponding batch records.

8.2 The parties agree to use [*] ($[*]) as the weighted average price for the previous three quarters to be used for this calculation, provided that if the Average Net Selling Price Per Gram for Q3 2003 varies from $[*], the actual Average Net Selling Price Per gram for Q3 shall be used to calculate the weighted average price according to the method in Exhibit A.

8.3 Multiply the Invoiced Grams of Bulk Product by the weighted average price calculated in accordance with 8.2 above.

8.4 Roche shall credit the resulting number in 8.3 against the first payments due Roche from ESP.

8.5 ESP shall pay Roche $[*] times the Total Grams of Bulk Product from 8.1 as payment for those grams ten (10) days after the Audit Date.

9. Beginning with the date of the signing of this letter and continuing until the earlier of (i) the Amendment Date or (ii) December 31, 2003, Roche shall grant ESP on a per Bulk Product shipment basis an additional [*] percent ([*]%) credit for free goods, for a total

of [*] percent ([*]%) when added to the [*] percent ([*]%) now given pursuant to Section 3.6(a). This shall be the total of free goods available to ESP and ESP agrees not to make any claim against Roche under Section 3.4(d) of the License and Supply Agreement.

All other terms of the Agreement remain in full force and effect.

Sincerely,

/s/ David R. Austin
David R. Austin

AGREED
ESP PHARMA, INC.

By /s/ Howard Weisman
Name Howard Weisman
Date 9-8-03

EXHIBIT A

Example of Transition Arrangement ESP Contract Change

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: May 5, 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

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: May 5, 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 will be provided to the Securities and Exchange Commission or its staff upon request.

Dated: May 5, 2005

By:

/s/ Mark McDade
Mark McDade
Chief Executive Officer

/s/ Glen Sato
Glen Sato
Chief Financial Officer