UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

[x] **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2005

or

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

For the transition period from _____ to _____ .

Commission file number: 1-9813

GENENTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-2347624**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1 DNA Way, South San Francisco, California 94080-4990
(Address of principal executive offices and Zip Code)

(650) 225-1000
(Registrant's telephone number, including area code)

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	**Number of Shares Outstanding**
Common Stock $0.02 par value	1,054,512,414 Outstanding at October 25, 2005

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In this report, "Genentech," "we," "us" and "our" refer to Genentech, Inc. "Common Stock" refers to Genentech's common stock, par value $0.02 per share, "Special Common Stock" refers to Genentech's callable putable common stock, par value $0.02 per share, all of which was redeemed by Roche Holdings, Inc. on June 30, 1999.

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin® (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis™ (ranibizumab, rhuFab V2) anti-VEGF antibody fragment; Nutropin® (somatropin (rDNA origin) for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen® (somatropin (rDNA origin) for injection) liquid formulation growth hormone; Nutropin Depot® (somatropin (rDNA origin) for injectable suspension) encapsulated sustained-release growth hormone; Omnitarg™ (pertuzumab) HER dimerization inhibitor; Protropin® (somatrem for injection) growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva® (efalizumab) anti-CD11a antibody; and TNKase™ (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva® (erlotinib HC1) is a registered trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks and trade names of other companies.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

GENENTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Operating revenues				
Product sales (including amounts from related parties: three months - 2005-$57,841 2004-$23,855; nine months - 2005-$140,195; 2004-$79,347)	$1,450,979	$1,005,511	$3,911,095	$2,682,577
Royalties (including amounts from related party: three months - 2005-$123,327; 2004-$83,099; nine months - 2005-$335,585; 2004-$238,468)	237,777	153,942	670,014	459,899
Contract revenue (including amounts from related parties: three months - 2005-$36,850; 2004-$15,271; nine months - 2005-$93,735; 2004-$85,783)	63,066	43,191	159,170	163,381
Total operating revenues	1,751,822	1,202,644	4,740,279	3,305,857
Costs and expenses				
Cost of sales (including amounts for related parties: three months - 2005-$44,802; 2004-$22,529; nine months - 2005-$133,658; 2004-$71,194)	230,127	165,990	750,649	467,153
Research and development (including amounts for related parties: three months - 2005-$54,984; 2004-$36,870; nine months - 2005-$142,839; 2004-$131,444) (including contract related: three months - 2005-$47,207; 2004-$18,673; nine months - 2005-$110,918; 2004-$90,168)	328,850	234,086	850,215	637,317
Marketing, general and administrative	349,323	264,648	1,021,174	788,616
Collaboration profit sharing (including amounts for related party: three months - 2005-$40,893; 2004-$21,560; nine months - 2005-$93,268; 2004-$48,209)	219,591	151,894	594,666	423,546
Recurring charges related to redemption	27,191	34,534	96,155	110,952
Special items: litigation-related	13,507	13,419	44,291	40,276
Total costs and expenses	1,168,589	864,571	3,357,150	2,467,860
Operating income	583,233	338,073	1,383,129	837,997
Other income, net	22,391	23,510	70,290	61,274
Income before taxes	605,624	361,583	1,453,419	899,271
Income tax provision	246,211	130,709	513,666	321,040
Net income	$ 359,413	$ 230,874	$ 939,753	$ 578,231
Earnings per share				
Basic	$ 0.34	$ 0.22	$ 0.89	$ 0.55
Diluted	$ 0.33	$ 0.21	$ 0.87	$ 0.53
Weighted-average shares used to compute earnings per share:				
Basic	1,060,539	1,055,140	1,055,028	1,057,006
Diluted	1,086,964	1,077,093	1,080,921	1,082,081

See Notes to Condensed Consolidated Financial Statements

GENENTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2005	**2004**
Cash flows from operating activities		
Net income	$ 939,753	$ 578,231
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	275,632	259,583
Deferred income taxes	(67,320)	(60,325)
Deferred revenue	(33,067)	(6,250)
Litigation-related liabilities	38,568	38,568
Tax benefit from employee stock options	480,390	274,918
Net gain on sales of securities available-for-sale and other, net	(4,070)	(11,736)
Write-down of securities available-for-sale	5,406	12,033
Changes in assets and liabilities:		
Receivables, prepaid expenses, and other current assets	(76,422)	(282,518)
Inventories	(31,046)	(90,280)
Investments in trading securities	(12,523)	(38,021)
Accounts payable, other accrued liabilities, and other long-term liabilities	131,966	177,854
Net cash provided by operating activities	1,647,267	852,057
Cash flows from investing activities		
Purchases of securities available-for-sale	(693,666)	(825,950)
Proceeds from sales and maturities of securities available-for-sale	574,637	772,058
Capital expenditures	(1,106,930)	(418,214)
Change in other assets	(23,235)	(33,674)
Transfer to restricted cash	(53,000)	4,600
Net cash used in investing activities	(1,302,194)	(501,180)
Cash flows from financing activities		
Stock issuances	633,685	421,093
Stock repurchases	(1,090,008)	(821,354)
Repayment of long-term debt and noncontrolling interests	(425,000)	-
Proceeds from issuance of long-term debt	1,987,955	-
Net cash provided by (used in) financing activities	1,106,632	(400,261)
Net increase (decrease) in cash and cash equivalents	1,451,705	(49,384)
Cash and cash equivalents at beginning of period	270,123	372,152
Cash and cash equivalents at end of period	$ 1,721,828	$ 322,768
Supplemental disclosure of cash flow information		
Non-cash investing and financing activities		
Capitalization of construction in progress related to financing lease transaction	$ 93,831	$ -
Exchange of XOMA note receivable for a prepaid royalty and other long-term asset	29,205	-

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2005	December 31, 2004
Assets		
Current assets		
Cash and cash equivalents	$ 1,721,828	$ 270,123
Short-term investments	1,183,715	1,394,982
Accounts receivable -- product sales (net of allowances: 2005-$68,668; 2004-$59,366; including amounts from related parties: 2005-$21,887; 2004-$11,237)	509,465	599,052
Accounts receivable -- royalties (including amounts from related party: 2005-$147,151; 2004-$119,080)	264,179	217,482
Accounts receivable -- other (net of allowances: 2005-$2,132; 2004-$2,191; including amounts from related parties: 2005-$109,909; 2004-$68,594)	189,341	143,421
Inventories	621,389	590,343
Prepaid expenses	109,157	45,864
Other current assets	195,505	164,073
Total current assets	4,794,579	3,425,340
Long-term marketable debt and equity securities	1,242,866	1,115,327
Property, plant and equipment, net	3,128,089	2,091,404
Goodwill	1,315,019	1,315,019
Other intangible assets	587,911	668,391
Restricted cash and investments	735,000	682,000
Other long-term assets	295,842	105,914
Total assets	$ 12,099,306	$ 9,403,395
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 193,321	$ 104,832
Taxes payable	34,478	151,406
Deferred revenue	44,586	45,989
Other accrued liabilities (including amounts to related parties: 2005-$140,562; 2004-$108,416)	1,082,553	935,803
Total current liabilities	1,354,938	1,238,030
Long-term debt	2,087,538	412,250
Deferred revenue	236,142	267,805
Litigation-related and other long-term liabilities	697,430	703,120
Total liabilities	4,376,048	2,621,205
Commitments and contingencies		
Stockholders' equity		
Preferred stock	-	-
Common stock	21,163	20,943
Additional paid-in capital	9,012,338	8,002,754
Accumulated other comprehensive income	259,146	290,948
Accumulated deficit, since June 30, 1999	(1,569,389)	(1,532,455)
Total stockholders' equity	7,723,258	6,782,190
Total liabilities and stockholders' equity	$ 12,099,306	$ 9,403,395

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of Presentation

We prepared the condensed consolidated financial statements following the requirements of the Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by accounting principles generally accepted in the United States of America (or "GAAP") can be condensed or omitted. 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 for the year ended December 31, 2004. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of our financial position and operating results.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those expected for the full year or any future period.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Genentech and all subsidiaries. As of December 31, 2004, Genentech also consolidated a variable interest entity in which Genentech was the primary beneficiary pursuant to Financial Accounting Standards Board (or "FASB") Interpretation No. 46 (or "FIN 46") "Consolidation of Variable Interest Entities," as amended, and recorded a noncontrolling interest in "litigation-related and other long-term liabilities" in the accompanying condensed consolidated balance sheet at December 31, 2004. As discussed below in Note 3, "Leases and Contingencies", during the third quarter of 2005, we paid $425.0 million to extinguish the debt and the noncontrolling interests related to a synthetic lease obligation on our manufacturing plant in Vacaville, California, and no longer consolidate this entity. Material intercompany accounts and transactions have been eliminated.

Use of Estimates and Reclassifications

The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in our condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Certain reclassifications of prior period amounts have been made to our condensed consolidated financial statements to conform to the current period presentation.

Recent Accounting Pronouncements

In December 2004, the FASB issued a revision of Statement of Financial Accounting Standards (or "FAS") No. 123, "Accounting for Stock-Based Compensation." The revision is referred to as "FAS 123R -- Share-Based Payment", which supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," (or "APB 25") and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock plans. We expect to adopt FAS 123R using the modified prospective basis on January 1, 2006. We expect that our adoption of FAS 123R will result in compensation expense comparable to that disclosed below, before the effect of capitalizing manufacturing related compensation expenses into inventory. We are currently evaluating option valuation methodologies and assumptions in light of FAS 123R; the methodologies and assumptions we ultimately use to adopt FAS 123R may be different from those currently used as discussed below. We currently expect that our adoption of FAS 123R will have a

material impact on our consolidated results of operations.

Accounting for Stock-Based Compensation

Until we adopt FAS 123R, we will continue to follow APB 25 to account for employee stock options. Under APB 25, the intrinsic value method of accounting, no compensation expense is recognized because the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant. We apply FAS 123 for disclosure purposes only.

The following proforma net income and earnings per share (or "EPS") were determined as if we had accounted for our employee stock options and stock issued under our employee stock plan under the fair value method prescribed by FAS 123.

The Black-Scholes option valuation model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions and these assumptions can vary over time.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(In thousands, except per share amounts)			
Net income - as reported	$359,413	$ 230,874	$939,753	$ 578,231
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	43,083	45,920	125,736	133,643
Pro forma net income	$316,330	$ 184,954	$814,017	$ 444,588
Earnings per share:				
Basic-as reported	$ 0.34	$ 0.22	$ 0.89	$ 0.55
Basic-pro forma	$ 0.30	$ 0.18	$ 0.77	$ 0.42
Diluted-as reported	$ 0.33	$ 0.21	$ 0.87	$ 0.53
Diluted-pro forma	$ 0.29	$ 0.17	$ 0.75	$ 0.41

The fair value of options was estimated at the date of grant using a Black-Scholes option valuation model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Risk-free interest rate	4.2%	3.4%	4.2%	3.4%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility factors of the expected market price of our Common Stock	29%	33%	29%	33%
Weighted-average expected life of option (years)	4.2	4.2	4.2	4.3

Due to the redemption of our special common stock in June 1999 (or "Redemption") by Roche Holdings, Inc. (or "Roche"), there is limited historical information available to support our estimate of certain assumptions required to value employee stock options and the stock issued under our employee stock plan. In developing our estimate of expected term, we have determined that our historical share option exercise experience is a relevant indicator of future exercise patterns. We also take into account other available information, including industry averages. We primarily base our determination of expected volatility through our assessment of the implied volatility of our common stock. Implied volatility is the volatility assumption inherent in the market prices of a company's traded options.

Earnings Per Share

The following is a reconciliation of the denominator used in basic and diluted earnings per share (or "EPS") computations *(in thousands)*:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Numerator:				
Net income	$ 359,413	$ 230,874	$ 939,753	$ 578,231
Denominator:				
Weighted-average shares outstanding used for basic earnings per share	1,060,539	1,055,140	1,055,028	1,057,006
Effect of dilutive stock options	26,425	21,953	25,893	25,075
Weighted-average shares and dilutive stock options used for diluted earnings per share	1,086,964	1,077,093	1,080,921	1,082,081

The following is a summary of the outstanding options to purchase common stock that were excluded from the computation of diluted EPS because such options were anti-dilutive *(in thousands, except for exercise prices)*:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Number of shares	608	19,619	17,765	19,128
Range of exercise prices	$88.76 - $93.27	$49.90 - $59.61	$73.12 - $93.27	$52.43 - $59.61

Comprehensive Income

Comprehensive income is comprised of net income and other comprehensive income (or "OCI"). OCI includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in OCI changes in the fair value of derivatives designated as effective cash flow hedges and unrealized gains and losses on our available-for-sale securities.

The components of accumulated OCI, net of income taxes, were as follows *(in millions)*:

	September 30, 2005	December 31, 2004
Unrealized gains on securities available-for-sale	$ 238.0	$ 305.1
Unrealized gains (losses) on derivatives	21.1	(14.2)
Accumulated other comprehensive income	$ 259.1	$ 290.9

The activity in comprehensive income, net of income taxes, was as follows *(in millions)*:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income	$ 359.4	$ 230.9	$ 939.8	$ 578.3
Decrease in unrealized gains on securities available-for-sale	(12.3)	(2.7)	(67.1)	(6.8)
Increase (decrease) in unrealized gains on derivatives	(1.5)	2.0	35.3	1.2
Comprehensive income	$ 345.6	$ 230.2	$ 908.0	$ 572.7

Derivative Financial Instruments

At September 30, 2005, estimated net gains on cash flow hedge derivative instruments expected to be reclassified from accumulated OCI to "other income, net" during the next twelve months are $37.8 million.

In July 2005, we entered into a series of interest rate swaps with a total notional value of $500.0 million. In these swaps, we pay a floating rate and receive a fixed rate that matches the coupon rate of the 5 year Notes due in 2010 (see Note 4, "Debt Issuance"). The objective of these swaps is to protect the debt maturing in five years against changes in fair value due to changes in interest rates.

Note 2. Consolidated Financial Statement Detail

Inventories

The components of inventories were as follows *(in millions)*:

	September 30, 2005	December 31, 2004
Raw materials and supplies	$ 62.4	$ 57.1
Work in process	383.9	451.8
Finished goods	175.1	81.5
Total	$ 621.4	$ 590.4

Other Intangible Assets

The components of our other intangible assets, including those that are acquisition-related and arising from the Redemption and push-down accounting were as follows *(in millions)*:

	September 30, 2005			December 31, 2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Developed product technology	$ 1,194.1	$ 906.2	$ 287.9	$ 1,194.1	$ 847.7	$ 346.4
Core technology	443.5	366.9	76.6	443.5	351.0	92.5
Developed science technology	467.5	467.5	-	467.5	452.9	14.6
Tradenames	144.0	81.9	62.1	144.0	74.7	69.3
Patents	158.9	61.5	97.4	138.0	53.2	84.8
Other intangible assets	111.9	48.0	63.9	101.3	40.5	60.8
Total	$ 2,519.9	$ 1,932.0	$ 587.9	$ 2,488.4	$ 1,820.0	$ 668.4

Amortization expense of our other intangible assets was $32.7 million and $38.7 million for the third quarters of 2005 and 2004, respectively, and $112.0 million and $143.1 million in the first nine months of 2005 and 2004, respectively.

The expected future annual amortization expense of our other intangible assets is as follows *(in millions)*:

For the Year Ending December 31,	Amortization Expense
2005 (remaining three months)	$ 32.2
2006	125.7
2007	124.4
2008	122.6
2009	73.5
Thereafter	109.5
Total expected future annual amortization	$ 587.9

Property, Plant and Equipment

In June 2005, we acquired Biogen Idec Inc.'s Oceanside, California biologics manufacturing facility (or "Oceanside plant") for $408.1 million in cash plus $9.3 million in closing costs. The purchase price allocation for this purchase is as follows (*in millions*):

Land and land improvements	$	42.2
Building		110.2
Equipment		36.7
Construction in progress		228.3
Total	$	417.4

Note 3. Leases and Contingencies

Leases

During the third quarter of 2005, we paid $160.0 million to exercise our right to purchase a research facility in South San Francisco, California, subject to a synthetic lease obligation. As a result, the value of the building in South San Francisco is now included in the accompanying condensed consolidated balance sheet at September 30, 2005. Also during the third quarter of 2005, we paid $425.0 million to extinguish the debt and the noncontrolling interests related to a synthetic lease obligation on our manufacturing plant in Vacaville, California. As discussed in Note 6, "Leases, Commitments and Contingencies" of our Annual Report on Form 10-K for the year ended December 31, 2004, the lease for our manufacturing plant in Vacaville was accounted for under the provisions of FIN 46R, a revision of Interpretation 46.

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to our South San Francisco campus. The property will be developed into eight buildings and two parking structures. The lease of the property will take place in two phases pursuant to separate lease agreements for each building as contemplated by the Master Lease Agreement. Phase I building leases will begin throughout 2006 and Phase II building leases may begin as early as 2008. For accounting purposes, due to the nature of our involvement with the construction of the buildings subject to the Master Lease Agreement, we are considered to be the owner of the assets during the construction period through the lease commencement date, even though the funds to construct the building shell and some infrastructure costs are paid by the lessor. As such, in the first nine months of 2005, we have capitalized $93.8 million of construction costs in property, plant and equipment, and have also recognized a corresponding amount as a construction financing obligation in "long-term debt" in the accompanying condensed consolidated balance sheets. We expect at the time of completion of the project, if all the buildings and infrastructure were completed by the lessor, our construction asset and related obligation will be in excess of $365.0 million. Our aggregate lease payments as contemplated by the Master Lease Agreement through 2020 (if there is no acceleration or delay in the rent commencement date for the second phase of the buildings) will be approximately $540.1 million.

Contingencies

We are a party to various legal proceedings, including patent infringement litigation and licensing and contract disputes, and other matters.

On October 4, 2004, we received a subpoena from the United States (or "U.S.") Department of Justice, requesting documents related to the promotion of Rituxan, a prescription treatment approved for the treatment of relapsed or refractory, low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma. We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. The outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (or "COH") are parties to a 1976 agreement relating to work

conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, Genentech has entered into license agreements with various companies to make, use and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to the COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. On June 10, 2002, a jury voted to award the COH approximately $300 million in compensatory damages. On June 24, 2002, a jury voted to award the COH an additional $200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and were included in the accompanying condensed consolidated balance sheets in "litigation-related and other long-term liabilities" at September 30, 2005 and December 31, 2004. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. On October 21, 2004, the California Court of Appeal affirmed the verdict and damages awards in all respects. On November 22, 2004, the California Court of Appeal modified its opinion without changing the verdict and denied Genentech's request for rehearing. On November 24, 2004, Genentech filed a petition seeking review by the California Supreme Court. On February 2, 2005, the California Supreme Court granted that petition. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter; however, we expect that it may take longer than one year to further resolve the matter.

We recorded accrued interest and bond costs related to the COH trial judgment of $13.5 million and $13.4 million in the third quarters of 2005 and 2004, respectively, and $40.5 million and $40.3 million in the first nine months of 2005 and 2004, respectively. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of $682.0 million at December 31, 2004 to secure the bond. During the third quarter of 2005, COH requested that we increase the surety bond value by $50.0 million to secure the accruing interest, and we correspondingly increased the pledge amount to secure the bond by $53.0 million to $735.0 million at September 30, 2005. These amounts are reflected in "restricted cash and investments" in the accompanying condensed consolidated balance sheets. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results.

On August 12, 2002, the U.S. Patent and Trademark Office (or "Patent Office") declared an interference between U.S. Patent No. 6,054,561, owned by Chiron Corporation (or "Chiron"), and a patent application exclusively licensed by Genentech from a university relating to anti-HER2 antibodies. On October 24, 2002, the Patent Office redeclared the interference to include, in addition to the above-referenced Chiron patent and university patent application, a number of patents and patent applications owned by either Chiron or Genentech, including Chiron's U.S. Patent No. 4,753,894 that is also at issue in the separate patent infringement lawsuit described below. On November 30, 2004, the Patent Office's Board of Patent Appeals (the "Board") and Interferences issued rulings on several preliminary motions. These rulings terminated both interferences involving the patent application referenced above that Genentech licensed from a university, redeclared interferences between the Genentech and Chiron patents and patent applications, and made several determinations which could affect the validity of the Genentech and Chiron patents and patent applications involved in the remaining interferences. On January 28, 2005, Genentech filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. On June 1, 2005, we and Chiron agreed to a settlement of both these interference proceedings and the below-referenced lawsuit. Under the settlement agreement, Chiron has abandoned the contest as to each count in both of the redeclared interferences referenced above. On September 30, 2005, the Board filed two Orders and issued two Judgments ordering judgment against both parties as to the subject matter of both counts at issue in the interferences and declaring that neither party is entitled to any of the claims corresponding to the count. We are evaluating on which issues, if any, we will seek review so the final outcome of this matter with respect to our patents and patent applications cannot be determined at this time.

On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 (or "the '415 patent" or "Cabilly patent") that is co-owned by Genentech and COH and under which MedImmune and other companies have been licensed and are paying royalties to Genentech. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking to have the '415 patent declared invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the '415 patent on sales of its

Synagis® antibody product, an injunction to prevent Genentech from enforcing the '415 patent, an award of actual and exemplary damages, and other relief. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in Genentech's favor on all of MedImmune's antitrust and unfair competition claims. MedImmune sought to amend its complaint to reallege certain claims for antitrust and unfair competition. On February 19, 2004, the Court denied this motion in its entirety and final judgment was entered in favor of Genentech and Celltech and against MedImmune on March 15, 2004 on all antitrust and unfair competition claims. MedImmune filed a notice of appeal of this judgment with the U.S. Court of Appeals for the Federal Circuit. Concurrently, in the District Court litigation, Genentech filed a motion to dismiss all remaining claims in the case. On April 23, 2004, the District Court granted Genentech's motion and dismissed all remaining claims. Final judgment was entered in Genentech's favor on May 3, 2004, thus concluding proceedings in the District Court. On October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. Because MedImmune still has the opportunity to seek further review of this decision before the Federal Circuit and the United States Supreme Court, the final outcome of this matter cannot be determined at this time.

On May 13, 2005, a request was filed by a third party for reexamination of the '415 or Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent Office ordered reexamination of the '415 patent. On September 13, 2005, the Patent Office issued an initial "non-final" Office action rejecting the claims of the '415 or Cabilly patent. This action is a routine and expected next step in the reexamination procedure. Our response is due within 60 days from the mailing date of the action; however on October 26, 2005 we filed a request with the Patent Office for an additional 30 days in which to file the response. The Patent Office has not yet acted on that request. Because the reexamination process is ongoing, the final outcome of this matter cannot be determined at this time. The '415 patent, which expires in 2018, relates to methods we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. We have licensed the '415 patent to other companies and derive significant royalties from those licenses. The claims of the '415 patent remain valid and enforceable throughout the reexamination process.

Note 4. Debt Issuance

On July 18, 2005, we completed a private placement of the following debt instruments: $500.0 million principal amount of 4.40% Senior Notes due 2010, $1.0 billion principal amount of 4.75% Senior Notes due 2015 and $500.0 million principal amount of 5.25% Senior Notes due 2035 (collectively, the "Notes"). Interest on each series of notes is payable on January 15 and July 15 of each year, beginning on January 15, 2006. Net proceeds resulting from issuance of the Notes, after debt discount and issuance costs, were approximately $1.99 billion. The Notes contain certain restrictive covenants on incurring property liens and entering into sale and lease-back transactions.

Interest expense related to the debt issuance, net of amounts capitalized, was $18.3 million for the third quarter of 2005.

As of September 30, 2005, the future minimum principal payments under the Notes are as follows *(in millions)*:

2006	$	-
2007		-
2008		-
2009		-
2010		500.0
Thereafter		1,500.0
Total	$	2,000.0

Note 5. Relationship with Roche and Related Party Transactions

Relationship with Roche

Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock

We issue additional shares of common stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. The affiliation agreement provides that we will repurchase a sufficient number of shares pursuant to this program such that, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance will be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999, October 2000 and May 2004. We repurchased shares of our common stock in 2005 and 2004 (see discussion below in "Liquidity and Capital Resources -- Cash Provided by or Used in Financing Activities" in Management's Discussion and Analysis of Financial Condition and Results of Operations in Part I, Item 2 of this Form 10-Q). As long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, the affiliation agreement provides that we will repurchase a sufficient number of shares of our common stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The affiliation agreement also provides that, upon Roche's request, we will repurchase shares of our common stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. The Minimum Percentage at September 30, 2005 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be 55.7%. At September 30, 2005, Roche's ownership percentage was 55.5%. We expect that future share repurchases under our share repurchase program will increase Roche's ownership percentage.

Related Party Transactions

We enter into transactions with our related parties, Roche and other Roche affiliates (including F. Hoffmann-La Roche (or "Hoffmann-La Roche")) and Novartis Pharma AG (or "Novartis"), in the ordinary course of business. The accounting policies we apply to our transactions with our related parties are consistent with those applied in transactions with independent third-parties and all related party agreements are negotiated on an arm's-length basis.

Hoffmann-La Roche

Under our existing arrangements with Hoffmann-La Roche, including our licensing and marketing agreements, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of $23.9 million and $4.3 million in the third quarters of 2005 and 2004, respectively, and $58.8 million and $53.9 million in the first nine months of 2005 and 2004, respectively. All other revenues from Hoffmann-La Roche and their affiliates, principally royalties and product sales, were $181.4 million and $106.9 million in the third quarters of 2005 and 2004, respectively, and $470.9 million and $317.5 million in the first nine months of 2005 and 2004, respectively. Cost of sales (or "COS") included amounts related to Hoffmann-La Roche of $44.8 million and $22.5 million in the third quarters of 2005 and 2004, respectively, and $118.6 million and $70.8 million in the first nine months of 2005 and 2004, respectively. Research and development (or "R&D") expenses included amounts related to Hoffmann-La Roche of $42.4 million and $25.7 million in the third quarters of 2005 and 2004, respectively, and $110.4 million and $100.4 million in the first nine months of 2005 and 2004, respectively.

Novartis

We understand that the Novartis Group holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, the Novartis Group is deemed to have an indirect beneficial ownership

interest under FAS 57 "Related Party Disclosures" of more than 10% of Genentech's voting stock.

Under an arrangement with Novartis, a holding company of the Novartis Group, and Tanox, Inc., we currently supply Xolair and receive cost plus a mark-up similar to other supply arrangements. Novartis will be manufacturing all future worldwide bulk supply of Xolair at their Huningue production facility in France, upon U.S. Food and Drug Administration licensure, expected in early 2006. Future production costs of Xolair may initially be higher than those currently reflected in our COS as a result of any production shift from Genentech to Novartis until production economies of scale can be achieved by that manufacturing party.

Contract revenue from Novartis related to manufacturing, commercial and ongoing development activities, was $13.0 million and $11.0 million in the third quarters of 2005 and 2004, respectively, and $34.9 million and $31.9 million in the first nine months of 2005 and 2004, respectively. Revenue from Novartis related to product sales was not material in the third quarters and the first nine months of 2005 and 2004. COS was not material in the third quarters of 2005 and 2004. COS was $15.1 million in the first nine months of 2005, which included a one-time payment in the second quarter of 2005 related to our release from future manufacturing obligations. COS was not material in the first nine months of 2004. R&D expenses include amounts related to Novartis of $12.6 million and $11.2 million in the third quarters of 2005 and 2004, respectively, and $32.4 million and $31.0 million in the first nine months of 2005 and 2004, respectively. Collaboration profit sharing expenses were $40.9 million and $21.6 million in the third quarters of 2005 and 2004, respectively, and $93.3 million and $48.2 million in the first nine months of 2005 and 2004, respectively.

Note 6. Income Taxes

The effective income tax rate was 41% in the third quarter and 35% for first nine months of 2005, as compared to 36% in the third quarter and first nine months of 2004. The increase in the income tax rate from the third quarter of 2004 is primarily due to increased income before taxes and a reduction of $27.1 million in estimated R&D tax credits primarily related to the current year. The decrease in the income tax rate from the first nine months of 2004 primarily relates to a net benefit from recognizing additional R&D tax credits, partially offset by higher income before taxes.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Genentech, Inc.

We have reviewed the condensed consolidated balance sheet of Genentech, Inc. as of September 30, 2005, and the related condensed consolidated statements of income for the three-month and nine-month periods ended September 30, 2005 and 2004, and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2005 and 2004. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the condensed consolidated interim financial statements referred to above for them to be in conformity with U.S. generally accepted accounting principles.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Genentech, Inc. as of December 31, 2004, and the related consolidated statements of income, stockholders' equity, and cash flows for the year then ended not presented herein, and in our report dated February 18, 2005, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2004, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ ERNST & YOUNG LLP

Palo Alto, California
October 10, 2005

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

GENENTECH, INC.
FINANCIAL REVIEW

Overview

The Company

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. We manufacture multiple biotechnology products and commercialize such products directly in the United States (or "U.S.") and also receive royalties from companies that are licensed to market products based on our technology.

Recent Developments

In the third quarter of 2005, our total operating revenues were $1,751.8 million, an increase of 46% from the third quarter of 2004, and our net income was $359.4 million, an increase of 56% from the third quarter of 2004. In the first nine months of 2005, our total operating revenues were $4,740.3 million, an increase of 43% from the first nine months of 2004, and our net income was $939.8 million, an increase of 63% from the first nine months of 2004.

On July 18, 2005, we completed a private placement of the following debt instruments: $500.0 million principal amount of 4.40% Senior Notes due 2010, $1.0 billion principal amount of 4.75% Senior Notes due 2015 and $500.0 million principal amount of 5.25% Senior Notes due 2035. We received approximately $1.99 billion in net proceeds from this offering, after deducting estimated selling and offering expenses.

As announced in September 2005, we plan to file a complete Biologics License Application (or"BLA") for Lucentis in the treatment of the wet form of age-related macular degeneration (or "AMD") in December 2005, based, in part, on a Lucentis Phase III clinical trial that met its primary efficacy endpoint of maintaining vision in patients with wet AMD. We are aware that some retinal specialists are currently using Avastin to treat wet AMD, an unapproved use. We have no clinical data on either the safety or efficacy of Avastin in this use nor do we have any plans for a clinical development program evaluating Avastin in AMD. Further, we are concerned about the potential sterility issues associated with aliquoting vials of Avastin into smaller portions and held for use as an intravitreal injection. However, there may be continued Avastin use in this setting even after Lucentis has been approved for commercial use, which may decrease the market potential for Lucentis. We remain focused on making Lucentis available to patients by seeking FDA approval as soon as possible.

Our Strategy

We are in the final year of our 5x5 business plan. We expect to exceed our most important goal of average annual non-GAAP EPS growth. We believe that we are well-positioned to exceed our goal of five significant products/indications in late stage development and have already exceeded our goal of five new products or indications approved through 2005. We expect to have substantive progress against our goal of $500 million in new revenue from alliances and/or acquisitions; however, we may not meet this goal. We do not expect to meet our non-GAAP net income as a percentage of total operating revenues goal, due primarily to the success of Rituxan and the associated profit split with Biogen Idec, Inc. (or "Biogen Idec"). Information on our 5x5 plan can be found on our website at http://www.gene.com.

We have a long-term plan (Horizon 2010) and the key elements of Horizon 2010 include:

- aim to become the number one U.S. oncology company (measured by U.S. sales) by 2010;

- position ourselves for continued leadership in our oncology business by bringing five new oncology products or indications for existing products into clinical development and into the market by 2010;

- build a leading immunology business by expanding the fundamental understanding of immune disorders, bringing at least five new immunology products or indications into clinical development, and obtaining U.S. Food and Drug Administration (or "FDA") approval of at least five new indications or products by 2010;

- increase our leadership in developing biotherapeutics for disorders of tissue growth and repair, with a major focus on angiogenic disorders, and to move at least three new projects into late-stage research or developmental research and three or more new projects into clinical development by 2010; and

- achieve average annual non-GAAP EPS growth rates through 2010 sufficient to be considered a growth company.

Our actual performance against these goals may be impacted by economic and industry-wide factors and by the cautionary factors described later in this Form 10-Q.

Economic and Industry-wide Factors

Our goals and objectives are challenged by economic and industry-wide factors that affect our business. Some of the most important factors are discussed below:

- Successful development of biotherapeutics is highly difficult and uncertain. Our long-term business growth depends upon our ability to commercialize important new therapeutics to treat unmet medical needs such as cancer. Since the underlying biology of these diseases is not completely understood, it is very challenging to discover and develop safe and effective treatments, and the majority of potential new therapeutics fail to generate the safety and efficacy data required to obtain regulatory approval. In addition, there is tremendous competition in the diseases of interest to us. Our business requires significant investments in research and development (or "R&D") over many years, often for products that fail during the R&D process. In addition, after our products receive FDA approval, they remain subject to ongoing FDA regulation, including changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisement to physicians, or product recalls. We believe that our continued focus on excellent science, compelling biological mechanisms, and designing high quality clinical trials to address significant medical needs positions us well to deliver sustainable growth.

- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection on one or more products could result in lost sales to competing products and negatively affect our sales, royalty revenues and operating results. We are often involved in disputes over contracts and intellectual property and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.

- Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. The manufacture of a biotherapeutic requires developing and maintaining a process to reliably manufacture and formulate the product at an appropriate scale, obtaining regulatory approval to manufacture the product, and is subject to changes in regulatory requirements or standards that may require modifications to the involved manufacturing process or FDA action (see below in "Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively impact our financial performance" of "Forward-Looking Information and Cautionary Factors That May Affect Future Results").

- The Medicare Modernization Act was enacted into law in December 2003. On November 3, 2004, the 2005 Physician Fee Schedule and Hospital Outpatient Prospective Payment System Final Rules were announced and were in-line with our expectations. As Centers for Medicare and Medicaid Services (or "CMS") is our single largest payer, the new rules represent an important area of focus in 2005. To date, we have not seen any detectable effects of the new rules on our product sales. For the remainder of 2005, we continue to anticipate minimal impact to our revenues. On July 1, 2005, CMS released its Interim Final Rule (or "IFR") with comment on the Medicare Part B Competitive Acquisition Program (or "CAP"). The CAP option, which the CMS expects to begin in July 2006, required under the Medicare Modernization Act, will be offered to physicians providing services under Part B of Medicare. Under the CAP, physicians could choose to either obtain drugs directly from qualified CAP vendors, or continue to purchase drugs directly and be reimbursed by the Medicare program at the Average Selling Price + 6% rate. Although final details of the program will not be made public until later this year, we anticipate that the impact of the program on Genentech will be minimal.

- With respect to follow-on biologics, we believe that current technology cannot prove a follow-on biotechnology product to be safe and effective outside the New Drug Application and BLA process. We filed a Citizen Petition with the FDA in April 2004 requesting that the agency re-assess its approach to approvals of follow-on biologics and put processes in place to protect trade secrets and confidential information from use by others. The FDA initiated a public process to discuss the complex scientific issues surrounding follow-on biologics and we participated in the FDA Stakeholder meeting in September 2004. Following this meeting, the FDA and Drug Information Association held a scientific workshop in February 2005, which we hope will be followed by a similar public discussion of the critical legal issues involved with establishing an approval pathway for follow-on biologics.

- Our ability to attract and retain highly qualified and talented people in all areas of the company, and our ability to maintain our unique culture, will be critical to our success over the long-term. In 2004 we experienced a 23% growth in the number of employees to approximately 7,600 employees and we have since grown to approximately 9,000 employees company-wide as of September 30, 2005. This significant growth in employees is challenging to manage and we are working diligently across the company to make sure that we successfully hire, train and integrate new employees into the Genentech culture and environment. Consistent with our desire to maintain and protect our culture, we have made a decision to continue with a broad based stock option program in 2005. We believe our broad-based stock option program is critical to attracting, retaining, and motivating our employees in the marketplace where we compete for talent, and we believe that employee ownership drives commitment to meeting our corporate goals.

Marketed Products

We commercialize in the U.S. the biotechnology products listed below.

Oncology

Avastin (bevacizumab) is an anti-VEGF humanized antibody approved for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum.

Rituxan (rituximab) is an anti-CD20 antibody, which we commercialize with Biogen Idec. It is approved for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, including retreatment and bulky disease.

Herceptin (trastuzumab) is a humanized anti-HER2 antibody approved for the treatment of certain patients with metastatic breast cancer. Herceptin is approved for use as a first-line therapy in combination with Taxol® (paclitaxel), a product made by Bristol-Myers Squibb Company, and as a single agent in second- and third-line therapy in patients with metastatic breast cancer who have tumors that overexpress the human epidermal growth

factor receptor 2 (or "HER2") protein.

Tarceva (erlotinib HC1), which we commercialize with OSI Pharmaceuticals, Inc. (or "OSI"), is a small molecule inhibitor of the tyrosine kinase activity of the HER1/epidermal growth factor receptor (or "EGFR") signaling pathway. Tarceva is approved for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (or "NSCLC") after failure of at least one prior chemotherapy regimen and in combination with gemcitabine chemotherapy for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

Specialty Biotherapeutics

Xolair (omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis in the U.S., approved for the treatment of moderate-to-severe persistent allergic asthma in adults and adolescents.

Raptiva (efalizumab) is a humanized anti-CD11a antibody approved for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy.

Nutropin (somatropin [rDNA origin] for injection) and *Nutropin AQ* are growth hormone products approved for the treatment of growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency prior to kidney transplantation, short stature associated with Turner syndrome and long-term treatment of idiopathic short stature (or "ISS").

Activase (alteplase, recombinant) is a tissue plasminogen activator (or "t-PA") approved for the treatment of acute myocardial infarction (heart attack), acute ischemic stroke (blood clots in the brain) within three hours of the onset of symptoms and acute massive pulmonary embolism (blood clots in the lungs).

Cathflo Activase (alteplase, recombinant) is a t-PA approved in adult and pediatric patients for the restoration of function to central venous access devices that have become occluded due to a blood clot.

TNKase (tenecteplase) is a single-bolus thrombolytic agent approved for the treatment of acute myocardial infarction (heart attack).

Pulmozyme (dornase alfa, recombinant) is an inhalation solution of deoxyribonuclease (rhDNase) I approved for the treatment of cystic fibrosis.

Licensed Products

We receive royalties from F. Hoffmann-La Roche (or "Hoffmann-La Roche") on sales of:

- Herceptin, Pulmozyme, and Avastin outside of the U.S.,
- Rituxan outside of the U.S., excluding Japan, and
- Nutropin products, Activase, Cathflo Activase and TNKase in Canada.

Available Information

The following information can be found on our website at http://www.gene.com or can be obtained free of charge by contacting our Investor Relations Department at (650) 225-1599 or by sending an e-mail message to investor.relations@gene.com:

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;

- our policies related to corporate governance, including Genentech's Principles of Corporate Governance, Good Operating Principles (Genentech's code of ethics applying to Genentech's directors, officers and employees) as well as Genentech's Code of Ethics applying to our Chief Executive Officer, Chief Financial Officer and senior financial officials; and

- the charter of the Audit Committee of our Board of Directors.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States (or "GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our condensed consolidated financial statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

Legal Contingencies

We are currently involved in certain legal proceedings as discussed in Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. We assess the likelihood of any adverse judgments or outcomes to these legal matters as well as potential ranges of probable losses. As of September 30, 2005, we have accrued $663.6 million in "litigation-related and other long-term liabilities" in the accompanying condensed consolidated balance sheet, which represents our estimate of the costs for the current resolution of these matters. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters different than previously estimated could materially impact our financial position or our results of operations in any one quarter.

Revenue Recognition

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

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

- We recognize revenue from royalties based on licensees' sales of our products or technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectibility is reasonably assured. Generally, royalty revenue is estimated in advance of collection using historical information and forecasted trends.

- Contract revenue generally includes upfront and continuing licensing fees, manufacturing fees, milestone payments and reimbursements of development and post-marketing costs.

    - Nonrefundable upfront fees, including product opt-ins, for which no further performance obligations exist, are recognized as revenue on the earlier of when payments are received or collection is assured.

    - Nonrefundable upfront licensing fees, including product opt-ins, and 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:

        - ratably over the development period if development risk is significant, or

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

    - Manufacturing fees are recognized as revenue as the related manufacturing services are rendered, generally on a straight-line basis over the longer of the manufacturing obligation period or the expected product life.

    - Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.

    - Estimated reimbursements of development and post-marketing costs are recognized as revenue as the related costs are incurred.

Income Taxes

Income tax expense is based on income before taxes and is computed using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, past and future levels of R&D spending, and changes in overall levels of income before taxes.

Inventories

Inventories consist of currently marketed products, products manufactured under contract, product candidates awaiting regulatory approval and currently marketed products manufactured at facilities awaiting regulatory approval, which are capitalized based on management's judgment of probable near term commercialization. The valuation of inventory requires us to estimate the value of inventory that may become obsolete prior to use or that may fail to be released. The determination of obsolete inventory requires us to estimate the future demands for our products, and in the case of pre-approval inventories, an estimate of the regulatory approval date for the product. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies or new information that suggests that the inventory will not be releasable. In the event that a pre-approval product candidate receives regulatory approval, subsequent sales of previously reserved inventory will result in increased gross margins.

Results of Operations
(In millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	2004	% Change	2005	2004	% Change
Product sales	$ 1,451.0	$ 1,005.5	44 %	$ 3,911.1	$ 2,682.6	46 %
Royalties	237.8	153.9	55	670.0	459.9	46
Contract revenue	63.0	43.2	46	159.2	163.4	(3)
Total operating revenues	1,751.8	1,202.6	46	4,740.3	3,305.9	43
Cost of sales	230.1	166.0	39	750.6	467.2	61
Research and development	328.9	234.1	40	850.2	637.3	33
Marketing, general and administrative	349.3	264.6	32	1,021.2	788.6	29
Collaboration profit sharing	219.6	151.9	45	594.7	423.5	40
Recurring charges related to redemption	27.2	34.5	(21)	96.1	111.0	(13)
Special items: litigation-related	13.5	13.4	1	44.3	40.3	10
Total costs and expenses	1,168.6	864.5	35	3,357.1	2,467.9	36
Operating income	583.2	338.1	72	1,383.2	838.0	65
Other income, net	22.4	23.5	(5)	70.3	61.3	15
Income before taxes	605.6	361.6	67	1,453.5	899.3	62
Income tax provision	246.2	130.7	88	513.7	321.0	60
Net income	$ 359.4	$ 230.9	56	$ 939.8	$ 578.3	63
Operating margin	33 %	28 %		29 %	25 %	
COS as a % of product sales	16	17		19	17	
R&D as a % of operating revenues	19	19		18	19	
MG&A as a % of operating revenues	20	22		22	24	
NI as a % of operating revenues	21	19		20	17	

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Percentages in this table and throughout our discussion and analysis of financial condition and results of operations may reflect rounding adjustments.

Total Operating Revenues

Total operating revenues increased 46% in the third quarter of 2005 and 43% in the first nine months of 2005 from the comparable periods in 2004. These increases were primarily due to higher product sales and royalty income, and are further discussed below.

Total Product Sales
(In millions)

Product Sales	Three Months Ended September 30, 2005	2004	% Change	Nine Months Ended September 30, 2005	2004	% Change
Net U.S. Product Sales						
Rituxan	$ 456.2	$ 393.0	16 %	$ 1,347.0	$ 1,144.8	18 %
Avastin	325.2	183.0	78	773.8	354.1	119
Herceptin	215.1	126.3	70	497.1	353.0	41
Tarceva	73.2	-	-	191.0	-	-
Nutropin products	88.6	84.9	4	275.6	256.9	7
Xolair	81.6	53.9	51	227.3	127.3	79
Thrombolytics	57.9	52.9	9	160.1	147.1	9
Pulmozyme	46.6	39.8	17	137.5	114.4	20
Raptiva	20.9	16.2	29	58.8	36.0	63
Total U.S. product sales	1,365.3	950.0	44	3,668.2	2,533.6	45
Net product sales to collaborators	85.7	55.5	54	242.9	149.0	63
Total product sales	$ 1,451.0	$ 1,005.5	44	$ 3,911.1	$ 2,682.6	46

Total product sales increased 44% to $1,451.0 million in the third quarter and 46% to $3,911.1 million in the first nine months of 2005 from the comparable periods in 2004. Net U.S. sales increased 44% to $1,365.3 million in the third quarter and 45% to $3,668.2 million in the first nine months of 2005 from the comparable periods in 2004. These increases in net U.S. sales were due to higher sales across all products, in particular higher sales of our oncology products. Net U.S. oncology sales accounted for 78% of net U.S. product sales in the third quarter of 2005 compared to 74% in the third quarter of 2004, and 77% in the first nine months of 2005 compared to 73% in the first nine months of 2004. Increased U.S. sales volume, including new product shipments, accounted for 88%, or $358.4 million, of the increase in U.S. net product sales in the third quarter of 2005, and 89%, or $1,001.9 million, of the increase in the first nine months of 2005. Changes in net U.S. sales prices across the portfolio accounted for most of the remainder of the increases in U.S. net product sales in the third quarter and first nine months of 2005.

Avastin

Net U.S. sales of Avastin increased 78% to $325.2 million in the third quarter and 119% to $773.8 million in the first nine months of 2005 from the comparable periods in 2004, mainly driven by increased use in colorectal cancer. In the treatment of colorectal cancer in both the first-line (our approved indication) and relapsed/refractory (unapproved uses) settings, Avastin is being combined with a wide range of 5FU-based chemotherapies. While there has been rapid uptake in the first-line setting, opportunities remain to further increase duration of therapy on Avastin and to continue efforts to appropriately identify eligible patients. We also anticipate long-term growth to result from use in potential new indications, including metastatic non-small-cell lung and breast cancers. Our market research indicates that approximately 15% of patients receiving Avastin in the third quarter of 2005 were outside of metastatic colorectal cancer, compared to approximately 10% in the second quarter of 2005. Treatment of metastatic NSCLC, which is an unapproved use of Avastin, comprises the largest portion of these patients. In addition, adoption has been seen across several other tumor types which are also unapproved uses.

In August and September 2005, the U.S. Pharmacopeia Drug Information® (or "USP DI") issued certain decisions on the use of Avastin in lung, renal cell carcinoma and relapsed colorectal cancer. On September 6, 2005, the USP DI accepted the Avastin NSCLC data. A review that is deemed acceptable by the USP DI supports Medicare reimbursement by statute and facilitates reimbursement with the private payers. We anticipate that payers will take one to three months to update their systems. In contrast, the USP DI has deemed the data on Avastin use in renal cell carcinoma and relapsed colorectal cancer as not sufficient to establish acceptance at this time. We plan to re-submit the request in relapsed colorectal cancer. We are still waiting for the decision on the first-line metastatic breast cancer submission for Avastin.

On September 23, 2005, we announced that enrollment into a multi-center, single-arm Phase II study of Avastin in platinum-refractory ovarian cancer patients has been discontinued due to a higher rate of gastrointestinal (or "GI") perforations seen than in previous studies with Avastin.

On October 31, the FDA approved production of Avastin at Genentech España, our manufacturing facility in Porriño, Spain, for commercial marketing. Since July 2004, our Porriño facility has been manufacturing bulk Avastin, which has been exported to our South San Francisco facility for filling and used for clinical studies.

In the fourth quarter of 2005, we plan to submit a supplemental Biologics License Application (or "sBLA") for Avastin in relapsed colorectal cancer, based on the results announced in November 2004 from the E3200 study that showed Avastin in combination with FOLFOX4 (5-FU, leucovorin, oxaliplatin) improved overall survival in patients with metastatic colorectal cancer as compared to FOLFOX alone.

Rituxan

Net U.S. sales of Rituxan increased 16% to $456.2 million in the third quarter and 18% to $1,347.0 million in the first nine months of 2005 from the comparable periods in 2004. Net U.S. sales in the first nine months of 2005 included $9.6 million for a reorder to replace a shipment that was destroyed while in transit to a wholesaler in the first quarter of 2005. Net U.S. sales growth was primarily driven by increased sales volumes resulting from increased physician adoption for treatment of indolent non-Hodgkin's lymphoma (or "NHL") maintenance and chronic lymphocytic leukemia, which are both unapproved uses of Rituxan. With respect to indolent maintenance, we are working with the FDA toward a nomenclature that the FDA believes better describes this approach to treating patients with Rituxan. Also contributing to the increase in the third quarter and first nine months of 2005 over the comparable periods in 2004 was a price increase that was effective on July 6, 2005.

On August 17, 2005, we, Biogen Idec and Roche announced that the companies completed the filing of a sBLA with the FDA for an additional indication for Rituxan, in previously untreated (front-line) patients with intermediate grade or aggressive, CD-20-positive, B-cell, NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens. In October 2005, the FDA notified us that priority review had been granted for this filing.

On August 31, 2005, we and Biogen Idec announced that the companies submitted a sBLA with the FDA for a new indication for Rituxan in patients with active rheumatoid arthritis who inadequately respond to an anti-TNF therapy. In October 2005, the FDA notified us that priority review had also been granted for this filing.

In September 2005, we obtained FDA licensure of Lonza Biologic's Portsmouth, New Hampshire manufacturing plant for the production of Rituxan bulk drug substance.

Herceptin

Net U.S. sales of Herceptin increased 70% to $215.1 million in the third quarter and 41% to $497.1 million in the first nine months of 2005 from the comparable periods in 2004. During the first nine months of 2005, treatment of first-line metastatic breast cancer increased and cumulative treatment duration was maintained by physicians relative to the comparable period in 2004. In addition, we have seen an increase in the use of Herceptin as an adjuvant breast cancer treatment, which is not an approved indication. Also contributing, to a lesser extent, to the increase in the third quarter and first nine months of 2005 over the comparable periods in 2004 was a price increase that was effective on February 24, 2005.

In September 2005, the USP DI accepted the Herceptin adjuvant breast cancer data. The USP DI decision should help support Medicare reimbursement by statute and facilitate reimbursement with the private payers. We anticipate that payers will take one to three months to update their systems.

We believe that the opportunity for continued Herceptin sales growth is primarily in the adjuvant setting, an unapproved use. We expect to submit an sBLA for Herceptin in the treatment of HER2 positive adjuvant breast

cancer in the first quarter of 2006 based on data from the National Surgical Adjuvant Breast and Bowel Project and the North Central Cancer Treatment Group trials. On September 13, 2005, we announced the results from an interim analysis of another Phase III trial of Herceptin plus chemotherapy in the adjuvant HER2 positive breast cancer setting. This study, conducted by the Breast Cancer International Research Group, showed that adding Herceptin to Taxotere following Adriamycin and Cytoxan chemotherapy or adding Herceptin to Taxotere and carboplatin chemotherapies resulted in improved disease-free survival compared to chemotherapy alone.

Tarceva

Tarceva was approved by the FDA on November 18, 2004. Since its launch, net U.S. sales of Tarceva were $73.2 million in the third quarter, $70.2 million in the second quarter and $47.6 million in the first quarter of 2005 as compared to $13.3 million in the fourth quarter of 2004. The increase in net U.S. product sales was driven primarily by growth in market share in second-line and third-line NSCLC. Product sales growth in the third quarter of 2005 was partially impacted by a reduction in wholesaler inventory levels. Tarceva's share of the oral EGFR market continues to increase. New patient share reached 98 percent in the third quarter of 2005, while total patient share reached 82 percent for the same period. In light of the share levels already achieved and the recent changes to the labeling for Iressa™ (gefitinib), a competing product, we expect that Tarceva's total prescription share of the oral EGFR class will near 100 percent over time. Future sales growth in NSCLC will result from gains in penetration within second-line and third-line NSCLC against chemotherapy. Also impacting our product sales was a price increase that was effective on April 5, 2005.

On November 2, 2005, we and OSI announced that the FDA approved Tarceva in combination with gemcitabine chemotherapy for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

Xolair

Net U.S. sales of Xolair increased 51% to $81.6 million in the third quarter and 79% to $227.3 million in the first nine months of 2005 from the comparable periods in 2004. This year over year growth was driven by an increase of our patient and prescriber base and, to some extent, a price increase that was effective on July 21, 2005.

On October 27, 2005, Novartis AG announced that the European Commission has granted marketing authorization for Xolair in all 25 European Union member states. Novartis plans to introduce Xolair in certain European countries in the near future.

Raptiva

Net U.S. sales of Raptiva increased 29% to $20.9 million in the third quarter and 63% to $58.8 million in the first nine months of 2005 from the comparable periods in 2004. Contributing to the increase in product sales was a price increase that was effective on April 21, 2005.

Nutropin Products

Combined net U.S. sales of our Nutropin products increased 4% to $88.6 million in the third quarter and 7% to $275.6 million in the first nine months of 2005 from the comparable periods in 2004, primarily as a result of price increases, partially offset by lower sales volumes in the third quarter of 2005.

On June 28, 2005, the FDA approved Nutropin and Nutropin AQ for the treatment of the long-term treatment of ISS, also called non-growth hormone-deficient short stature.

Thrombolytics

Combined net U.S. sales of our three thrombolytics products, Activase, Cathflo Activase, and TNKase, increased 9% to $57.9 million in the third quarter and 9% to $160.1 million in the first nine months of 2005 from the comparable

periods in 2004. The increase in the third quarter of 2005 was driven by price increases. Also contributing to the increase in the third quarter and first nine months of 2005 was growth in our catheter clearance and stroke markets.

Pulmozyme

Net U.S. sales of Pulmozyme increased 17% to $46.6 million in the third quarter and 20% to $137.5 million in the first nine months of 2005 from the comparable periods in 2004. The increases reflect a price increase that was effective on April 26, 2005 and an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease..

Sales to Collaborators

Product sales to collaborators, the majority of which were for non-U.S. markets, were $85.7 million in the third quarter of 2005 and $242.9 million in the first nine months of 2005, compared with $55.5 million in the third quarter of 2004 and $149.0 million in the first nine months of 2004. The increase in the first nine months of 2005 was primarily due to sales of Avastin and Herceptin to Hoffman-La Roche and sales of product manufactured under a contract with a third party.

For the full year 2005, we expect sales to collaborators to increase by approximately 60% relative to sales of $197.7 million in 2004.

Royalties

Royalty revenues increased 55% to $237.8 million in the third quarter and 46% to $670.0 million in the first nine months of 2005 from the comparable periods in 2004. These increases were due to higher sales by Hoffmann-La Roche primarily on our Herceptin and Rituxan products, a new license arrangement with ImClone under which we receive royalties on sales of ERBITUX®, and to higher sales by various other licensees on other products. Of the overall royalties received, royalties from Hoffmann-La Roche represented approximately 54% in the third quarter and 51% in the first nine months of 2005. Royalties from other licensees include royalty revenue on our patents including our Cabilly patents noted below. The increase in the first nine months included a one-time payment to us in the first quarter of 2005, relating to royalties on ERBITUX® sales from the period between launch of the product last year and the signing of the agreement in January 2005. For the full year 2005, we expect royalties to increase in the range of 40-45% compared to $641.1 million in 2004, reflecting primarily the recent strength in sales of our licensed products by Roche.

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 and No. 4,816,567 (the "Cabilly patents"), under which we receive royalty revenue on sales of products that are covered by one or more of the Cabilly patents. The licensed products for which we receive the most significant Cabilly royalties are Humira®, Remicade®, Synagis® and ERBITUX®. Cabilly royalties impact three lines on our consolidated statement of income: (i) We record gross royalties we receive from Cabilly patent licensees as royalty revenue; (ii) On royalties we receive from Cabilly licensees, we in turn pay City of Hope National Medical Center (or "COH") a percentage of our royalty income and these payments to COH are recorded with our MG&A expenses as royalty expense; (iii) We pay royalty expenses directly to COH on sales of our products that are covered by the Cabilly patents and these payments to COH are recorded in cost of sales (or "COS"). The overall net pre-tax contribution from revenues and expenses related to the Cabilly patents was approximately $20.2 million in the third quarter of 2005, or approximately $0.01 per share. We believe that our third quarter 2005 Cabilly related income before taxes represents approximately one quarter of the full year's expected results, excluding the effects of the one-time licensee payment we recorded in the first quarter of 2005 as discussed above. See also Note 3, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on our Cabilly patent reexamination.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase simple foreign currency put option contracts (or "options") and forwards to hedge these foreign currency cash flows. The terms of these options and forwards are generally one to five years. See also Note 1, "Summary of Significant

Accounting Policies -- Derivative Financial Instruments" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

Contract Revenues

Contract revenues increased 46% to $63.0 million in the third quarter of 2005 from the comparable period in 2004. The increase was primarily due to higher contract revenues from our collaborator, Hoffmann-La Roche. Contract revenues decreased 3% to $159.2 million in the first nine months of 2005 from the comparable period in 2004 due to lower contract revenues from our collaborators. See "Related Party Transactions" below for more information on contract revenue from Hoffmann-La Roche.

Contract revenues vary each quarter and are dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones and opt-in payments received, and new contract arrangements. For the full year 2005, we expect contract revenues to decrease by approximately 10-15% as compared to $231.2 million in 2004.

Cost of Sales

COS as a percentage of product sales were 16% in the third quarter of 2005 and 17% in the third quarter of 2004. This decrease is primarily due to higher sales volume of our higher margin products (primarily Avastin and Herceptin) and a reversal of a royalty accrual of approximately $7.3 million. COS as a percentage of product sales were 19% for the first nine months of 2005 and 17% for the same period in 2004. This increase was primarily driven by: (i) one-time charges of $41.0 million in the second quarter of 2005, representing payments to Amgen Inc. and another collaborator to cancel and amend certain future manufacturing obligations, and (ii) higher production costs and inventory reserves. These increases were partially offset by higher sales volume of our higher margin products (primarily Avastin, Herceptin and Rituxan products), prior year charges of $18.8 million related to our decision to discontinue commercialization of Nutropin Depot, and a prior year provision of $21.3 million related to filling failures for other products. Also contributing to the increase for the first nine months of 2005, as compared to the same period in 2004, was the impact of lower costs in the first quarter of 2004 related to sales of previously reserved pre-launch products and lower production costs due to manufacturing efficiencies primarily related to Herceptin and Rituxan.

For the full year 2005, we expect COS to be approximately 18-19% of net product sales, compared to 18% in 2004. We expect continued quarter-to-quarter variability based on product volume and mix changes, acknowledging that there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing, or inventory related issues.

Research and Development

R&D expenses increased 40% to $328.9 million in the third quarter and 33% to $850.2 million in the first nine months of 2005 from the comparable periods in 2004. These increases reflect increased activity across our entire product portfolio, including late-stage clinical development of our Lucentis, Rituxan Immunology, Tarceva and Avastin products, increased clinical manufacturing and development runs at our contract manufacturing sites, and ongoing development of various other pipeline products. Also contributing to the increases were post-marketing studies on new and existing indications for Avastin, Rituxan and Tarceva. R&D as a percentage of revenues was 19% in the third quarters of 2005 and 2004. R&D as a percentage of revenues was 18% in the first nine months of 2005 as compared to 19% in the comparable period in 2004, primarily due to higher revenues.

We expect R&D absolute dollar expenses to continue to rise in the fourth quarter of 2005 due to continued growth in headcount and outside services to support increased activity in our late-stage clinical trials, including the preparation of potential regulatory filings, higher clinical production costs, increased activity on early-stage research projects, and higher expenses related to in-licensing. For the full year 2005, we expect R&D as a percentage of operating revenues to be approximately 18-19%.

The major components of R&D expenses were as follows *(in millions)*:

Research and Development	Three Months Ended September 30, 2005	2004	% Change	Nine Months Ended September 30, 2005	2004	% Change
Product development	$ 216.5	$ 135.3	60 %	$ 528.3	$ 372.8	42 %
Post-marketing studies	49.4	33.7	47	123.9	92.3	34
Total development	265.9	169.0	57	652.2	465.1	40
Research	57.2	54.9	4	179.1	149.5	20
In-licensing	5.8	10.2	(43)	18.9	22.7	(17)
Total	$ 328.9	$ 234.1	40	$ 850.2	$ 637.3	33

Marketing, General and Administrative

Overall marketing, general and administrative (or "MG&A") expenses increased 32% to $349.3 million in the third quarter and 29% to $1,021.2 million in the first nine months of 2005 from the comparable periods in 2004. The increase in 2005 was primarily due to: (i) an increase of $18.4 million in the third quarter and $78.6 million in the first nine months of 2005 in commercial activities primarily in support of the launch of Tarceva and increased Avastin marketing costs; (ii) an increase of $44.6 million in the third quarter and $96.8 million in the first nine months of 2005, primarily due to increased headcount and promotional costs for other recent product launches, including Xolair and Raptiva, and pre-launch costs associated with pipeline products, including Rituxan Immunology and Lucentis; (iii) an increase of $27.0 million in the third quarter and $62.5 million in the first nine months of 2005 in general corporate expenses to support our continued growth and higher legal costs, and (iv) partially offset by the reversal of a royalty accrual in the third quarter of 2005.

MG&A as a percentage of operating revenues was 20% in the third quarter of 2005 as compared to 22% for the comparable period in 2004 and 22% for the first nine months of 2005 as compared to 24% for the comparable period of 2004. We expect absolute dollar spending on MG&A to increase significantly in the fourth quarter of 2005, primarily due to our preparations for potential launches including Lucentis, Rituxan in rheumatoid arthritis, as well as potential new indications for Tarceva, Herceptin and Avastin. For the full year 2005, we expect MG&A expenses to be approximately 22-23% of operating revenues.

Collaboration Profit Sharing

Collaboration profit sharing expenses increased 45% to $219.6 million in the third quarter and 40% to $594.7 million in the first nine months of 2005 from the comparable periods in 2004 due to higher sales of Tarceva, Rituxan and Xolair and the related profit sharing expenses. For the full year 2005, our collaboration profit sharing expenses are expected to grow in proportion to our Rituxan, Xolair and Tarceva sales growth.

Recurring Charges Related to Redemption

We record recurring charges related to the June 1999 redemption of our special common stock and push-down accounting (see discussion below in "Relationship with Roche -- Redemption of Our Special Common Stock"). These charges were $27.2 million in the third quarter of 2005 and $34.5 million in the third quarter of 2004; and $96.1 million in the first nine months of 2005 and $111.0 million for the first nine months of 2004. These charges were comprised of the amortization of Redemption-related other intangible assets in the periods presented.

Special Items: Litigation-Related

We recorded accrued interest and bond costs related to the COH trial judgment of $13.5 million for the third quarter of 2005 and $13.4 million for the third quarter of 2004, and $40.5 million for the first nine months of 2005 and $40.3 million for the same period in 2004. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of

the California Supreme Court's review of the matter; however, we expect that it may take longer than one year to resolve this matter. See Note 3, "Leases and Contingencies," in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding our litigation. Also included in this line is a charge in the second quarter of 2005 related to a litigation settlement and amounts received during the first quarter of 2005 for a litigation settlement.

Operating Income

Operating income was $583.2 million in the third quarter of 2005, a 72% increase from the third quarter of 2004, and was $1,383.2 million in the first nine months of 2005, a 65% increase from the comparable period in 2004.

Other Income, Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
Other Income, Net *(in millions)*	**2005**	**2004**	**% Change**	**2005**	**2004**	**% Change**
			(In millions)			
Gains on sales of biotechnology equity securities and other	$ 3.5	$ 10.5	(67)%	$ 5.0	$ 11.6	(57)%
Write-downs of biotechnology debt, equity securities and other	(2.1)	(12.0)	(83)	(5.7)	(12.0)	(53)
Interest income	41.2	26.9	53	97.9	66.4	47
Interest expense	(20.2)	(1.9)	963	(26.9)	(4.7)	472
Total other income, net	$ 22.4	$ 23.5	(5)	$ 70.3	$ 61.3	15

Other income, net decreased 5% to $22.4 million in the third quarter and increased 15% to $70.3 million in the first nine months of 2005 from the comparable periods in 2004. The components of net income have changed primarily due to the effects of our debt issuance in July 2005. Interest expense increased in the third quarter of 2005 due to the new debt service costs, and investment income increased as a result of the higher average cash balances maintained.

Income Tax Provision

The effective income tax rate was 41% in the third quarter and 35% for first nine months of 2005, as compared to 36% in the third quarter and first nine months of 2004. The increase in the income tax rate from the third quarter of 2004 is primarily due to increased income before taxes and a reduction of $27.1 million in estimated R&D tax credits primarily related to the current year. The decrease in the income tax rate from the first nine months of 2004 primarily relates to a net benefit from recognizing additional R&D tax credits, partially offset by higher income before taxes.

We anticipate that our annual 2005 effective income tax rate will be approximately 36-37%. Various factors may have favorable or unfavorable effects on our effective tax rate during the remainder of 2005 and in subsequent years. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, past and future levels of R&D spending, and changes in overall levels of income before taxes, all of which may result in periodic revisions to our effective tax rate.

Liquidity and Capital Resources

Liquidity and Capital Resources	September 30, 2005	December 31, 2004
	(In millions)	
Unrestricted cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	$ 4,148.4	$ 2,780.4
Net receivable - equity hedge instruments	90.7	21.3
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	4,239.1	2,801.7
Working capital	3,439.6	2,187.3
Current ratio	3.5:1	2.8:1

Unrestricted cash, cash equivalents, short-term investments and long-term marketable securities were approximately $4.1 billion at September 30, 2005, an increase of approximately $1.4 billion, or 49%, from December 31, 2004. This increase primarily reflects cash generated from our July 2005 debt issuance, operations, which includes income from investments, and proceeds from activity related to our employee stock plans; partially offset by cash used for capital expenditures, including repayment of our lease commitments, repurchase of our common stock, purchase of marketable securities, and repayment of our long-term debt and noncontrolling interests obligation under a synthetic lease. To mitigate the risk of market value fluctuation, certain of our biotechnology equity securities are hedged with zero-cost collars and forward contracts, which are carried at fair value. Unrestricted cash, cash equivalents, short-term investments and long-term marketable securities, including the fair value of the equity hedge instruments, were approximately $4.2 billion at September 30, 2005, an increase of approximately $1.4 billion from December 31, 2004. See Note 1, "Summary of Significant Accounting Policies -- Comprehensive Income," in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding activity in our marketable investment portfolio and derivative instruments.

On July 18, 2005, we completed a private placement of $2.0 billion aggregate principal amount of five-year, 10-year and 30-year senior notes (collectively, the "Notes"). We used approximately $585.0 million of the net proceeds to repay our remaining obligations under synthetic lease arrangements. We intend to use part of the proceeds to fund capital expenditures, including modifications plus start-up and validation costs at our recently acquired biologics manufacturing facility in Oceanside, California. We intend to use the balance of the net proceeds for general corporate purposes, which may include working capital requirements, stock repurchases, R&D expenses and acquisitions of or investments in products, technologies, facilities and businesses. Pending the use of the remaining funds in this manner, we invest them in interest-bearing or other yield producing investments.

See "Leases" below for a discussion of our leasing arrangements. See "Our affiliation agreement with Roche Holdings, Inc. (or "Roche") could limit our ability to make acquisitions and could have a material negative impact on our liquidity" below in the "Forward-Looking Information and Cautionary Factors" section and Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for factors that could negatively affect our cash position.

Cash Provided by Operating Activities

Cash provided by operating activities is primarily driven by increases in our net income. However, operating cash flows differ from net income as a result of non-cash charges or differences in the timing of cash flows and earnings recognition. Significant components of cash provided by operating activities are as follows:

Our "accounts receivable -- product sales" was $509.5 million at September 30, 2005, a decrease of $89.6 million from December 31, 2004. The average collection period of our "accounts receivable -- product sales" as measured in days sales outstanding (or "DSO") was 32 days for the third quarter 2005, as compared to 50 days in the third quarter of 2004 and 36 days in the second quarter of 2005. The decline in the accounts receivable balance and the DSO reflect the termination of the extended payment term incentive program in the first quarter of 2005. The level

of accounts receivable with extended dating has declined steadily as customer payments have been received. The DSO has normalized this quarter due to the payment of the remaining accounts receivables with extended dating earlier this quarter. The DSO for the third quarter of 2005 also decreased by an additional four days primarily due to favorable collections. As a result, we expect our near term DSO to be consistent with our third and second quarter 2005 DSO and range between 32 and 36 days. For future new product launches, we may offer, for a limited period, extended payment terms to allow customers and doctors purchasing the drug sufficient time to process reimbursements.

On January 12, 2005, we and XOMA Ltd. (or "XOMA") restructured our collaboration agreement related to Raptiva, effective January 1, 2005. Under this restructured agreement, the previous costs and profit sharing arrangement in the U.S. was modified to a royalty arrangement. As a result of restructuring the XOMA collaboration agreement, in the first quarter of 2005 we reclassified the former development loan receivable (approximately $29.2 million) to a prepaid royalty, of which $4.5 million was included in "prepaid expenses" and $24.7 million was included in "other long-term assets" in the accompanying condensed consolidated balance sheets. The prepaid royalty is being amortized to COS associated with the related Raptiva revenues.

Cash Used in Investing Activities

Cash used in investing activities primarily relate to purchases, sales and maturities of investments and capital expenditures. Capital expenditures were $1.1 billion during the first nine months of 2005 compared to $418.2 million during the first nine months of 2004. Capital expenditures in the first nine months of 2005 included the purchase of the Oceanside plant for $408.1 million in cash plus $9.3 million in closing costs, $160.0 million repayment of our synthetic lease obligation on a research facility in South San Francisco, California, ongoing construction of our manufacturing facility in Vacaville, California, the purchase of land, equipment and information systems, and ongoing construction costs in support of our manufacturing and corporate infrastructure needs. We expect to incur additional capital costs at the Oceanside plant over the next 21 months, primarily for modifications and start-up and validation costs.

We currently anticipate that our capital expenditures for the full year 2005 will be approximately $1.6 billion, which includes the June 2005 purchase of the Oceanside plant and $160.0 million for the repayment of our synthetic lease obligation on a research facility in South San Francisco, California.

Cash Provided by or Used in Financing Activities

Cash provided by or used in financing activities is primarily related to activity under our employee stock plans and our stock repurchase program. We received $633.7 million during the first nine months of 2005 and $421.1 million during the first nine months of 2004, related to stock option exercises and stock issuances under our employee stock plans. We also used cash for stock repurchases of $1.1 billion during the first nine months of 2005 and $821.4 million during the first nine months of 2004 pursuant to our stock repurchase program approved by our Board of Directors.

Using the proceeds of our recently completed debt issuance, we extinguished our remaining $425.0 million total lease obligation with respect to our Vacaville, California, manufacturing facility during the third quarter of 2005.

On June 15, 2005, the Board of Directors approved an extension of our stock repurchase program for the repurchase of up to an additional $2.0 billion of our common stock for a total of $4.0 billion through June 30, 2006. The Board also amended the current repurchase program by increasing the maximum number of shares that can be repurchased from 50 million to 80 million shares. Under this stock repurchase program, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. Genentech intends to use the repurchased stock to offset dilution caused by the issuance of shares in connection with Genentech's employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to make prudent investments of our cash resources; (ii) to allow for an effective mechanism to provide stock for our employee stock plans; and (iii)

to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage. See below in "Relationship with Roche" for more information on Roche's minimum ownership percentage. We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately 1.5 million shares and will run through December 31, 2005.

Our shares repurchased during the first nine months of 2005 were as follows *(shares in millions)*:

	Total Number of Shares Purchased in 2005	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
January 1-31, 2005	1.4	$ 48.98		
February 1-28, 2005	1.3	47.13		
March 1-31, 2005	0.5	48.90		
April 1-30, 2005	0.1	56.83		
July 1-31, 2005	1.3	88.57		
August 1-31, 2005	9.2	88.58		
Total	13.8	78.95	39.5	40.5

The par value method of accounting is used for common stock repurchases. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital with the amounts in excess of the estimated original sales price charged to accumulated deficit.

Off-Balance Sheet Arrangements

We have certain contractual arrangements that create risk for Genentech and are not recognized in our condensed consolidated balance sheets, as prescribed by generally accepted accounting principles. Discussed below are those off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operation, liquidity, capital expenditures or capital resources.

Leases

During the third quarter of 2005, we paid $160.0 million to exercise our right to purchase a research facility in South San Francisco, California, which was subject to a synthetic lease. As a result, the value of the building in South San Francisco is included in the accompanying condensed consolidated balance sheets at September 30, 2005. Also during the third quarter of 2005, we paid $425.0 million to extinguish the debt and the noncontrolling interests related to a synthetic lease obligation on our manufacturing plant in Vacaville, California. As discussed in Note 6, "Leases, Commitments and Contingencies" of our Annual Report on Form 10-K for the year ended December 31, 2004, the synthetic lease for the manufacturing plant in Vacaville was accounted for under the provisions of FIN 46R, a revision of Interpretation 46.

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to our South San Francisco campus. The property will be developed into eight buildings and two parking structures. The lease of the property will take place in two phases pursuant to separate lease agreements for each building as contemplated by the Master Lease Agreement. Phase I building leases will begin throughout 2006 and Phase II building leases may begin as early as 2008. For accounting purposes, due to the nature of our involvement with the construction of the buildings subject to the Master Lease Agreement, we are considered to be the owner of the assets during the construction period through the lease commencement date, even though the funds to construct the building shell and some infrastructure costs are paid by the lessor. As such, in the first nine months of 2005, we have capitalized $93.8 million of construction costs in property, plant and equipment, and have also recognized a corresponding amount as a construction financing obligation in "long-term debt" in the accompanying condensed

consolidated balance sheets. We expect at the time of completion of the project, if all the buildings and infrastructure were completed by the lessor, our construction asset and related obligation will be in excess of $365.0 million. Our aggregate lease payments as contemplated by the Master Lease Agreement through 2020 (if there is no acceleration or delay in the rent commencement date for the second phase of the buildings) will be approximately $540.1 million.

Contractual Obligations

During the first nine months of 2005, we believe there have been no significant changes in our payments due under contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2004, except for the following: (i) We extinguished our $412.3 million debt and $12.7 million noncontrolling interests obligation related to a synthetic lease on our manufacturing facility in Vacaville, California (see "Liquidity and Capital Resources" above for more information on this synthetic lease transaction); (ii) On July 18, 2005, we issued the following debt instruments: $500.0 million principal amount of 4.40% Senior Notes due 2010, $1.0 billion principal amount of 4.75% Senior Notes due 2015 and $500.0 million principal amount of 5.25% Senior Notes due 2035. See Note 4, "Debt Issuance," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information.

Contingencies

We are party to various legal proceedings, including patent infringement litigation and licensing and contract disputes, and other matters. See Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part 1, Item 1 of this Form 10-Q for further information.

Relationship with Roche

Redemption of Our Special Common Stock

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche Holdings, Inc. (or "Roche") at a price of $10.31 per share in cash with funds deposited by Roche for that purpose. We refer to this event as the "Redemption." As a result, on that date, Roche's percentage ownership of our outstanding Common Stock increased from 65% to 100%. Consequently, under GAAP, we were required to use push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value. Push-down accounting required us to record $1,685.7 million of goodwill and $1,499.0 million of other intangible assets on our balance sheet on June 30, 1999. Refer to Note 2, "Consolidated Financial Statement Detail -- Other Intangible Assets," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information about these intangible assets.

Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock

We issue additional shares of common stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. The affiliation agreement provides that we will repurchase a sufficient number of shares pursuant to this program such that, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance will be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999, October

2000 and May 2004. We repurchased shares of our common stock in 2005 and 2004 (see discussion above in "Liquidity and Capital Resources -- Cash Provided by or Used in Financing Activities"). As long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, the affiliation agreement provides that we will repurchase a sufficient number of shares of our common stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The affiliation agreement also provides that, upon Roche's request, we will repurchase shares of our common stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. The Minimum Percentage at September 30, 2005 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be 55.7%. At September 30, 2005, Roche's ownership percentage was 55.5%. We expect that future share repurchases under our share repurchase program will increase Roche's ownership percentage.

Related Party Transactions

We enter into transactions with our related parties, Roche and other Roche affiliates (including Hoffmann-La Roche) and Novartis, under existing agreements in the ordinary course of business. The accounting policies we apply to our transactions with our related parties are consistent with those applied in transactions with independent third-parties and all related party agreements are negotiated on an arm's-length basis.

Hoffmann-La Roche

Under our existing arrangements with Hoffmann-La Roche, including our licensing and marketing agreement, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of $23.9 million in the third quarter of 2005 and $4.3 million in the third quarter of 2004, and $58.8 million in the first nine months of 2005 and $53.9 million in the first nine months of 2004. All other revenues from Hoffmann-La Roche and their affiliates, principally royalties and product sales, were $181.4 million in the third quarter of 2005 and $106.9 million in the third quarter of 2004, and $470.9 million in the first nine months of 2005 and $317.5 million in the first nine months of 2004. COS included amounts related to Hoffmann-La Roche of $44.8 million in the third quarter of 2005 and $22.5 million in the third quarter of 2004, and $118.6 million in the first nine months of 2005 and $70.8 million in the first nine months of 2004. R&D expenses included amounts related to Hoffmann-La Roche of $42.4 million in the third quarter of 2005 and $25.7 million in the third quarter of 2004, and $110.4 million in the first nine months of 2005 and $100.4 million in the first nine months of 2004.

Novartis

We understand that the Novartis Group holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, the Novartis Group is deemed to have an indirect beneficial ownership interest under FAS 57 "Related Party Disclosures" of more than 10% of Genentech's voting stock.

Under an arrangement with Novartis, a holding company of the Novartis Group, and Tanox, Inc., we currently supply Xolair and receive cost plus a mark-up similar to other supply arrangements. Novartis will be manufacturing all future worldwide bulk supply of Xolair at their Huningue production facility in France, upon FDA licensure, expected in early 2006. Future production costs of Xolair may initially be higher than those currently reflected in our COS as a result of any production shift from Genentech to Novartis until production economies of scale can be achieved by that manufacturing party.

Contract revenue from Novartis related to manufacturing, commercial and ongoing development activities, was $13.0 million in the third quarter of 2005 and $11.0 million in the third quarter of 2004, and $34.9 million in the first nine months of 2005 and $31.9 million in the first nine months of 2004. Revenue from Novartis related to product sales was not material in the third quarters and the first nine months of 2005 and 2004. COS was not material in the third quarters of 2005 and 2004. COS was $15.1 million in the first nine months of 2005, which included a one-time payment in the second quarter of 2005 related to our release from future manufacturing obligations. COS was not material in the first nine months of 2004. R&D expenses include amounts related to Novartis of $12.6 million in the third quarter of 2005 and $11.2 million in the third quarter of 2004, and $32.4 million in the first nine months of

2005 and $31.0 million in the first nine months of 2004. Collaboration profit sharing expenses were $40.9 million in the third quarter of 2005 and $21.6 million in the third quarter of 2004, and $93.3 million in the first nine months of 2005 and $48.2 million in the first nine months of 2004.

Stock Options

Option Program Description

Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our program primarily consists of our amended and restated 1999 Stock Plan (the "Plan"), a broad-based plan under which stock options are granted to employees, directors and other service providers. Substantially all of our employees participate in our stock option program. In the past, we granted options under our amended and restated 1996 Stock Option/Stock Incentive Plan, our amended and restated 1994 Stock Option Plan and our amended and restated 1990 Stock Option/Stock Incentive Plan. Although we no longer grant options under these plans, exercisable options granted under these plans are still outstanding. In addition, our stockholders approved in April 2004 our 2004 Equity Incentive Plan under which stock options, restricted stock, stock appreciation rights and performance shares and units may be granted to our employees, directors and consultants in the future.

All stock option grants are made after a review by, and with the approval of, the Compensation Committee of the Board of Directors. See "The Compensation Committee Report" appearing in our 2005 Proxy Statement for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

General Option Information

Summary of Option Activity
(Shares in thousands)

		Options Outstanding	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
December 31, 2003	40,732	96,126	$ 25.18
Grants	(20,967)	20,967	53.04
Exercises	-	(21,484)	20.81
Cancellations	1,843	(1,843)	29.92
Additional shares reserved[(1)]	80,000	-	-
December 31, 2004	101,608	93,766	32.32
Grants	(18,909)	18,909	83.78
Exercises	-	(23,390)	24.69
Cancellations	1,551	(1,551)	40.25
September 30, 2005 (Year to date)	84,250	87,734	45.31

(1) Additional shares have been reserved for issuance under the 2004 Equity Incentive Plan approved by stockholders on April 16, 2004. No awards have been made under this Plan.

In-the-Money and Out-of-the-Money Option Information

(Shares in thousands)

	Exercisable		Unexercisable		Total	
As of September 30, 2005	**Shares**	**Wtd. Avg. Exercise Price**	**Shares**	**Wtd. Avg. Exercise Price**	**Shares**	**Wtd. Avg. Exercise Price**
In-the-Money	38,925	$ 28.90	31,765	$ 43.58	70,690	$ 35.50
Out-of-the-Money[(1)]	3	85.83	17,041	86.00	17,044	86.00
Total Options Outstanding	38,928		48,806		87,734	

(1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of Genentech Common Stock, $84.21, at the close of business on September 30, 2005.

Dilutive Effect of Options

Net grants, as a percentage of outstanding shares, were 1.65% for the nine months ended September 30, 2005, 1.82% for the twelve months ended December 31, 2004 and 1.69% for the twelve months ended December 31, 2003.

Equity Compensation Plan Information

Our stockholders have approved all of our equity compensation plans under which options are outstanding.

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Our Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding achievement of our 5x5 goals, including growth in non-GAAP EPS, and the number of products/indications in late stage development; our Horizon 2010 goals, including becoming the number one U.S. oncology company by 2010, adding programs into research and clinical development and bringing products/indications to market, building a leading immunology business, increasing our leadership in tissue growth and repair, and achieving non-GAAP growth rates to be considered a growth company; Avastin, Herceptin, and Tarceva sales growth opportunities; the timeframe of licensure of manufacturing facilities or processes; FDA filings for Avastin, Herceptin and Lucentis; the impact of Medicare legislation on sales of our products; and sales to collaborators, royalties, contract revenues, cost of sales, R&D and MG&A expenses, collaboration profit-sharing expenses and capital expenditures. Actual results could differ materially.

For a discussion of the risks and uncertainties associated with achieving our 5x5 and Horizon 2010 goals of adding programs into research and clinical development and bringing products/indications to market, our estimates of our capital expenditures, cost of sales, R&D and MG&A expenses, collaboration profit-sharing expenses, and timeframe of licensure of manufacturing facilities or processes, FDA filings for Avastin, Herceptin and Lucentis, see "The successful development of biotherapeutics is highly uncertain and requires significant expenditures," "We may be unable to obtain or maintain regulatory approvals for our products," "Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively impact our financial performance," "Protecting our proprietary rights is difficult and costly," "If there is an adverse outcome in our pending litigation or other legal actions our business may be harmed," and "We may be unable to retain skilled personnel and maintain key relationships" sections of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below; for our Horizon 2010 goal of becoming number one in U.S. oncology sales and building a leading immunology business, increasing our leadership in tissue growth and repair, Avastin, Herceptin and Tarceva sales growth opportunities and expected revenues from sales to collaborators, see all of the foregoing and "We may be unable to manufacture certain of our products if there is BSE contamination of our bovine source raw material," "We face competition," "Other factors could affect our product sales," "We may incur material product liability costs," "Insurance coverage is increasingly more difficult to obtain or maintain," and "We are subject to environmental and other risks;" for royalties and contract revenues, see "Our results of operations are affected by our royalty and contract;" for the impact of Medicare legislation on our product sales, see "Decreases in third party reimbursement rates may affect our product sales, results of operations and financial condition;" for non-

GAAP EPS growth, see all of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below. We disclaim and do not undertake any obligation to update or revise any forward-looking statements in this Form 10-Q.

FORWARD-LOOKING INFORMATION AND CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of Genentech, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, royalties, contract revenues, expenses, net income and earnings per share.

The successful development of biotherapeutics is highly uncertain and requires significant expenditures

Successful development of biotherapeutics is highly uncertain. Products that appear promising in research or early phases of development may fail to reach later stages of development or the market for several reasons including:

- Preclinical tests may show the product to be toxic or lack efficacy in animal models.
- Clinical trial results that may show the product to be less effective than desired (e.g., the trial failed to meet its objectives) or to have harmful or problematic side effects.
- Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, extended length of time to achieve study endpoints, additional time requirements for data analysis or biologic licensing application (or "BLA") preparation, discussions with the U.S. Food and Drug Administration (or "FDA"), an FDA request for additional preclinical or clinical data, or unexpected safety, efficacy or manufacturing issues.
- Difficulties formulating the product, scaling the manufacturing process or in getting approval for manufacturing.
- Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being developed or commercialized.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. If our large-scale clinical trials are not successful, we will not recover our substantial investments in the product.

Factors affecting our research and development (or "R&D") productivity and the amount of our R&D expenses include, but are not limited to:

- The number of and the outcome of clinical trials currently being conducted by us and/or our collaborators. For example, our R&D expenses may increase based on the number of late-stage clinical trials being conducted by us and/or our collaborators.
- The number of products entering into development from late-stage research. For example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us. In the past, some promising candidates did not yield sufficiently positive preclinical results to meet our stringent development criteria.

- Decisions by F. Hoffmann-La Roche (or "Hoffmann-La Roche") whether to exercise its options to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.

- In-licensing activities, including the timing and amount of related development funding or milestone payments. For example, we may enter into agreements requiring us to pay a significant upfront fee for the purchase of in-process R&D, which we may record as an R&D expense.

- We participate in a number of collaborative research arrangements. On many of these collaborations, our share of expenses recorded in our financial statements is subject to volatility based on our collaborators' spending activities as well as the mix and timing of activities between the parties.

- We may incur charges associated with expanding our product manufacturing capabilities, as described in "Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively impact our financial performance" below.

- Future levels of revenue.

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

We are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA's requirements covering R&D, testing, manufacturing, quality control, labeling and promotion of drugs for human use. A biotherapeutic cannot be marketed in the United States (or "U.S.") until it has been approved by the FDA, and then can only be marketed for the indications approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application or a BLA, are substantial and can require a number of years. In addition, even if our products receive regulatory approval, they remain subject to ongoing FDA regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians or a product recall.

We may not obtain necessary regulatory approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or maintain necessary regulatory approvals for our existing products, and all of the following could have a material adverse effect on our business:

- Significant delays in obtaining or failing to obtain required approvals as described in "The successful development of biotherapeutics is highly uncertain and requires significant expenditures" above.

- Loss of, or changes to, previously obtained approvals, including those resulting from post-approval safety or efficacy issues.

- Failure to comply with existing or future regulatory requirements.

- Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

In addition, the current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing, which may affect our ability to obtain or maintain approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively effect our financial performance

Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated for

this purpose. It can take longer than five years to design, construct, validate, and license a new biotech manufacturing facility. We currently produce all of our products at our manufacturing facilities located in South San Francisco, California, Vacaville, California, Porriño, Spain, or through various contract-manufacturing arrangements. Problems with any of our or our contractors' manufacturing processes could result in failure to produce adequate product supplies or product defects which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all. In addition, we may need to record period charges associated with manufacturing or inventory failures or other production-related costs that are not absorbed into inventory or incur costs to secure additional sources of capacity. Furthermore, there are inherent uncertainties associated with forecasting future demand, especially for newly introduced products of ours or of those for whom we produce products, and as a consequence we may have inadequate capacity to meet our own actual demands and/or the actual demands of those for whom we produce product.

In order to maintain adequate supply to keep up with growing demand for our products, we must successfully implement a number of manufacturing capacity enhancement projects on schedule, utilize nearly 100 percent of our production capacity in the next several years and maintain a state of regulatory compliance at all of our production sites. If we for any reason fail to obtain licensure for our capacity enhancement projects on schedule, fail to operate at or near capacity, fail to maintain a state of regulatory compliance, or if actual demand significantly exceeds our internal forecasts, we may be unable to maintain an adequate supply of our product to meet all demand. Key capacity enhancement projects, which we must successfully implement, include the following: (i) licensure of Novartis' plant in Huningue, France to produce Xolair bulk drug substance by early 2006; (ii) licensure of our Wyeth Pharmaceuticals contract manufacturing facility at Andover, Massachusetts, to produce Herceptin bulk drug substance by the end of 2006; (iii) licensure of additional capacity at our Porriño, Spain facility in 2006 to produce Avastin bulk drug substance for commercial use; (iv) licensure of yield improvement processes for Rituxan by the end of 2006 and for Avastin by early 2007; (v) licensure of our recently acquired Oceanside, California manufacturing facility during the first half of 2007; (vi) construction, qualification and licensure of our new plant in Vacaville, California by the end of 2009.

We had equipment malfunctions in early 2004 in our filling facility, and consequently, several product lots were not able to be released and a scheduled facility maintenance shut-down was extended. If we experience another significant malfunction in our filling facility, we could experience a shortfall or stock out of one or more products, which, if it were to continue for a significant period of time, could result in a material adverse effect on our product sales and our business.

Furthermore, certain of our raw materials and supplies required for the production of our principal products or products we make for others are available only through sole source suppliers (the only recognized supplier available to us) or single source suppliers (the only approved supplier for us among other sources), and such raw materials cannot be obtained from other sources without significant delay or at all. If such sole source or single source suppliers were to limit or terminate production or otherwise fail to supply these materials for any reason, such failures could also have a material adverse impact on our products sales and our business.

Any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall or stock-out of available product inventory, any of which could have a material adverse impact on our business. A number of factors could cause prolonged interruptions, including:

- the inability of a supplier to provide raw materials used for manufacture of our products;
- equipment obsolescence, malfunctions or failures;
- product contamination problems;
- damage to a facility, including our warehouses and distribution facility, due to natural disasters, including earthquakes as our South San Francisco, Oceanside and Vacaville facilities are located in areas where earthquakes could occur;

- changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes;

- action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products we make for others due to regulatory issues;

- a contract manufacturer going out of business or failing to produce product as contractually required;

- other similar factors.

Because our manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our or our contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share, damage our reputation and could result in a material adverse effect on our product sales, financial condition and results of operations.

We face competition

We face competition from pharmaceutical companies, pharmaceutical divisions of chemical companies, and biotechnology companies.

The introduction of new products or follow-on biologics or new information about existing products may result in lost market share for us and/or lower prices, even for products protected by patents. Over the longer term, our and our collaborators' abilities to successfully market current products, expand their usage and bring new products to the marketplace will depend on many factors, including but not limited to the effectiveness and safety of the products, FDA and foreign regulatory agencies' approvals of new products and indications, the degree of patent protection afforded to particular products, and the effect of managed care as an important purchaser of pharmaceutical products.

With respect to Avastin, another biologic being used in the metastatic colorectal cancer setting is ImClone/Bristol-Myers Squibb's ERBITUX®, which is an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer patients. We are also aware of products in development at other biotechnology or pharmaceutical companies that, if successful in clinical trials, may compete with Avastin for the indication for which we have approval or for indications for which we are seeking, or may seek, approval.

We are aware that some retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration, an unapproved use, and that there may be continued Avastin use in this setting even after Lucentis has been approved for commercial use, which may decrease the market potential for Lucentis.

Rituxan's current competitors include BEXXAR® (GSK), VELCADE® (Millennium) and ZEVALIN® (Biogen Idec).

Tarceva faces competition from new and established chemotherapy regimens. Specifically, Tarceva competes with the chemotherapeutic products Taxotere® and Alimta®, both of which are indicated for the treatment of relapsed non-small cell lung cancer.

Regarding Xolair, in mid-October 2005, Critical Therapeutics, Inc. launched Zyflo for the prevention and chronic treatment of asthma in patients 12 years of age and older. While not a direct competitor to Xolair, we understand that Critical Therapeutics' marketing efforts are directed at the use of Zyflo prior to Xolair. We are also aware of other asthma therapies that may compete with Xolair.

Raptiva competes with established therapies for moderate-to-severe psoriasis including oral systemics such as methotrexate and cyclosporin, as well as ultraviolet light therapies. In addition, Raptiva competes with FDA-approved biologic agents Amevive® and ENBREL® which are marketed by Biogen Idec and Amgen Inc.,

respectively. Although not FDA approved for use in psoriasis, both Remicade® and Humira®, marketed by Centocor and Abbott, respectively, are used off-label in the psoriasis market. In October 2005, Centocor filed with the FDA for approval of Remicade® for the treatment of psoriasis and we expect Abbott to seek FDA approval for a psoriasis indication for Humira® in the future.

In the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. Some competitors have additional indications of Prader Willi Syndrome and SGA (small for gestational age) for which Nutropin is not approved. As a result of multiple competitors, we have experienced and may continue to experience a loss of market share and a demand for increasing discounts to managed care.

We face competition in our acute myocardial infarction market with sales of TNKase and Activase impacted by the adoption of mechanical reperfusion strategies by physicians. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow.

In addition to the commercial products listed above, there are numerous products in development at other biotech and pharmaceutical companies that, if successful in clinical trials, may compete with our products.

We may be unable to manufacture certain of our products if there is BSE contamination of our bovine source raw material

Most biotechnology companies, including Genentech, have historically used bovine source raw materials to support cell growth in cell production processes. Bovine source raw materials from within or outside the U.S. are increasingly subject to greater public and regulatory scrutiny because of the perceived risk of contamination with bovine spongiform encephalopathy (or "BSE"). Should BSE contamination occur during the manufacture of any of our products that require the use of bovine source raw materials, it would negatively impact our ability to manufacture those products for an indefinite period of time (or at least until an alternative process is approved), negatively affect our reputation and could result in a material adverse effect on our product sales, financial condition and results of operations.

Decreases in third party reimbursement rates may affect our product sales, results of operations and financial condition

Sales of our products will depend significantly on the extent to which reimbursement for the cost of our products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third party payers and governmental health administration authorities are increasingly attempting to limit and/or regulate the price of medical products and services, especially branded prescription drugs. For example, the Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003 (or "Medicare Act"), provides for, among other things, a reduction in the Medicare reimbursement rates for many drugs, including our oncology products. The Medicare Act as well as other changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for our products may reduce or eliminate reimbursement of our products' costs to physicians. Decreases in third-party reimbursement for our products could reduce physician usage of the product and have a material adverse effect on our product sales, results of operations and financial condition.

Protecting our proprietary rights is difficult and costly

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the breadth of claims allowed in these companies' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material litigation and other legal proceedings relating to our proprietary rights, such as the Cabilly reexamination and the other matters discussed in Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. Such litigation and other legal proceedings are costly in their own right and could subject us to

significant liabilities to third-parties. An adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third-parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

The presence of patents or other proprietary rights belonging to other parties may lead to our termination of the R&D of a particular product, a loss of our entire investment in the product and subject us to infringement claims.

If there is an adverse outcome in our pending litigation or other legal actions our business may be harmed

Litigation to which we are currently or have been subjected relates to, among other things, our patent and other intellectual property rights, licensing arrangements with other persons, product liability and financing activities. We cannot predict with certainty the eventual outcome of pending litigation, which may include an injunction against the manufacture or sale of a product or potential product or a judgment with significant monetary award, including the possibility of punitive damages, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in defending these lawsuits and these lawsuits could divert management's attention from ongoing business concerns.

Our activities relating to the sale and marketing of our products are subject to regulation under the Federal Food, Drug and Cosmetic Act and other federal statutes, including those relating to government program fraud and abuse. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). In 1999 we agreed to pay $50 million to settle a federal investigation relating to our past clinical, sales and marketing activities associated with human growth hormone. We are currently being investigated by the Department of Justice with respect to our promotional practices of Rituxan, and may in the future be investigated for our promotional practices relating to any of our products. If the government were to bring charges against or convict us of violating these laws, or if we were subject to third party litigation relating to the same promotional practices, there could be a material adverse effect on our business, including our financial condition and results of operations.

We may be unable to retain skilled personnel and maintain key relationships

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, (ii) successfully integrate large number of new employees into our corporate culture, and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense.

Among other benefits, we use stock options to attract and retain personnel. However, our affiliation agreement with Roche provides that, among other things, we will establish a stock repurchase program designed to maintain Roche's percentage ownership in our common stock if we issue or sell any shares. In addition, changes in stock option accounting rules will require us to recognize all stock-based compensation costs as expenses. These factors could adversely effect the number of shares management and our board of directors choose to grant under our stock option plans. We therefore cannot assure you that we will be able to attract or retain skilled personnel or maintain key relationships or that the costs of retaining such personnel or maintaining such relationships will not materially increase.

Other factors could affect our product sales

Other factors that could affect our product sales include, but are not limited to:

- The timing of FDA approval, if any, of competitive products.

- Our pricing decisions, including a decision to increase or decrease the price of a product, and the pricing decisions of our competitors.

- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.

- Negative safety or efficacy data from new clinical studies could cause the utilization and sales of our products to decrease.

- Negative safety or efficacy data from post-approval marketing experience could cause sales of our products to decrease or for a product to be recalled.

- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.

- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.

- The increasing use and development of alternate therapies.

- The rate of market penetration by competing products.

- The termination of, or change in, an existing arrangement with any of the wholesalers who supply our products.

Any of these factors could have a material adverse effect on our sales and results of operations.

Our results of operations are affected by our royalty and contract revenues

Royalty and contract revenues in future periods could vary significantly. Major factors affecting these revenues include, but are not limited to:

- Hoffmann-La Roche's decisions whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.

- Variations in Hoffmann-La Roche's sales and other licensees' sales of licensed products.

- The expiration or termination of existing arrangements with other companies and Hoffmann-La Roche, which may include development and marketing arrangements for our products in the U.S., Europe and other countries outside the U.S.

- The timing of non-U.S. approvals, if any, for products licensed to Hoffmann-La Roche and to other licensees.

- Fluctuations in foreign currency exchange rates.

- The initiation of new contractual arrangements with other companies.

- Whether and when contract milestones are achieved.

- The failure of or refusal of a licensee to pay royalties.

- The expiration or invalidation of our patents or licensed intellectual property. For example, patent litigations, interferences, oppositions, and other proceedings involving our patents often include claims by third-parties that such patents are invalid or unenforceable. If a court, patent office, or other authority were to determine that a patent under which we receive royalties and/or other revenues is invalid or unenforceable, that determination could cause us to suffer a loss of such royalties and/or revenues, and could cause us to incur other monetary damages.

- Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

We may incur material product liability costs

The testing and marketing of medical products entail an inherent risk of product liability. Liability exposures for biotherapeutics could be extremely large and pose a material risk. Our business may be materially and adversely affected by a successful product liability claim or claims in excess of any insurance coverage that we may have.

Insurance coverage is increasingly more difficult and costly to obtain or maintain

While we currently have a certain amount of insurance for our business, property and our products first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future or make significant expenditures to maintain our current levels of insurance. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policy may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

We are subject to environmental and other risks

We use certain hazardous materials in connection with our research and manufacturing activities. In the event such hazardous materials are stored, handled or released into the environment in violation of law or any permit, we could be subject to loss of our permits, government fines or penalties and/or other adverse governmental or private actions. The levy of a substantial fine or penalty, the payment of significant environmental remediation costs or the loss of a permit or other authorization to operate or engage in our ordinary course of business could materially adversely affect our business.

We also have acquired, and may continue to acquire in the future, land and buildings as we expand our operations. Some of these properties are "brownfields" for which redevelopment or use is complicated by the presence or potential presence of a hazardous substance, pollutant or contaminant. Certain events could occur which may require us to pay significant clean-up or other costs in order to maintain our operations on those properties. Such events include, but are not limited to, changes in environmental laws, discovery of new contamination, or unintended exacerbation of existing contamination. The occurrence of any such event could materially affect our ability to continue our business operations on those properties.

Fluctuations in our operating results could affect the price of our common stock

Our operating results may vary from period to period for several reasons including:

- The overall competitive environment for our products as described in "We face competition" above.

- The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.

- The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the U.S. and the amount and timing of sales to their respective customers, which directly impacts both our product sales and royalty revenues.

- The timing and volume of bulk shipments to licensees.

- The availability and extent of government and private third-party reimbursements for the cost of therapy.

- The extent of product discounts extended to customers.

- The effectiveness and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.

- The rate of adoption by physicians and use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.

- The potential introduction of new products and additional indications for existing products.

- The ability to successfully manufacture sufficient quantities of any particular marketed product.

- The number and size of any product price increases we may issue.

Our integration of new information systems could disrupt our internal operations, which could harm our revenues and increase our expenses

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors. As part of our Enterprise Resource Planning efforts, we are implementing new information systems, but we may not be successful in implementing all of the new systems, and transitioning data and other aspects of the process could be expensive, time consuming, disruptive and resource intensive. Any disruptions that may occur in the implementation of new systems or any future systems could adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows. Disruptions to these systems also could adversely impact our ability to fulfill orders and interrupt other operational processes. Delayed sales, lower margins or lost customers resulting from these disruptions could adversely affect our financial results.

Our stock price, like that of many biotechnology companies, is volatile

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. In addition, the market price of our common stock has been and may continue to be volatile.

In addition, the following factors may have a significant impact on the market price of our common stock.

- Announcements of technological innovations or new commercial products by us or our competitors.

- Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors.

- Developments or outcome of litigation, including litigation regarding proprietary and patent rights.

- Regulatory developments or delays concerning our products in the U.S. and foreign countries.

- Issues concerning the safety of our products or of biotechnology products generally.

- Economic and other external factors or a disaster or crisis.

- Period to period fluctuations in our financial results.

Our affiliation agreement with Roche Holdings, Inc. (or "Roche") could adversely affect our cash position

Our affiliation agreement with Roche provides that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock based on an established Minimum Percentage. For more information on our stock repurchase program, see discussion above in "Liquidity and Capital Resources -- Cash Provided by or Used in Financing Activities." See Note 5, "Relationship with Roche and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for information regarding the Minimum Percentage.

While the dollar amounts associated with future stock repurchase programs cannot currently be determined, future stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access additional capital in the financial markets, and may have the effect of limiting our ability to use our capital stock as consideration for acquisitions.

Future sales of our common stock by Roche could cause the price of our common stock to decline

As of September 30, 2005, Roche owned 587,189,380 shares of our common stock or 55.5% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our common stock. Sales of a substantial number of shares of our common stock by Roche in the public market could adversely affect the market price of our common stock.

Roche Holdings, Inc., our controlling stockholder, may have interests that are adverse to other stockholders

Roche as our majority stockholder controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our board of directors shall consist of at least three directors designated by Roche, three independent directors nominated by the nominating committee and one Genentech executive officer nominated by the nominating committee. Currently, three of our directors, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles, also serve as officers and employees of Roche Holding Ltd and its affiliates. As long as Roche owns in excess of 50% of our common stock, Roche directors will comprise two of the three members of the nominating committee. However, at any time until Roche owns less than 5% of our stock, Roche will have the right to obtain proportional representation on our board. We cannot assure you that Roche will not seek to influence our business operations in a manner that is contrary to our goals or strategies.

Our affiliation agreement with Roche could limit our ability to make acquisitions and could have a material negative impact on our liquidity

The affiliation agreement between us and Roche contains provisions that:

- Require the approval of the directors designated by Roche to make any acquisition or any sale or disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues.

- Enable Roche to maintain its percentage ownership interest in our common stock.

- Require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock based on an established Minimum Percentage. For information regarding Minimum Percentage, see Note 5, "Relationship with Roche and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for a discussion of our relationship with Roche and Roche's ability to maintain its percentage ownership interesting our stock. For more information on our stock repurchase program, see discussion above in "Liquidity and Capital Resources -- Cash Provided by or Used in Financing Activities."

These provisions may have the effect of limiting our ability to make acquisitions and while the dollar amounts associated with our future stock repurchases cannot currently be estimated, stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access additional capital in the financial markets.

Our stockholders may be unable to prevent transactions that are favorable to Roche but adverse to us

Our certificate of incorporation includes provisions relating to the following matters:

- Competition by Roche affiliates with us.
- Offering of corporate opportunities.
- Transactions with interested parties.
- Intercompany agreements.
- Provisions limiting the liability of specified employees

Our certificate of incorporation provides that any person purchasing or acquiring an interest in shares of our capital stock shall be deemed to have consented to the provisions in the certificate of incorporation relating to competition with Roche, conflicts of interest with Roche, the offer of corporate opportunities to Roche and intercompany agreements with Roche. This deemed consent might restrict the ability to challenge transactions carried out in compliance with these provisions.

Potential conflicts of interest could limit our ability to act on opportunities that are favorable to us but adverse to Roche

Persons who are directors and/or officers of Genentech and who are also directors and/or officers of Roche may decline to take action in a manner that might be favorable to us but adverse to Roche. Three of our directors currently serve as officers and employees of Roche Holding Ltd and its affiliates.

Our effective tax rate may vary significantly

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include but are not limited to changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, future levels of R&D spending, and changes in overall levels of income before taxes.

To pay our indebtedness will require a significant amount of cash and may adversely affect our operations and financial results

Our ability to make payments on and to refinance our indebtedness, including our long-term debt obligations, and to fund planned capital expenditures, R&D, as well as stock repurchases and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase our vulnerability to general adverse economic and industry conditions, require us to dedicate a

substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts and other general corporate purposes, and limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

Accounting pronouncements may impact our future financial position and results of operations

Under Financial Accounting Standards Board (or "FASB") Interpretation No. 46R (or "FIN 46R"), a revision to Interpretation 46, "Consolidation of Variable Interest Entities," we are required to assess new business development collaborations as well as to reassess, upon certain events, some of which are outside our control, the accounting treatment of our existing business development collaborations based on the nature and extent of our variable interests in the entities as well as the extent of our ability to exercise influence in the entities with which we have such collaborations. Our continuing compliance with FIN 46R may result in our consolidation of companies or related entities with which we have a collaborative arrangement and this may have a material impact on our financial condition and/or results of operations in future periods.

There may be potential new accounting pronouncements or regulatory rulings, which may have an impact on our future financial position and results of operations. In December 2004, the FASB issued a revision of Statement of Financial Accounting Standards (or "FAS") No. 123, "Accounting for Stock-Based Compensation." The revision is referred to as "FAS 123R -- Share-Based Payment", which supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock plans. We expect to adopt FAS 123R using the modified prospective basis on January 1, 2006. We expect that our adoption of FAS 123R will result in compensation expense comparable, before the effect of capitalizing manufacturing related compensation expenses into inventory, to those disclosed in Note 1, "Summary of Significant Accounting Policies -- Accounting for Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of our Form 10-Q. We are currently evaluating option valuation methodologies and assumptions in light of FAS 123R; the methodologies and assumptions we ultimately use to adopt FAS 123R may be different than those currently used as discussed in Note 1, "Summary of Significant Accounting Policies -- Accounting for Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of our Form 10-Q. We currently expect that our adoption of FAS 123R will have a material impact on our consolidated results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 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, except as a result of additional economic interest rate risks corresponding with our debt issuance in July 2005.

On July 18, 2005, we completed a private placement of $500.0 million in Senior Notes due 2010, $1.0 billion in Senior Notes due 2015 and $500.0 million in Senior Notes due 2035. Simultaneously, we entered into a series of interest rate swap agreements to protect against interest rate volatility with respect to the 2010 Notes. See Note 4, "Debt Issuance" and Note 1, "Summary of Significant Accounting Policies -- Derivative Financial Instruments" section in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

Loss with respect to interest rate risk is defined in the value at risk estimation as fair market value loss due to market movements in interest rates on a portfolio, given a specified confidence level and holding period. Given that the maturity dates for our Senior Notes due 2015 and 2035 are significantly longer than the average maturity of our interest-bearing asset portfolio, the estimated fair market value exposures discussed below are largely driven by these Senior Notes.

As of September 30, 2005, changes in interest rates, within a 95% confidence level based on historical interest rate movements, could result in potential losses in the fair value of our combined interest rate sensitive assets, Senior Notes and related interest rate derivative instruments of $40.1 million.

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* The Company's principal executive and financial officers reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15(d)-15(e)) as of the end of the period covered by this Form 10-Q. Based on that evaluation, the Company's principal executive and financial officers concluded that the Company's disclosure controls and procedures are effective in providing them with material information relating to the Company in a timely manner, as required to be disclosed in the reports the Company files under the Exchange Act.

(b) *Changes in internal control over financial reporting.* On August 1, 2005, the Company implemented the first of two phases of an Enterprise Resource Planning (or "ERP") system, using SAP software and methodology, replacing the Company's general ledger, financial reporting, order management, procurement and data warehouse systems.

Other than the changes discussed above, there were no other changes in the Company's internal control over financial reporting that occurred during the period covered by this Form 10-Q that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

In connection with the interference proceeding regarding Chiron and United States (or "U.S.") Patent No. 6,054,561, on September 30, 2005, the Board filed two Orders and issued two Judgments ordering judgment against both parties as to the subject matter of both counts at issue in the interferences and declaring that neither party is entitled to any of the claims corresponding to the count. We are evaluating on which issues, if any, we will seek review.

In connection with the reexamination of the '415 Cabilly patent, on September 13, 2005, the U.S. Patent Office issued an initial "non-final" Office action rejecting the claims of the '415 or Cabilly patent. This action is a routine and expected next step in the reexamination procedure. Our response is due within 60 days from the mailing date of the action; however on October 26, 2005 we filed a request with the Patent Office for an additional 30 days in which to file the response. The Patent Office has not yet acted on that request. The reexamination process is ongoing. The claims of the '415 patent remain valid and enforceable throughout the reexamination process.

With respect to the MedImmune lawsuit, on October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. MedImmune still has the opportunity to seek further review of this decision before the Federal Circuit and the United States Supreme Court.

See also Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q.

See also Item 3 of our report on Form 10-K for the year ended December 31, 2004, and Part II, Item 1 of each of our reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On June 15, 2005, the Board of Directors approved an extension of our stock repurchase program for the repurchase of up to an additional $2.0 billion of our common stock for a total of $4.0 billion through June 30, 2006. The Board also amended the current repurchase program by increasing the maximum number of shares that can be repurchased from 50 million to 80 million shares. Under this stock repurchase program, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. Genentech intends to use the repurchased stock to offset dilution caused by the issuance of shares in connection with Genentech's employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to make prudent investments of our cash resources; (ii) to allow for an effective mechanism to provide stock for our employee stock plans; and (iii) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage. See above in "Relationship with Roche" for more information on Roche's minimum ownership percentage. We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately 1.5 million shares and will run through December 31, 2005.

Our shares repurchased for the three months ended September 30, 2005 were as follows *(shares in millions)*:

	Total Number of Shares Purchased in 2005	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1-31, 2005	1.3	$ 88.57		
August 1-31, 2005	9.2	88.58		
September 1-30, 2005	-	-		
Total	10.5		39.5	40.5

The par value method of accounting is used for common stock repurchases. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital with the amounts in excess of the estimated original sales price charged to accumulated deficit.

Item 6. Exhibits

(i)	10.30	Purchase Agreement, dated as of July 13, 2005, among Genentech, Inc. and Citigroup Global Markets, Inc. and Goldman, Sachs & Co. as representatives of the initial purchasers.
(ii)	10.31*	Manufacturing and Supply Agreement between Genentech, Inc. and Lonza Biologics, Inc. dated December 7, 2003.
(iii)	10.32*	Toll Manufacturing Agreement by and between Wyeth, acting through its Wyeth Pharmaceuticals Division, and Genentech, Inc. dated September 15, 2004.
(iv)	15.1	Letter regarding Unaudited Interim Financial Information.
(v)	31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
(vi)	31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
(vii)	32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

SIGNATURES

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

GENENTECH, INC.

Date: October 31, 2005

/s/ARTHUR D. LEVINSON
Arthur D. Levinson, Ph.D.
Chairman and Chief Executive Officer

Date: October 31, 2005

/s/DAVID A. EBERSMAN
David A. Ebersman
Senior Vice President and
Chief Financial Officer

Date: October 31, 2005

/s/JOHN M. WHITING
John M. Whiting
Vice President, Controller and
Chief Accounting Officer

EXHIBIT 10.30

GENENTECH, INC.

$500,000,000, 4.40% Senior Notes due 2010
$1,000,000,000, 4.75% Senior Notes due 2015
$500,000,000, 5.25% Senior Notes due 2035

Purchase Agreement

July 13, 2005

Citigroup Global Markets Inc.
Goldman, Sachs & Co.
As Representatives of the Initial Purchasers
c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, New York 10013

Ladies and Gentlemen:

Genentech, Inc., a corporation organized under the laws of Delaware (the "Company"), proposes to issue and sell to the several parties named in Schedule I hereto (the "Initial Purchasers"), for whom you (the "Representatives") are acting as representatives, $500,000,000 aggregate principal amount of its 4.40% Senior Notes due 2010 (the "2010 Notes"), $1,000,000,000 aggregate principal amount of its 4.75% Senior Notes due 2015 (the "2015 Notes") and $500,000,000 aggregate principal amount of its 5.25% Senior Notes due 2035 (the "2035 Notes," and together with the 2010 Notes and the 2035 Notes, the "Securities"). The Securities are to be issued under an indenture, to be dated as of the Closing Date, between the Company and The Bank of New York Trust Company, N.A., as trustee (the "Trustee"), as supplemented by an Officers' Certificate to be dated as of the Closing Date (as supplemented, the "Indenture"). Holders of the Securities will have the benefit of a registration rights agreement (the "Registration Rights Agreement"), to be dated as of the Closing Date, between the Company and the Initial Purchasers, pursuant to which the Company will agree to register the Securities under the Act subject to the terms and conditions therein specified. To the extent there are no additional parties listed on Schedule I other than you, the term Representatives as used herein shall mean you as the Initial Purchasers, and the terms Representatives and Initial Purchasers shall mean either the singular or plural as the context requires. The use of the neuter in this Agreement shall include the feminine and masculine wherever appropriate. Certain terms used herein are defined in Section 18 hereof.

The sale of the Securities to the Initial Purchasers will be made without registration of the Securities under the Act in reliance upon exemptions from the registration requirements of the Act.

In connection with the sale of the Securities, the Company has prepared a preliminary offering memorandum, dated July 13, 2005 (as amended or supplemented at the date thereof, including any and all exhibits thereto and any information incorporated by reference therein, the "Preliminary Memorandum"), and a final offering memorandum, dated July 13, 2005 (as amended or supplemented at the Execution Time, including any and all exhibits thereto and any information incorporated by reference therein at the Execution Time, the "Final Memorandum"). Each of the Preliminary Memorandum and the Final Memorandum sets forth certain information concerning the Company and the Securities. The Company hereby confirms that it has authorized the use of the Preliminary Memorandum and the Final Memorandum, and any amendment or supplement thereto, in connection with the offer and sale of the Securities by the Initial Purchasers. Unless stated to the contrary, any references herein to the terms "amend," "amendment" or "supplement" with respect to the Final Memorandum shall be deemed

to refer to and include any information filed under the Exchange Act subsequent to the Execution Time that is incorporated by reference therein.

1. Representations and Warranties. The Company represents and warrants to each Initial Purchaser as set forth below in this Section 1.

(a) The Preliminary Memorandum, at the date thereof, did not contain any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. At the Execution Time and on the Closing Date, the Final Memorandum did not and will not (and any amendment or supplement thereto, at the date thereof and at the Closing Date will not) contain any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representation or warranty as to the information contained in or omitted from the Preliminary Memorandum or the Final Memorandum, or any amendment or supplement thereto, in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of the Initial Purchasers through the Representatives specifically for inclusion therein.

(b) The Securities satisfy the eligibility requirements of Rule 144A(d)(3) under the Act.

(c) No registration under the Act of any of the Securities is required for the offer and sale of the Securities to or by the Initial Purchasers in the manner contemplated herein and in the Final Memorandum, including as a result of any general advertising or solicitation (within the meaning of Regulation D) or any violation of the offering restrictions of Regulation S.

(d) The Company is not, and after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Final Memorandum will not be, an "investment company" as defined in the Investment Company Act.

(e) The Company is subject to and in full compliance with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act.

(f) The Company has not paid or agreed to pay to any person any compensation for soliciting another to purchase any securities of the Company (except as contemplated in this Agreement).

(g) The Company has not taken, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result, under the Exchange Act or otherwise, in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities.

(h) Each of the Company and its significant subsidiaries as defined under Rule 1-02(w) of Regulation S-X (the "Material Subsidiaries") has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction in which it is chartered or organized with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as described in the Final Memorandum, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction that requires such qualification, except in each case where the failure to so qualify or to be in good standing would not have a material adverse effect on the condition (financial or otherwise), prospects, earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business (a "Material Adverse Effect").

(i) All the outstanding shares of capital stock of each Material Subsidiary have been duly authorized and validly issued and are fully paid and nonassessable, and, except as otherwise set forth in the Final Memorandum, all outstanding shares of capital stock of such Material Subsidiaries are owned by the Company either directly or through wholly owned subsidiaries free and clear of any security interest, claim, lien or encumbrance.

(j) The statements in the Final Memorandum under the headings "Description of Notes," "Exchange Offer; Registration Rights" fairly summarize the matters therein described.

(k) This Agreement has been duly authorized, executed and delivered by the Company; the Indenture has been duly authorized and, assuming due authorization, execution and delivery thereof by the Trustee, when executed and delivered by the Company on the Closing Date, will constitute a legal, valid, binding instrument enforceable against the Company in accordance with its terms (subject, as to the enforcement of remedies, to applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance or other laws affecting creditors' rights generally from time to time in effect and to general principles of equity); the Securities have been duly authorized, and, when executed and authenticated in accordance with the provisions of the Indenture and delivered to and paid for by the Initial Purchasers, will have been duly executed and delivered by the Company on the Closing Date and will constitute the legal, valid and binding obligations of the Company entitled to the benefits of the Indenture (subject, as to the enforcement of remedies, to applicable bankruptcy, reorganization, insolvency, fraudulent conveyance, moratorium or other laws affecting creditors' rights generally from time to time in effect and to general principles of equity); and the Registration Rights Agreement has been duly authorized by the Company and, when executed and delivered by the Company on the Closing Date, will constitute the legal, valid, binding and enforceable instrument of the Company (subject, as to the enforcement of remedies, to applicable bankruptcy, reorganization, insolvency, fraudulent conveyance, moratorium or other laws affecting creditors' rights generally from time to time in effect, to general principles of equity and as rights to indemnification and contribution may be limited by relevant law and public policy), provided that no representation is made with respect to Section 8 thereof.

(l) No consent, approval, authorization, filing with or order of any court or governmental agency or body is required in connection with the transactions contemplated herein, in the Indenture or in the Registration Rights Agreement, except as such agreements expressly require, or such as may be required under the blue sky laws of any jurisdiction in which the Securities are offered and sold and, in the case of the Registration Rights Agreement, such as will be obtained under the Act and the Trust Indenture Act.

(m) None of the execution and delivery of the Indenture, this Agreement or the Registration Rights Agreement, the issuance and sale of the Securities, or the consummation of any other of the transactions herein or therein contemplated will conflict with, result in a breach or violation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its Material Subsidiaries pursuant to, (i) the charter or by-laws of the Company or any of its Material Subsidiaries; (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company or any of its Material Subsidiaries is a party or bound or to which its or their property is subject; (iii) any applicable law; or (iv) any judgment, order or decree of any governmental body, agency or court, arbitrator or other authority having jurisdiction over the Company or any of its Material Subsidiaries or any of its or their properties, except in the case of (ii), (iii) or (iv), such as would not have a Material Adverse Effect.

(n) Neither the Company nor any of its subsidiaries has sustained since the date of the latest audited financial statements incorporated by reference in the Final Memorandum any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the Final Memorandum; and, since the respective dates as of which information is given in the Final Memorandum, there has not been any material change in the common stock or increase in long-term debt of the Company or any of its subsidiaries or any material adverse change, or any development involving a prospective material adverse change, in or affecting the financial position, stockholders' equity or results of operations of the Company and its subsidiaries, taken as a whole, otherwise than as set forth or contemplated in the Final Memorandum.

(o) The consolidated historical financial statements and schedules of the Company and its consolidated subsidiaries included or incorporated by reference in the Final Memorandum present fairly the financial condition, results of operations and cash flows of the Company as of the dates and for the periods indicated, comply as to form with the applicable accounting requirements of Regulation S-X and have been prepared in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved (except as otherwise noted therein).

(p) No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Material Subsidiaries is pending or, to the knowledge of the Company, threatened that (i) could reasonably be expected to have a material adverse effect on the performance of this Agreement, the Indenture or the Registration Rights Agreement, or the consummation of any of the transactions contemplated hereby or thereby or (ii) could reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Final Memorandum.

(q) Neither the Company nor any of its material subsidiaries (as to (i) and all subsidiaries as to (ii) and (iii)) is in violation or default of (i) any provision of its charter or bylaws; (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which it is a party or bound or to which its property is subject; (iii) any applicable law; or (iv) any judgment, order or decree of any governmental body, agency or court, arbitrator or other authority having jurisdiction over the Company or any of its Material Subsidiaries or any of its or their properties, except in the case of (ii), (iii) or (iv), as would not cause a Material Adverse Effect or as set forth in the Final Memorandum.

(r) Ernst & Young LLP, who have certified certain financial statements of the Company and its consolidated subsidiaries and delivered their report with respect to the audited consolidated financial statements and schedules included or incorporated by reference in the Final Memorandum, are independent public accountants with respect to the Company within the meaning of the Act.

(s) The Company has filed all non-U.S., U.S. federal, state and local tax returns that are required to be filed or has requested extensions thereof (except in any case in which the failure so to file would not have a Material Adverse Effect and except as set forth in or contemplated in the Final Memorandum).

(t) The Company and each of its Material Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which they are engaged; and neither the Company nor any of its subsidiaries has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect except as set forth in or contemplated in the Final Memorandum.

(u) No Material Subsidiary of the Company is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's property or assets to the Company or any other subsidiary of the Company, except as described in or contemplated in the Final Memorandum or as would not materially interfere with the Company's ability to satisfy its obligations under the Indenture and the Securities.

(v) The Company and each of its Material Subsidiaries possess all licenses, certificates, permits and other authorizations issued by the appropriate U.S. federal, state or non-U.S. regulatory authorities necessary to conduct their respective businesses, and neither the Company nor any of its Material Subsidiaries has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect, except as set forth in or contemplated in the Final Memorandum.

(w) The Company and its subsidiaries on a consolidated basis maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(x) Such system of internal controls over financial reporting were evaluated for effectiveness and were effective as of December 31, 2004 and since such evaluation, there have been no significant changes in the system of internal controls over financial reporting or in other systems, processes or otherwise that could materially adversely affect the system of internal controls over financial reporting.

(y) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) of the Exchange Act) that have been designed to ensure that material information relating to the Company and its consolidated subsidiaries is made known to the Company's principal executive officer and principal financial officer by others within those entities; such disclosure controls and procedures were effective in all material respects to perform the functions for which they were established as of the end of the quarter ended March 31, 2005 and, as of the date hereof, the Company is not aware of any material weaknesses in such disclosure controls and procedures.

(z) The Company and its subsidiaries are (i) in compliance with any and all applicable non-U.S., U.S. federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws"); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) have not received notice of any actual or potential liability under any Environmental Law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not have a Material Adverse Effect, except as set forth in or contemplated in the Final Memorandum. Except as set forth in the Final Memorandum, neither the Company nor any of its subsidiaries is currently named as a "potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(aa) The Company has no "significant subsidiaries" (as defined in Rule l-02 of Regulation S-X under the Act).

(bb) The Company has not taken any action or omitted to take any action (such as issuing any press release relating to any Securities without an appropriate legend) which may result in the loss by any of the Initial Purchasers of the ability to rely on any stabilization safe harbor provided by the Financial Services Authority under the Financial Services and Markets Act 2000 (the "FSMA"). The Company has been informed of the guidance relating to stabilization provided by the Financial Services Authority, in particular in Section MAR 2 Annex 2G of the Financial Services Handbook.

(cc) The Company and its subsidiaries own, possess, license or have other rights to use on reasonable terms, all patents, trade and service marks, trade names, copyrights, domain names (in each case including all registrations and applications to register same), inventions, trade secrets, technology, know-how, and other intellectual property necessary for the conduct of the Company's business (collectively, the "Intellectual Property") as now conducted or as proposed in the Final Memorandum to be conducted. Except as set forth in the Final Memorandum, (i) the Company owns, or has rights to use under license, all such Intellectual Property free and clear in all respects of all adverse claims, liens or other encumbrances; (ii) to the knowledge of the Company, there is no infringement by third parties of any such Intellectual Property; (iii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by any third party challenging the Company's or its Material Subsidiaries' rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (iv) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by any third party challenging the validity, scope or enforceability of any such Intellectual Property, and the Company is unaware of any facts that would form a reasonable basis for any such claim; (v) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by any third party that the Company or any subsidiary infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of any third party, and the Company is unaware of any other fact which would form a reasonable basis for any such claim; and (vi) to the knowledge of the Company, there is no valid and subsisting patent or published patent application that would preclude the Company, in any material respect, from practicing any such Intellectual Property, except in the case of each of (i) through (vi), such as would not have a Material Adverse Effect.

(dd) Since the respective dates as of which information is given in the Final Memorandum, the clinical studies conducted by or sponsored by the Company that are described in the Final Memorandum or the results of which are referred to in the Final Memorandum were and, if still pending, are being conducted in compliance in all respects with all applicable U.S. Food and Drug Administration (the "FDA") rules, regulations and policies except for such noncompliance that would not have a Material Adverse Effect. The descriptions of the results of such studies in the Final Memorandum are accurate in all material respects and fairly present the data derived from such studies. Except as disclosed in the Final Memorandum, the Company has operated and currently is in compliance in all respects with all applicable FDA rules, regulations and policies except for such noncompliance that would not have a Material Adverse Effect. The Company has not received any notices or other correspondence from the FDA or any other governmental agency requiring the termination or suspension of any clinical studies that are described in the Final Memorandum or the results of which are referred to in the Final Memorandum which termination or suspension could reasonably be expected to have a Material Adverse Effect.

Any certificate signed by any officer of the Company and delivered to the Representatives or counsel for the Initial Purchasers in connection with the offering of the Securities shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Initial Purchaser.

2. Purchase and Sale. Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company agrees to sell to each Initial Purchaser, and each Initial Purchaser agrees, severally and not jointly, to purchase from the Company, (a) at a purchase price of 99.642% of the principal amount thereof the principal amount of the 2010 Notes set forth opposite such Initial Purchaser's name in Schedule I hereto, (b) at a purchase price of 99.487% of the principal amount thereof the principal amount of the 2015 Notes set forth opposite such Initial Purchaser's name in Schedule I hereto, (c) at a purchase price of 98.975% of the principal amount thereof the principal amount of the 2035 Notes set forth opposite such Initial Purchaser's name in Schedule I hereto.

3. Delivery and Payment. Delivery of and payment for the Securities shall be made at 10:00 A.M., New York City time, on July 18, 2005, or at such time on such later date not more than three Business Days after the foregoing date as the Representatives shall designate, which date and time may be postponed by agreement between the Representatives and the Company or as provided in Section 9 hereof (such date and time of delivery and payment for the Securities being herein called the "Closing Date"). Delivery of the Securities shall be made to the Representatives for the respective accounts of the several Initial Purchasers against payment by the several Initial Purchasers through the Representatives of the purchase price thereof to or upon the order of the Company by wire transfer payable in same-day funds to the account specified by the Company. Delivery of the Securities sold pursuant to Clauses 4(b)(i) shall be made through the facilities of The Depository Trust Company unless the Representatives shall otherwise instruct. Certificates for such Securities shall be registered in the name of Cede & Co., as nominee of the Depositary Trust Company. The Company agrees to have the Securities available for inspection by the Representatives in New York, New York, not later than 1:00 PM on the Business Day prior to the Closing Date.

4. Offering by Initial Purchasers. (a) Each Initial Purchaser acknowledges that the Securities have not been and will not be registered under the Act and may not be offered or sold within the United States or to, or for the account or benefit of, U.S. persons, except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Act.

(b) Each Initial Purchaser, severally and not jointly, represents and warrants to and agrees with the Company that:

(i) it has not offered or sold, and will not offer or sell, any Securities within the United States or to, or for the account or benefit of, U.S. persons (x) as part of their distribution at any time or (y) otherwise until 40 days after the later of the commencement of the offering and the date of closing of the offering except:

(A) to those it reasonably believes to be "qualified institutional buyers" (as defined in Rule 144A under the Act); or

(B) in accordance with Rule 903 of Regulation S;

(ii) neither it nor any person acting on its behalf has made or will make offers or sales of the Securities in the United States by means of any form of general solicitation or general advertising (within the meaning of Regulation D) in the United States;

(iii) in connection with each sale pursuant to Section 4(b)(i)(A), it has taken or will take reasonable steps to ensure that the purchaser of such Securities is aware that such sale is being made in reliance on Rule 144A;

(iv) neither it, nor any of its Affiliates nor any person acting on its or their behalf has engaged or will engage in any directed selling efforts (within the meaning of Regulation S) with respect to the Securities;

(v) it has not entered and will not enter into any contractual arrangement with any distributor (within the meaning of Regulation S) with respect to the distribution of the Securities, except with its affiliates or with the prior written consent of the Company;

(vi) it and its Affiliates have complied and will comply with the offering restrictions requirement of Regulation S;

(vii) at or prior to the confirmation of sale of Securities (other than a sale of Securities pursuant to Section 4(b)(i)(A) of this Agreement), it shall have sent to each distributor, dealer or person receiving a selling concession, fee or other remuneration that purchases Securities from it during the distribution compliance period (within the meaning of Regulation S) a confirmation or notice to substantially the following effect:

> "The Securities covered hereby have not been registered under the U.S. Securities Act of 1933 (the "Act") and may not be offered or sold within the United States or to, or for the account or benefit of, U.S. persons (i) as part of their distribution at any time or (ii) otherwise until 40 days after the later of the commencement of the offering and the date of closing of the offering, except in either case in accordance with Regulation S or Rule 144A under the Act. Additional restrictions on the offer and sale of the Securities are described in the offering memorandum for the Securities. Terms used in this paragraph have the meanings given to them by Regulation S."

(viii) it has not offered or sold and, prior to the date six months after the date of issuance of the Securities, will not offer or sell any Securities to persons in the United Kingdom except to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses or otherwise in circumstances which have not resulted and will not result in an offer to the public in the United Kingdom within the meaning of the Public Offers of Securities Regulations 1995;

(ix) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the Securities in, from or otherwise involving the United Kingdom;

(x) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received by it in connection with the issue or sale of any Securities, in circumstances in which section 21(1) of the FSMA does not apply to the Company;

(xi) it is an "accredited investor" (as defined in Rule 501(a) of Regulation D); and

(xii) it will not offer, sell or deliver any of the Securities in any jurisdiction outside the United States except under circumstances that will result in compliance with applicable securities laws thereof, except as would not have a material adverse effect on the Company or the transactions contemplated hereby.

5. Agreements. The Company agrees with each Initial Purchaser that:

(a) The Company will furnish to each Initial Purchaser and to counsel for the Initial Purchasers, without charge, during the period referred to in paragraph (c) below, as many copies of the Final Memorandum and any amendments and supplements thereto as they may reasonably request.

(b) During the period referred to in Section 5(c) below, but in no event later than nine months following the Closing Date, the Company will not amend or supplement the Final Memorandum, other than by filing documents under the Exchange Act that are incorporated by reference therein, if after reasonable notice (unless with respect to Item 7.01 or 8.01 Current Reports on Form 8-K, time does not so permit under applicable law), the Representatives reasonably object; provided, however, that, prior to the completion of the distribution of the Securities by the Initial Purchasers (as determined by the Representatives), the Company will not file any document under the Exchange Act that is incorporated by reference in the Final Memorandum unless, prior to such proposed filing, the Company has furnished the Representatives with a copy of such document for their review and the Representatives have not reasonably objected to the filing of such document. The Company will promptly advise the Representatives when any document filed under the Exchange Act that is incorporated by reference in the Final Memorandum shall have been filed with the Commission.

(c) If at any time prior to the completion of the sale of the Securities by the Initial Purchasers (as reasonably determined by the Representatives), any event occurs as a result of which the Final Memorandum, as then amended or supplemented, would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, or if it should be necessary to amend or supplement the Final Memorandum to comply with applicable law, the Company will promptly (i) notify the Representatives of any such event; (ii) subject to the requirements of paragraph (b) of this Section 5, prepare an amendment or supplement that will correct such statement or omission or effect such compliance; and (iii) supply any supplemented or amended Final Memorandum to the several Initial Purchasers and counsel for the Initial Purchasers without charge in such quantities as they may reasonably request.

(d) The Company will arrange, if necessary, for the qualification of the Securities for sale by the Initial Purchasers under the laws of such jurisdictions as the Representatives may designate and will maintain such qualifications in effect so long as required for the sale of the Securities; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Securities or subject itself to taxation or qualify as a dealer in securities, in any jurisdiction where it is not now so subject. The Company will promptly advise the Representatives of the receipt by the Company of any notification with respect to the suspension of the qualification of the Securities for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose.

(e) The Company will not, and will not permit any of its controlled Affiliates to, resell any Securities that have been acquired by any of them during the period from the Closing Date until the passage of two years thereafter.

(f) None of the Company, its controlled Affiliates, or any person acting on its or their behalf will, directly or indirectly, make offers or sales of any security, or solicit offers to buy any security, under circumstances that would require the registration of the Securities under the Act other than as contemplated by the Registration Rights Agreement.

(g) None of the Company, its controlled Affiliates, or any person acting on its or their behalf will engage in any form of general solicitation or general advertising (within the meaning of Regulation D) in connection with any offer or sale of the Securities in the United States and none of the Company, its Affiliates, or any person acting on its or their behalf will engage in any directed selling efforts with respect to the Securities, and each of them will comply with the offering restrictions requirement of Regulation S. Terms used in this paragraph have the meanings given to them by Regulation S.

(h) So long as any of the Securities are "restricted securities" within the meaning of Rule 144(a)(3) under the Act, the Company will, during any period in which it is not subject to and in compliance with Section 13 or 15(d) of the Exchange Act, provide to each holder of such restricted securities and to each prospective purchaser (as designated by such holder) of such restricted securities, upon the request of such holder or prospective purchaser, any information required to be provided by Rule 144A(d)(4) under the Act. This covenant is intended to be for the benefit of the holders, and the prospective purchasers designated by such holders, from time to time of such restricted securities.

(i) The Company will cooperate with the Representatives and use its reasonable best efforts to permit the Securities to be eligible for clearance and settlement through The Depository Trust Company.

(j) The Company will not for a period of 60 days following the Execution Time, without the prior written consent of Citigroup and Goldman, Sachs, offer, sell or contract to sell, or otherwise dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any Affiliate of the Company or any person in privity with the Company or any Affiliate of the Company), directly or indirectly, or announce the offering of, any debt securities issued or guaranteed by the Company (other than the Securities).

(k) The Company will not take, directly or indirectly (excluding any action of the Initial Purchasers), any action designed to or which has constituted or which might reasonably be expected to cause or result, under the Exchange Act or otherwise, in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(l) The Company agrees to pay the costs and expenses relating to the following matters: (i) the issuance of the Securities and the fees of the Trustee; (ii) the preparation, printing or reproduction of the Preliminary Memorandum and the Final Memorandum and each amendment or supplement to either of them; (iii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Preliminary Memorandum and the Final Memorandum, and all amendments or supplements to either of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Securities; (iv) the preparation, printing, authentication, issuance and delivery of certificates for the Securities; (v) any stamp or transfer taxes in connection with the original issuance and sale of the Securities; (vi) the printing (or reproduction) and delivery of any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Securities; (vii) any registration or qualification of the Securities for offer and sale under the securities or blue sky laws of the several states and any other jurisdictions specified pursuant to Section 5(d) (including filing fees and the reasonable fees and expenses of counsel for the Initial Purchasers relating to such registration and qualification); (viii) admitting the Securities for trading in the PORTAL Market; (ix) the transportation and other expenses incurred by or for the Company in connection with presentations to prospective purchasers of the Securities; (x) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; and (xi) all other costs and expenses incident to the performance by the Company of its obligations hereunder.

(m) The Company will, for a period of twelve months following the Execution Time, if the Company is a public company, furnish to the Representatives (i) all reports or other communications (financial or other) generally made available to stockholders, and deliver such reports and communications to the Representatives as soon as they are available, unless such documents (A) are furnished to or filed with the Commission or any securities exchange on which any class of securities of the Company is listed and generally made available to the public or (B) are made available through the Company's website.

(n) The Company will not take any action or omit to take any action (such as issuing any press release relating to any Securities without an appropriate legend) which may result in the loss by any of the Initial Purchasers of the ability to rely on any stabilization safe harbor provided by the Financial Services Authority under the FSMA.

(o) The Company acknowledges and agrees that (i) the purchase and sale of the Securities pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the several Initial Purchasers, on the other, (ii) in connection therewith and with the process leading to such transaction each Initial Purchaser is acting solely as a principal and not the agent or fiduciary of the Company, (iii) no Initial Purchaser has assumed an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Initial Purchaser has advised or is currently advising the Company on other matters) or any other obligation to the Company except the obligations expressly set forth in this Agreement and (iv) the Company has consulted its own legal and financial advisors to the extent it deemed appropriate. The Company agrees that it will not claim that the Initial Purchasers, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

6. Conditions to the Obligations of the Initial Purchasers. The obligations of the Initial Purchasers to purchase the Securities shall be subject to the accuracy of the representations and warranties of the Company contained herein at the Execution Time and the Closing Date, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder and to the following additional conditions:

(a) The Company shall have requested and caused Wilson Sonsini Goodrich & Rosati, outside counsel for the Company, to furnish to the Representatives its opinion, dated the Closing Date and addressed to the Representatives, in the form attached hereto as Exhibit A, further relying on certificates of officers of the Company and others and containing assumptions, qualifications, and exemptions as are customary in transactions of this type.

(b) Stephen G. Juelsgaard, Esq., General Counsel of the Company, shall have furnished to the Representatives his opinion, dated the Closing Date and addressed to the Representatives, in the form attached hereto as Exhibit B further relying on certificates of officers of the Company and others and containing assumptions, qualifications, and exemptions as are customary in transactions of this type.

(c) The Representatives shall have received from Skadden, Arps, Slate, Meagher & Flom LLP, counsel for the Initial Purchasers, such opinion or opinions, dated the Closing Date and addressed to the Representatives, further relying on certificates of officers of the Company and others and containing assumptions, qualifications, and exemptions as are customary in transactions of this type with respect to the issuance and sale of the Securities, the Indenture, the Registration Rights Agreement, the Final Memorandum (as amended or supplemented at the Closing Date) and other related matters as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for the purpose of enabling them to pass upon such matters.

(d) The Company shall have furnished to the Representatives a certificate of the Company, signed by (x) the President or General Counsel, and (y) the principal financial or accounting officer of the Company, dated the Closing Date, to the effect that the signers of such certificate have carefully examined the Final Memorandum, any amendment or supplement to the Final Memorandum and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of the Closing Date with the same effect as if made on the Closing Date, and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date; and

(ii) since the date of the most recent financial statements included or incorporated by reference in the Final Memorandum (exclusive of any amendment or supplement thereto), there has been no material adverse change in the condition (financial or otherwise), prospects, earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Final Memorandum.

(e) At the Execution Time and at the Closing Date, the Company shall have requested and caused Ernst & Young LLP to furnish to the Representatives letters, dated respectively as of the Execution Time and as of the Closing Date, in form and substance satisfactory to the Representatives, confirming that they are independent accountants within the meaning of the Exchange Act and the applicable rules and regulations thereunder and stating in effect that:

(i) in their opinion the audited financial statements and financial statement schedules included or incorporated by reference in the Final Memorandum and reported on by them comply as to form with the applicable accounting requirements of Regulation S-X; and

(ii) on the basis of a reading of the latest unaudited financial statements made available by the Company and its subsidiaries; their limited review in accordance with the standards established under Statement on Auditing Standards No. 100 of the unaudited interim financial information for the three-month period ended March 31, 2005; carrying out certain specified procedures (but not an examination in accordance with generally accepted auditing standards) which would not necessarily reveal matters of significance with respect to the comments set forth in such letter; a reading of the minutes of the meetings of the stockholders, directors and the Audit, Compensation, Corporate Governance, Executive and Nominations committees of the Company and the Subsidiaries; and inquiries of certain officials of the Company who have responsibility for financial and accounting matters of the Company and its subsidiaries as to transactions and events subsequent to December 31, 2004, nothing came to their attention which caused them to believe that:

(A) any unaudited financial statements included on Form 10-Q and incorporated by reference in the Final Memorandum do not comply as to form with applicable accounting requirements of Regulation S-X and with the published rules and regulations of the Commission with respect to financial statements included or incorporated by reference in quarterly reports on Form 10 Q under the Exchange Act; and said unaudited financial statements are not in conformity with generally accepted accounting principles applied on a basis substantially consistent with that of the audited financial statements included or incorporated by reference in the Final Memorandum; or

(B) with respect to the period subsequent to March 31, 2005, there were any changes, at a specified date not more than five days prior to the date of the letter, in the long term debt of the Company and its subsidiaries or common stock of the Company, other accrued liabilities or litigation-related and other long-term liabilities or decreases in the total stockholders' equity of the Company, as compared with the amounts shown on the March 31, 2005 consolidated balance sheet included or incorporated by reference in the Final Memorandum, or for the period from April 1, 2005 to such specified date there were any decreases, as compared with the corresponding period in the preceding quarter in total operating revenues or income before taxes and cumulative effect of accounting change, net income, operating margin or per share amounts of net earnings of the Company and its subsidiaries, except in all instances for changes or decreases set forth in such letter, in which case the letter shall be accompanied by an explanation by the Company as to the significance thereof unless said explanation is not deemed necessary by the Representatives.

(iii) they have performed certain other specified procedures as a result of which they determined that certain information of an accounting, financial or statistical nature (which is limited to accounting, financial or statistical information derived from the general accounting records of the Company and its subsidiaries) set forth in the Final Memorandum, including the information set forth under the caption "Summary Financial Data" in the Final Memorandum, the information included or incorporated by reference in Items 1, 6, 7 and 11 of the Company's Annual Report on Form 10 K, incorporated by reference in the Final Memorandum, the information included in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" included or incorporated by reference in the Company's Quarterly Reports on Form 10-Q, incorporated by reference in the Final Memorandum, the Current Reports on Form 8-K filed with the Commission on January 10, February 24, April 11, April 20, June 15 and June 22, 2005 incorporated by reference in the Final Memorandum and the information included under the caption "Compensation of Named Executive Officers" in the Company's Definitive Proxy Statement filed with the Commission on March 11, 2005 incorporated by reference in the Final Memorandum agrees with the accounting records of the Company and its subsidiaries, excluding any questions of legal interpretation.

All references in this Section 6(d) to the Final Memorandum include any amendment or supplement thereto at the date of the applicable letter.

(f) Subsequent to the Execution Time or, if earlier, the dates as of which information is given in the Final Memorandum (exclusive of any amendment or supplement thereto), there shall not have been (i) any adverse change or decrease specified in the letter or letters referred to in paragraph (d) of this Section 6; or (ii) any adverse change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), prospects, earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Final Memorandum (exclusive of any amendment or supplement thereto), the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Representatives, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated in the Final Memorandum (exclusive of any amendment or supplement thereto).

(g) The Securities shall be eligible for clearance and settlement through The Depository Trust Company.

(h) Subsequent to the Execution Time, there shall not have been any decrease in the rating of any of the Company's securities by any "nationally recognized statistical rating organization" (as defined for purposes of Rule 436(g) under the Act) or any notice given of any intended or potential decrease in any such rating or of a possible change in any such rating that does not indicate the direction of the possible change.

(i) The Registration Rights Agreement, in form and substance consistent with the summary description contained in the Final Offering Memorandum and otherwise reasonably acceptable to the Company and the Representatives, shall have been executed by the Company and delivered to the Representatives.

(j) Prior to the Closing Date, the Company shall have furnished to the Representatives such further customary certificates and documents as the Representatives may reasonably request.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Representatives and counsel for the Initial Purchasers, this Agreement and all obligations of the Initial Purchasers hereunder may be cancelled at, or at any time prior to, the Closing Date by the Representatives. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 will be delivered at the office of counsel for the Company, at 650 Page Mill Road, Palo Alto, California 94304, on the Closing Date.

7. Reimbursement of Expenses. If the sale of the Securities provided for herein is not consummated because any condition to the obligations of the Initial Purchasers set forth in Section 6 hereof is not satisfied, because of any termination pursuant to Section 10 hereof and a similar transaction in which the Representatives act in similar capacities is not consummated within 90 days of the date of this Agreement, or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof other than by reason of a default by any of the Initial Purchasers, the Company will reimburse the Initial Purchasers severally through Citigroup on demand for all expenses (including reasonable fees and disbursements of counsel) that shall have been incurred by them in connection with the proposed purchase and sale of the Securities.

8. Indemnification and Contribution. (a) The Company agrees to indemnify and hold harmless each Initial Purchaser, the directors, officers, employees, Affiliates and agents of each Initial Purchaser and each person who controls any Initial Purchaser within the meaning of either the Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Act, the Exchange Act or other U.S. federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Preliminary Memorandum, the Final Memorandum or in any amendment or supplement thereto or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, and agrees to reimburse each such indemnified party, as incurred, for any legal or other expenses reasonably incurred by it in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made in the Preliminary Memorandum, the Final Memorandum or in any amendment thereof or supplement thereto, in reliance upon and in conformity with written information furnished to the Company by or on behalf of any Initial Purchaser through the Representatives specifically for inclusion therein. This indemnity agreement will be in addition to any liability that the Company may otherwise have.

(b) Each Initial Purchaser severally, and not jointly, agrees to indemnify and hold harmless the Company, each of its directors, each of its officers, and each person who controls the Company within the meaning of either the Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to each Initial Purchaser, but only with reference to written information relating to such Initial Purchaser furnished to the Company by or on behalf of such Initial Purchaser through the Representatives specifically for inclusion in the Preliminary Memorandum, the Final Memorandum or in any amendment or supplement thereto. This indemnity agreement will be in addition to any liability that any Initial Purchaser may otherwise have. Each of the parties hereto acknowledges that (i) the statements set forth in the last paragraph of the cover page and (ii), under the heading "Plan of Distribution," the fourteenth paragraph in the Preliminary Memorandum and the Final Memorandum constitute the only information furnished in writing by or on behalf of the Initial Purchasers for inclusion in the Preliminary Memorandum, the Final Memorandum or in any amendment or supplement thereto.

(c) Promptly after receipt by an indemnified party under this Section 8 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel (including local counsel) of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which

indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel, other than local counsel if not appointed by the indemnifying party, retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel (including local counsel) to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest; (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties that are different from or additional to those available to the indemnifying party; (iii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action; or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle, compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and (ii) does not include a statement as to, or an admission of, fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) In the event that the indemnity provided in paragraph (a) or (b) of this Section 8 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Initial Purchasers severally agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending any loss, claim, damage, liability or action) (collectively "Losses") to which the Company and one or more of the Initial Purchasers may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Initial Purchasers on the other from the offering of the Securities; provided, however, that in no case shall any Initial Purchaser be responsible for any amount in excess of the purchase discount or commission applicable to the Securities purchased by such Initial Purchaser hereunder. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Initial Purchasers severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and the Initial Purchasers on the other in connection with the statements or omissions that resulted in such Losses, as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total proceeds (net of the Initial Purchasers' discount) from the offering (before deducting expenses) received by it, and benefits received by the Initial Purchasers shall be deemed to be equal to the total purchase discounts and commissions. Relative fault shall be determined by reference to, among other things, whether any untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Initial Purchasers on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Initial Purchasers agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation that does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each person who controls an Initial Purchaser within the meaning of either the Act or the Exchange Act and each director, officer, employee, Affiliate and agent of an Initial Purchaser shall have the same rights to contribution as such Initial Purchaser, and each person who controls the Company within the meaning of either the Act or the Exchange Act and each officer and director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

9. Default by an Initial Purchaser. If any one or more Initial Purchasers shall fail to purchase and pay for any of the Securities agreed to be purchased by such Initial Purchaser hereunder and such failure to purchase shall constitute a default in the performance of its or their obligations under this Agreement, the remaining Initial

Purchasers shall be obligated severally to take up and pay for (in the respective proportions which the principal amount of Securities set forth opposite their names in Schedule I hereto bears to the aggregate principal amount of Securities set forth opposite the names of all the remaining Initial Purchasers) the Securities which the defaulting Initial Purchaser or Initial Purchasers agreed but failed to purchase; provided, however, that in the event that the aggregate principal amount of Securities which the defaulting Initial Purchaser or Initial Purchasers agreed but failed to purchase shall exceed 10% of the aggregate principal amount of Securities set forth in Schedule I hereto, the remaining Initial Purchasers shall have the right to purchase all, but shall not be under any obligation to purchase any, of the Securities, and if such nondefaulting Initial Purchasers do not purchase all the Securities, this Agreement will terminate without liability to any nondefaulting Initial Purchaser or the Company. In the event of a default by any Initial Purchaser as set forth in this Section 9, the Closing Date shall be postponed for such period, not exceeding five Business Days, as the Representatives shall determine in order that the required changes in the Final Memorandum or in any other documents or arrangements may be effected. Nothing contained in this Agreement shall relieve any defaulting Initial Purchaser of its liability, if any, to the Company or any nondefaulting Initial Purchaser for damages occasioned by its default hereunder.

10. Termination. This Agreement shall be subject to termination in the absolute discretion of the Representatives, by notice given to the Company prior to delivery of and payment for the Securities, if at any time prior to such time (i) trading in the Company's Common Stock shall have been suspended by the Commission or the New York Stock Exchange or trading in securities generally on the New York Stock Exchange shall have been suspended or limited or minimum prices shall have been established on such exchange; (ii) a banking moratorium shall have been declared either by U.S. federal or New York State authorities or a material disruption in commercial banking or securities settlement or clearance services in the United States; or (iii) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war or other calamity or crisis or any change in financial, political or economic conditions in the United States or elsewhere, the effect of which is such as to make it, in the sole judgment of the Representatives, impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated in the Final Memorandum (exclusive of any amendment or supplement thereto).

11. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers and of the Initial Purchasers set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Initial Purchasers or the Company or any of the indemnified persons referred to in Section 8 hereof, and will survive delivery of and payment for the Securities. The provisions of Sections 7 and 8 hereof shall survive the termination or cancellation of this Agreement.

12. Notices. All communications hereunder will be in writing and effective only on receipt, and, if sent to the Representatives, will be mailed, delivered or telefaxed to the Citigroup General Counsel (fax no.: (212) 816 7912) and confirmed to Citigroup at 388 Greenwich Street, New York, New York 10013, Attention: General Counsel and to Goldman, Sachs & Co., 85 Broad Street, New York, New York, 10004, Attention: Registration Department; or, if sent to the Company, will be mailed, delivered or telefaxed to (650) 225-6978 and confirmed to it at 1 DNA Way, South San Francisco, CA 94080-4990, attention of the Legal Department.

13. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the indemnified persons referred to in Section 8 hereof and their respective successors, and, except as expressly set forth in Section 5(h) hereof, no other person will have any right or obligation hereunder.

14. Applicable Law. This Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York. The parties hereto each hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any action, proceeding or counterclaim arising out of or relating to this Agreement or the transactions contemplated hereby.

15. Counterparts. This Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement.

16. Other Agreements. The agreement supersedes all prior agreements and understandings (whether written or oral) between the Company and the Initial Purchasers, or any of them, with respect to the subject matter hereof.

17. Headings. The section headings used herein are for convenience only and shall not affect the construction hereof.

18. Definitions. The terms that follow, when used in this Agreement, shall have the meanings indicated.

"Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Affiliate" shall have the meaning specified in Rule 501(b) of Regulation D.

"Business Day" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in The City of New York.

"Citigroup" shall mean Citigroup Global Markets Inc.

"Code" shall mean the Internal Revenue Code of 1986, as amended.

"Commission" shall mean the Securities and Exchange Commission.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Execution Time" shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

"Goldman, Sachs" shall mean Goldman, Sachs & Co.

"Investment Company Act" shall mean the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission promulgated thereunder.

"NASD" shall mean the National Association of Securities Dealers, Inc.

"Regulation D" shall mean Regulation D under the Act.

"Regulation S" shall mean Regulation S under the Act.

"Trust Indenture Act" shall mean the Trust Indenture Act of 1939, as amended, and the rules and regulations of the Commission promulgated thereunder.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement between the Company and the several Initial Purchasers.

Very truly yours,

Genentech, Inc.

By: /s/DAVID A. EBERSMAN
Name: David A. Ebersman
Title: Senior Vice President and
Chief Financial Officer

The foregoing Agreement is hereby
confirmed and accepted as of the
date first above written.

Citigroup Global Markets Inc.
Goldman, Sachs & Co.

By: Citigroup Global Markets Inc.

By: /s/GERARD L. EASTMAN, JR.
Name: Gerard L. Eastman, Jr.
Title: Managing Partner

GOLDMAN, SACHS & CO.

BY: /s/GOLDMAN, SACHS & CO.
(Goldman, Sachs & Co.)

For themselves and the other several Initial
Purchasers named in Schedule I to
the foregoing Agreement.

SCHEDULE I

Initial Purchasers	Principal Amount of 2010 Notes to be Purchased	Principal Amount of 2015 Notes to be Purchased	Principal Amount of 2035 Notes to be Purchased
Citigroup Global Markets Inc.	$187,500,000	375,000,000	187,500,000
Goldman, Sachs & Co.	187,500,000	375,000,000	187,500,000
BNP Paribas Securities Corp	37,500,000	75,000,000	37,500,000
Credit Suisse First Boston LLC	37,500,000	75,000,000	37,500,000
J.P. Morgan Securities Inc.	12,500,000	25,000,000	12,500,000
Lehman Brothers Inc	12,500,000	25,000,000	12,500,000
Morgan Stanley & Co. Incorporated	12,500,000	25,000,000	12,500,000
UBS Securities LLC	12,500,000	25,000,000	12,500,000
Total	$500,000,000	$1,000,000,000	$500,000,000

EXHIBIT 10.31

MANUFACTURING AND SUPPLY AGREEMENT

Between

GENENTECH, INC. and LONZA BIOLOGICS, INC.

Dated December 7, 2003

MANUFACTURING AND SUPPLY AGREEMENT

"THIS MANUFACTURING AND SUPPLY AGREEMENT ("Agreement") is made effective as of December 7 2003, by and between Lonza Biologics PLC, having its principal place of business at 228 Bath Road, Slough, Berkshire SL1 4DX, England ("LB"), Lonza Biologics, Inc. having its principal place of business at 101 International Drive Portsmouth, New Hampshire 03801 ("Lonza Inc") (collectively LB and Lonza Inc, hereinafter "Lonza"), and Genentech, Inc., a Delaware corporation, having its principal place of business at One DNA Way, South San Francisco, California 94080 ("Genentech").

BACKGROUND

Genentech markets and sells a certain proprietary biological pharmaceutical product known as Rituxan. Genentech desires to obtain additional supply of commercial quantities of Rituxan bulk drug substance. Lonza has the experience and expertise necessary to perform the manufacturing and related services needed to supply Rituxan bulk drug substance, and Lonza owns a facility that, with some modifications, could be suitable for production of commercial quantities of Rituxan bulk drug substance.

Genentech desires to retain Lonza as a nonexclusive manufacturer of commercial quantities of Rituxan bulk drug substance and purchase commercial quantities of such product from Lonza, and Lonza desires to perform such services and sell commercial quantities of such product to Genentech, all on the terms and conditions set forth in this Agreement.

Within ten (10) business days after the Effective Date (or such other date as agreed to by the Parties), Lonza and Genentech shall enter into a Tech Transfer Agreement and Quality Agreement (each as defined below) for the purpose of further effectuating the intent of the Parties hereunder.

AGREEMENT

NOW, THEREFORE, IN CONSIDERATION OF the mutual covenants set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1.
DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement.

1.1 "Acquisition Cost" means the actual invoiced price paid by Lonza to any Third Party for acquiring any raw materials, packaging components and intermediates used exclusively in the manufacture of the Product under this Agreement, including [*] in connection with the acquisition of such materials, packaging components and intermediates.

1.2 "Affiliate" means, with respect to any Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, resolution or otherwise. Notwithstanding the foregoing, Roche shall not be considered an Affiliate of Genentech.

1.3 "Batch" or "Lot" means the quantity of Bulk Drug produced from a single Run, and refers to a Commercial Batch or Lot, a Development Batch or Lot, and/or a Qualification Batch or Lot, as the context requires. A Run may result in more than one sub-batch or sub-lot due to splitting into tanks downstream in the Manufacturing Process.

1.4 "Batch Records" shall have the meaning set forth in the Quality Agreement.

1.5 "Bulk Drug" means the bulk form of the Product which has been manufactured by Lonza pursuant to this Agreement, which has been purified to a concentrated form from one or more Batches, and which has been manufactured in compliance with and conforms to cGMP, the Bulk Drug Specifications, Target Yield and the warranties in Section 7.1.

1.6 "Bulk Drug Commitment" refers to the [*] of each binding rolling Product Manufacturing Forecast (including all amendments thereto), and means a commitment by Lonza to comply with and make available the Lonza Facility during the Campaign specified therein and perform the number of Runs set forth therein (as described with more particularity in Section 5.3.1 hereof).

1.7 Bulk Drug Specifications" means specifications developed by Genentech for Bulk Drug, including, without limitation, testing methods and acceptance criteria for each Batch generated, a summary of which is attached to the Quality Agreement, as such specifications may be amended from time to time in accordance with Article 8 hereof, including, without limitation, such amendments as may be required to obtain and/or maintain Regulatory Approval in the Territory.

1.8 "Campaign" means a specified period of time in any calendar year (as further defined in Exhibit A) during which Lonza shall ensure that the Lonza Facility ready and available to perform Commercial Production.

1.9 "cGMP" means the regulatory requirements for current good manufacturing practices promulgated by the FDA under the FD&C Act, 21 C.F.R. §§ 210, 211 and 600 et *seq*. and under the PHS Act, 21 C.F.R. §§ 600-610, as the same may be amended from time to time and with respect to the product, the corresponding or similar laws, rules and regulations of those jurisdictions in which the Product is sold.

1.10 "Cell Line" [*]

1.11 "Certificate of Compliance" means, as further specified in the Quality Agreement, for each Batch, a document prepared by Lonza: (a) listing the manufacturing date, unique Batch number, and quantity of Bulk Drug in such Batch, and (b) certifying that such Batch was manufactured in accordance with cGMP, the Bulk Drug Specifications, Target Yield and the warranties set forth in Section 7.1. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement.

1.12 "Certificate of Testing" means, as further specified in the Quality Agreement, for each Batch, a document prepared by Lonza: (a) listing tests performed by Lonza, specifications, and test results, and (b) certifying the accuracy of the foregoing. The Parties shall from time to time agree upon a format or formats for the Certificate of Testing to be used under this Agreement.

1.13 "Commercial Batch" or "Commercial Lot" means a Batch or Lot produced from a Commercial Run.

1.14 "Commercial Run" means a Run that is initiated following the commencement of Commercial Production and is used to manufacture commercial Bulk Drug.

1.15 "Commercially Reasonable Efforts" means prompt efforts and resources consistent with prudent business judgment.

1.16 "Commercially Reasonable Best Efforts" [*]

1.17 "Confidential Information" means Genentech Confidential Information and/or Lonza Confidential Information, as the context requires.

1.18 "Development Batch" means a Batch or Lot produced from a Development Run.

1.19 "Development Run" means a Run used for process demonstration and confirmation of some or all of the Manufacturing Process steps, and is described in Section 4.4.1 hereof.

1.20 "Effective Date" means December 7 2003, which is the date set forth in the first paragraph of this Agreement and shall be the effective date of this Agreement.

1.21 "EMEA" means the European Medicines Evaluation Agency, or any successor agency.

1.22 "Facility Modifications and Services Costs" means the actual invoiced price paid by Lonza to any Third Party for acquiring services, including, without limitation, design and engineering services, and necessary equipment used exclusively to modify the Lonza Facility in order to implement the Manufacturing Process at the Lonza Facility, all to the extent incurred in accordance with the Tech Transfer Agreement.

1.23 "Facility Validation" shall have the meaning ascribed to it in the Tech Transfer Agreement.

1.24 "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as the same may be amended from time to time.

1.25 "FDA" means the United States Food and Drug Administration, or any successor agency thereto.

1.26 "Finished Product" means Bulk Drug which has been formulated, compounded, filled into containers, and labeled, and placed in final commercial packaging.

1.27 "For Cause Audit" shall have the meaning set forth in the Quality Agreement.

1.28 "Genentech Confidential Information" means the Cell Line, Master Cell Bank, Working Cell Bank, Manufacturing Documentation, Manufacturing Process, and Product, and all technical and other information, whether patented or unpatented, relating thereto and/or to Genentech processes, methods, operations, technologies, forecasts and business information that are disclosed or supplied to Lonza by or on behalf of Genentech pursuant to this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or of which Lonza may become aware of through the presence of its employees or agents at Genentech offices or facilities or at other facilities that manufacture the Product, including, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results and business and scientific plans and information and facility layout and schematics. All documents and records describing or to the extent relating to the Manufacturing Process at the Lonza Facility, including, without limitation, process trend and variability data related to the Product, shall be deemed to be Genentech Confidential Information.

1.29 "Lonza Confidential Information" means all technical and other information, whether patented or unpatented, relating to the Lonza Facility and/or Lonza processes, methods, operations, technologies, forecasts and business information that are disclosed or supplied to, or used on behalf of Genentech by Lonza pursuant to this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or of which Genentech may become aware of through the presence of their employees or agents at Lonza offices or at the Lonza Facility, including, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results and business and scientific plans and information and facility layout and schematics.

1.30 "Lonza Facility" means Lonza's commercial manufacturing facility located at Portsmouth, New Hampshire.

1.31 "Manufacturing Documentation" means all documents and records describing or otherwise related to the Manufacturing Process or any part of the Manufacturing Process provided to Lonza by or on behalf of Genentech under this Agreement, the Tech Transfer Agreement or the Quality Agreement, including, without limitation, documents and records consisting of or containing piping and instrumentation diagrams, software logic and descriptions, batch records, standard operating procedures, including, without limitation, standard operating procedures for in-process quality control testing, facility layout schematics, equipment and instrumentation specifications and process trend and variability data.

1.32 "Manufacturing Process" means the production process for the manufacture of Bulk Drug pursuant to this Agreement, as summarily described in the Quality Agreement and as described in the Tech Transfer Agreement, as such process may be changed from time to time in accordance with this Agreement.

1.33 "Master Cell Bank" [*]

1.34 "MHWJ means the Ministry of Health and Welfare in Japan, or any successor thereto.

1.35 "Non-Conforming Bulk Drug" means Bulk Drug that fails to conform to any of the warranties set forth in Section 7.1 hereof.

1.36 "Non-Portable Equipment" means the Equipment (as defined in Section 15.2 hereof), excluding any Portable Equipment. Components of the Non-Portable Equipment, such as valves, pumps and agitators, shall also be deemed Non-Portable Equipment. Non-Portable Equipment includes the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment.

1.37 "PHS Act" means the Public Health Service Act, Biological Products, as amended, as the same may be amended from time to time.

1.38 "Party" or "Parties" means Lonza and/or Genentech, as the context requires.

1.39 "Portable Equipment" means the portable equipment described with particularity in the Tech Transfer Agreement and referred to in Section 5.5 hereof, including, without limitation, the related documentation regarding the design, validation, operation, calibration, and maintenance of such equipment. The Portable Equipment is a part of the Genentech Equipment, as defined in Section 15.2 hereof. Components of the Portable Equipment, such as valves, pumps and agitators, shall also be deemed Portable Equipment.

1.40 "Product" means any pharmaceutical formulation containing Rituxan, or pursuant to Section 4.9 a substituted product, whether under development or approved by the appropriate regulatory agencies.

1.41 "Purchase Price" means the Purchase Price to be paid by Genentech to Lonza for Bulk Drug as determined in accordance with the terms of this Agreement.

1.42 "Qualification Batch" or "Qualification Lot" means a Batch or Lot produced from a Qualification Run.

1.43 "Qualification Run" means a Run used to document the operability and reproducibility of the Manufacturing Process at the Lonza Facility, and is described in Section 4.4.2 hereof.

1.44 "Quality Agreement" means the quality agreement entered into by and between the Parties after the Effective Date and which refers to this Agreement.

1.45 "Regulatory Approval" means any approvals, licenses, registrations or authorizations of any regional, national, federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the manufacture and sale of the Product in each regulatory jurisdiction in which the Product will be sold.

1.46 "Rituxan" means the proprietary anti-CD20 biological pharmaceutical product of Genentech, more particularly described in Genentech's BLA, including any successor or filing thereto with the FDA, and any supplements to or amendments to any of the foregoing.

1.47 "Roche" means Roche Holdings, Inc., a Delaware corporation, and its "Affiliates" (as hereinafter defined) other than Genentech and Genentech's subsidiaries. With respect to Roche, "Affiliates" means any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with Roche Holdings, Inc.; and, for purposes of this definition, the term "control" means direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of

the management or policies of such entity, whether through the ownership of voting securities, by contract, resolution or otherwise.

1.48 "Run" means a single fermentation run of the Manufacturing Process commencing at the [*] at the Lonza Facility and progressing through the [*], harvest, recovery, quality testing and release, and refers to a Commercial Run, Development Run and/or Qualification Run, as the context requires.

1.49 "sBLA" means a biologics license application for the Product, any equivalent successor filing thereto with the FDA, and any supplements or amendments to any of the foregoing.

1.50 "Successful" means, with respect to a Run, success, as determined in accordance with this Agreement, the Tech Transfer Agreement and the Quality Agreement, in achieving all requirements for Bulk Drug produced from a single Run.

1.51 "Target Yield" shall have the meaning set forth in Exhibit C attached hereto and incorporated herein by reference.

1.52 "Tech Transfer Agreement" means the technology transfer agreement and process implementation plan entered into by and between the Parties after the Effective Date, which refers to this Agreement, and which describes the agreement of the Parties regarding the transfer of technology and implementation of the Manufacturing Process, test methods and testing at the Lonza Facility, and the modifications to the Lonza Facility needed to implement the Manufacturing Process at the Lonza Facility, including a timeline, budget and statement of work jointly developed by the Parties, as the same may be amended from time to time by mutual written agreement of the Parties.

1.53 "Territory" means the entire world.

1.54 "Third Party" means any party other than Genentech, Lonza and their respective Affiliates.

1.55 "United States" or "U.S." means the United States of America, its territories and possessions, and the Commonwealth of Puerto Rico.

1.56 "Working Cell Bank" [*]

1.57 Each of the following definitions are found in the body of this Agreement, or elsewhere, as indicated below:

Defined Term	**Section**
"Acceptance Date"	5.4.6
"Annual Minimum"	Exhibit A
“Annual Minimum Success Rate”	Exhibit B
[*]	5.7.6(c)
[*]	4.5.1
"Batch Record"	Quality Agreement
"Campaign Maximum"	Exhibit A
"Campaign Minimum"	Exhibit A
"Campaign Minimum Run"	Exhibit A
"Change of Control"	20.2.5
"Commercial Production"	5.1
"Consequential Damages"	17.4.1
"Delivery Date"	5.4.2
"Delivery Schedule"	5.4.1
"Designated Carrier"	5.5
"[*]	4.5.1
“Development Run Initiation”	4.7.2
"Effective Period"	2.3

"Equipment"	15.2
“Executive Steering Committee”	3.1.1
"FDA Approval"	4.7.6
“Force Majeure Event”	23.1
"Genentech Equipment"	15.2
"Indemnitee"	17.2.1
"Indemnitor"	17.2.1
“Joint Project Team” or "JPT"	3.1.3
“JQT” or “Joint Quality Team”	Quality Agreement
“Lead Quality Representative”	Quality Agreement
"Liabilities"	17.1.1
"Lonza Equipment"	15.2
"Lonza Release Documentation	Quality Agreement
"Notified Party"	18.4.1
"Notifying Party"	18.4.1
“Phase A Completion”	4.7.1
“Phase B Completion”	4.7.4
"Pre-Campaign/Campaign Requirements"	5.2.3
"Product Manufacturing Forecast"	5.3.1
"Project Team Leader"	3.1.3(c)
“Qualification Run Initiation”	4.7.3
"Records"	6.6
“sBLA Enablement”	4.7.5
“Supplemental Batch Payment”	6.4.3(b)
“Technical Committee”	3.1.2
"Term"	20.1
"Warning Letter"	Quality Agreement

ARTICLE 2.
COMMITMENT TO MANUFACTURE; PURCHASE

2.1 Commitment to Manufacture; Purchase. Subject to the terms and conditions set forth in this Agreement, during the Term, Genentech shall retain Lonza as a non-exclusive manufacturer of Bulk Drug, Lonza shall make the Lonza Facility available to Genentech for manufacture of the Bulk Drug in accordance with the terms of this Agreement (including Exhibit A and the Campaigns specified therein), and manufacture and supply exclusively for the benefit of Genentech (and its designees) certain of Genentech's requirements of Bulk Drug, and, as set forth herein, Genentech shall purchase such Bulk Drug from Lonza.

2.2 LB and Lonza Inc. It is understood and agreed to by the Parties, that LB shall have primary responsibility for Lonza’s obligations hereunder, but may subcontract with, and does hereby subcontract with, Lonza Inc for actual performance of Lonza’s obligations hereunder; provided, LB shall remain primarily responsible for, and guarantees the performance of, Lonza’s obligations hereunder. It is further understood and agreed to by the Parties, that the foregoing shall not (i) in any way relieve Lonza Inc, Lonza LB, or any of their Affiliates of any financial and other obligations under this Agreement that can only be performed by such entity, or (ii) in any way limit or prohibit Genentech from bringing any cause of action directly against LB and/or Lonza Inc for either entity’s failure to perform any obligation due hereunder. It is further understood and agreed that with respect to Article 18 herein, all Genentech Confidential Information disclosed hereunder to Lonza shall remain at Lonza Inc, and shall not be transferred or disclosed to any employee of LB or any Lonza Affiliate unless on a need to know basis in order to perform an obligation of Lonza hereunder and only with prior written notice to Genentech specifying the name of the employee to whom the disclosure is to be made, the information to be disclosed, and the purpose of such disclosure.

2.3 Execution of Tech Transfer Agreement and Quality Agreement. It is understood and agreed by the Parties, that in order to timely effectuate the intent of the Parties hereunder, it is in both Parties’ interest to enter into and execute the Tech Transfer Agreement and Quality Agreement as soon as practicable after the Effective Date. In the event the Tech Transfer Agreement and Quality Agreement are not entered into and executed by the Parties within ten

(10) business days following the Effective Date or such longer period as the Parties may mutually agree in writing (the "Effective Period"), either Party may terminate this Agreement upon written notice to the other Party. Such right to terminate may only be exercised by a Party within ten (10) days after Effective Period, and such termination shall be effective immediately upon receipt of such written notice by the receiving Party. Following any such termination, neither Party shall have any rights or obligations hereunder, except as provided in Sections 20.3.4 and 20.3.5.

ARTICLE 3.
MANAGEMENT OF PROJECT

3.1 Management.

3.1.1 Executive Steering Committee.

(a) Within thirty (30) days of the Effective Date, the Parties will establish an Executive Steering Committee to oversee and manage the manufacture of Bulk Drug at the Lonza Facility. The Executive Steering Committee will be composed of two representatives appointed by each of Lonza and Genentech. All such representatives will be senior officers of Genentech or Lonza. Either Party may replace any or all of its representatives at any time upon prior written notice to the other Party. The Executive Steering Committee will meet at least once each calendar quarter, or more frequently, as agreed by the Executive Steering Committee, and will operate by unanimous decision, except as expressly set forth herein. If the Executive Steering Committee is unable to resolve a dispute regarding any issue presented to it, such dispute shall be resolved in accordance with Article 22 below.

(b) The Executive Steering Committee shall perform the following functions:

(i) determine the overall strategy for the manufacture of Bulk Drug at the Lonza Facility in the manner contemplated by this Agreement, including without limitation, overseeing and monitoring the transfer and implementation of the Manufacturing Process, and the manufacture of Bulk Drug, at the Lonza Facility;

(ii) establish a governance structure for the collaboration including overseeing the establishment and organization of one or more operating committees, or other structure to implement this Agreement. The establishment of certain operating committees is provided for in Sections 3.1.2 and 3.1.3 of this Agreement. Each operating committee contemplated by this Agreement shall be subordinate to the Executive Steering Committee. If any operating committee contemplated by this Agreement is not constituted or continued, any reference to such committee in this Agreement shall be deemed to be a reference to the Executive Steering Committee or such other committees or structures to which the Executive Steering Committee may delegate responsibility;

(iii) settle disputes or disagreements that are unresolved by an operating committee unless otherwise indicated in this Agreement; and

(iv) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.1.2 Technical Committee.

(a) Within thirty (30) days of the Effective Date, the Parties will establish a Technical Committee to oversee and control the transfer and implementation of the Manufacturing Process, and the manufacture of Bulk Drug, at the Lonza Facility. The Technical Committee will be composed of [*] representatives appointed by each of Lonza and Genentech. Each representative will have one vote on all matters within the Technical Committee's purview. Such representatives will include Product Managers, Technical Product Managers/Leads, Directors of Quality Assurance/Regulatory, Director of Manufacturing, or other individuals with expertise and responsibilities in the same areas of manufacturing, process sciences, quality control or regulatory affairs. Either Party may replace any or all of its representatives at any time upon written notice to the other Party. The Technical Committee will meet at least once each calendar month, or more frequently, as agreed by the Technical Committee. The Technical Committee will operate by

unanimous decision, except as expressly set forth herein. If the Technical Committee is unable to resolve a dispute regarding any issue presented to it, such dispute shall be resolved in accordance with Section 3.1.4 below.

(b) The Technical Committee shall: (i) oversee and manage the day to day activities of the transfer and implementation of the Manufacturing Process; (ii) settle disputes or disagreements that are unresolved by the Joint Project Team unless otherwise indicated in this Agreement; and; (iii) report to and keep the Executive Steering Committee informed of the progress of the transfer and implementation of the Manufacturing Process, and the manufacture of Development Lots and Qualifications Lots, at the Lonza Facility; and (iv) perform such other tasks and undertake such other responsibilities as may be specifically delegated to the Technical Committee by mutual agreement of the Parties. Following commencement of Commercial Production, the Parties may elect to change the name and function of the Technical Committee to serve other functions and responsibilities, as mutually agreed by the Parties.

3.1.3 Joint Project Team.

(a) Within thirty (30) days of the Effective Date, the Parties will establish a Joint Project Team (the "JPT"). The JPT shall be composed of [*] representatives appointed by each of Lonza and Genentech. Each representative will have one vote on all matters within the JPT's purview. Such representatives will include the Product Manager, Technical Lead, Manufacturing Lead, Quality Control Lead, Quality Assurance/Regulatory Lead, Raw Materials Lead, Supply Chain Lead and Engineering Lead, or other individuals with expertise and responsibilities in the same areas of manufacturing, process sciences, quality control or regulatory affairs. Either Party may replace any or all of its representatives at any time upon written notice to the other Party; provided, Lonza shall only appoint a new representative to succeed its prior representative with prior notice to, and after good faith consultation with, Genentech, and provided further, any such new representative shall be mutually agreed to by the Parties. Genentech shall not unreasonably withhold its agreement to any such new representative proposed by Lonza. The JPT will meet at least once each week, or more frequently, as agreed by the JPT. The JPT will operate by unanimous decision, except as expressly set forth herein. If the JPT is unable to resolve a dispute regarding any issue presented to it, such dispute shall be resolved in accordance with Section 3.1.4 below.

(b) The purposes of the JPT shall be to (i) monitor, review and guide the transfer and implementation of the Manufacturing Process, and the manufacture of Bulk Drug, at the Lonza Facility, (ii) coordinate the activities of the Parties hereunder to ensure transfer and implementation of the Manufacturing Process, and the manufacture of Bulk Drug, at the Lonza Facility, including management of technical aspects of routine manufacture of the Bulk Drug; iii) report to and keep the Technical Committee informed of the progress of the transfer and implementation of the Manufacturing Process, and the manufacture of Bulk Drug, at the Lonza Facility; and (iv) performing such other tasks and undertaking such other responsibilities as may be specifically delegated to the JPT by mutual agreement of the Parties.

(c) Appointment of Project Team Leader. Within thirty (30) days of the Effective Date, each Party shall appoint a Project Team Leader (each, a "Project Team Leader") to act as the primary contact for such Party in connection with matters related to the implementation of the Manufacturing Process, in connection with activities to be performed under the Tech Transfer Agreement and/or Commercial Production of the Bulk Drug (as defined in Section 5.1 below). Each such Project Team Leader, unless otherwise mutually agreed, shall serve as a member of the JPT. The initial Project Team Leaders are:

Genentech: [*]

Lonza: [*]

A Party may replace its Project Team Leader at any time and from time to time for any reason by providing written notice of the change to the other Party; [*].

3.1.4 Decision-making.

(a) All decisions of the Executive Steering Committee, the Technical Committee and the JPT, except as expressly set forth herein (including without limitation Section 3.1.4(c) and (d) below), shall be made by the unanimous agreement of all of its members or their designated representatives, and shall be reflected in written

meeting reports which summarily address topics discussed, delegation of work, schedules and decisions of such committee or team, which shall be signed by the authorized representatives of the Parties; provided no operating committee herein may materially amend this Agreement, including without limitation the Campaign Minimums, Campaign Minimum Runs, Annual Minimum Success Rate, Target Yield, target dates set forth in Section 4.7 or the milestones set forth in Section 6.3 without entering into a written agreement signed by both Parties that specifically states that the Parties are amending this Agreement.

(b) In the event that the JPT is unable, despite the good faith efforts of all members, to resolve within five (5) business days a disputed issue that is within the purview of the JPT, the disputed issue shall be referred immediately by the JPT to the Technical Committee. In the event the Technical Committee is unable to resolve the disputed issue within an additional five (5) business days, the disputed issue will be referred to, the Executive Steering Committee. If the dispute cannot be resolved by the Executive Steering Committee within an additional five (5) business days, the matter will be handled in accordance with Section 22.2 hereof.

(c) Notwithstanding anything to the contrary in this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, with respect to any disagreement over issues relating to quality, such issues shall be resolved in accordance with this Section 3.1.4(c)as follows: Each Party's Lead Quality Representative on the JQT (each, as defined in the Quality Agreement), or their respective designees, will in good faith attempt to mutually resolve such disagreements in a timely fashion (but in any event, in no more than five (5) days after such issue is referred to the JQT); provided,

(1) With respect to issues relating to: (i) interpretation of quality or cGMP , (ii) acceptability of validation results, (iii) acceptability of Product testing (including in-process testing), results or procedures, (iv) disposition of Bulk Drug (including non-Conforming Bulk Drug) and/or (v) changes to the Manufacturing Process and/or Bulk Drug Specifications, [*] (to the extent not otherwise provided in this Agreement, the Tech Transfer Agreement, the Quality Agreement and/or required by cGMP standards based on both industry precedents and Genentech's standards), the Parties will discuss in good faith and mutually agree on the costs to effect such implementation of such decision and Genentech shall pay such mutually agreed costs; and

(2) With respect to all other issues relating to quality (not otherwise specified in Section 3.1.4(c)(1) above), including without limitation operation of quality systems, change control, quality control issues, and/or quality control testing, in each case, if delay in making a decision could jeopardize the quality of the Bulk Drug, including without limitation the testing or control thereof, [*] such final decision shall be immediately referred to the Executive Steering Committee for reconciliation; provided, if time does not allow, as soon as possible thereafter. The Executive Steering Committee shall seek to reconcile such action within five (5) days in order to ensure that such disagreement over such issue will not be repeated in the future. If the Executive Steering Committee cannot reconcile such final decision within such five (5) day period, either Party shall have the right to request that such final decision be referred to the dispute resolution provisions of Article 22. [*] will result in additional cost to Lonza to implement (to the extent not otherwise expressly provided in this Agreement, the Tech Transfer Agreement and/or the Quality Agreement), the Parties will discuss in good faith and mutually agree on the timelines and costs to effect such implementation of such decision (with the expectation that such implementation shall be effected as soon as possible) and Genentech shall pay such mutually agreed costs and Lonza shall use Commercially Reasonable Best Efforts to effect such implementation.

(d) Notwithstanding anything to the contrary in this Agreement, the Quality Agreement and/or the Tech Transfer Agreement (but subject to Section 3.1.4(c) above), with respect to any disagreement over the implementation of the Manufacturing Process which could reasonably affect Product quality or total outcome of the Campaign at the Lonza Facility (including any procurement, engineering, installation, scale-up, testing and validation of the equipment and systems and other modifications to the Lonza Facility required to implement the Manufacturing Process) and the manufacture of the Product during each Campaign (including any related activities immediately preceding or following each such Campaign), including without limitation the related management processes and operations, control of production planning and scheduling, prioritization decisions, allocation of resources, timing of in-process testing, oversight of auxiliary facilities (e.g., in-process tests that need to be conducted at the labs), all start-up, registration and troubleshooting decisions, and any other related matters to manufacturing of the Product, the Project Team Leaders (or their respective designees) will in good faith attempt to mutually resolve such disagreement in a timely fashion; provided, if delay in making a decision could jeopardize the manufacture of Bulk Drug, including without limitation a delay that could affect the ability of the Parties to timely meet a target date and/or milestone set forth in

Section 4.7 and/or 6.3 herein, [*] such final decision shall be immediately referred to the Executive Steering Committee for reconciliation; provided, if time does not allow, as soon as possible thereafter. The Executive Steering Committee shall seek to reconcile such action within 5 days in order to ensure that such disagreement will not be repeated in the future. If the Executive Steering Committee cannot reconcile such final decision within such 5 day period, either Party shall have the right to request that such final decision be referred to the dispute resolution provisions of Article 22.

3.2 On-Site Participation of Genentech Personnel at the Lonza Facility.

3.2.1 Prior to Commercial Production. Pursuant to and as set forth in greater detail in the Tech Transfer Agreement and Quality Agreement, in order to expedite the implementation of the Tech Transfer Agreement and to coordinate, expedite and guide the Development Runs and Qualification Runs, Genentech may elect at its discretion to have up to [*] of its personnel on-site at the Lonza Facility, and such additional personnel in such numbers as may be agreed to by the Parties or as otherwise required to implement a decision made pursuant to Section 3.1.4. All such personnel will coordinate closely with Lonza in order to minimize impact on other Lonza operations. Unless otherwise agreed by Lonza, such Genentech personnel shall have access only to those portions of the Lonza Facility reasonably related to the technology transfer and implementation of the Manufacturing Process, cafeterias, designated office space and public areas.

3.2.2 After Commencement of Commercial Production. As further described in the Quality Agreement, Genentech shall have the right to designate at its discretion up to [*] of its personnel (and such additional personnel in such numbers as may be agreed to by the parties or as otherwise required to implement a decision made pursuant to Section 3.1.4) to be present in the Lonza Facility during all operational hours during the Term of this Agreement to coordinate, expedite and guide the Commercial Runs and Lonza's performance of its obligations under this Agreement. While at the Lonza Facility, such representative of Genentech shall have access to all areas as are relevant to the manufacture, storage and or quality testing of the Bulk Product, cafeterias, designated office space and public areas, or as otherwise authorized by Lonza, and shall comply with all applicable Lonza policies and procedures.

3.2.3 Office Space. With respect to any Genentech personnel assigned by Genentech to be present at the Lonza Facility, Lonza shall provide (a) reasonable access to the Lonza Facility during all operational hours[*]

3.3 Lonza Personnel at the Lonza Facility. It is understood that Genentech is entering into this Agreement, the Tech Transfer Agreement and the Quality Agreement in reliance upon the commitment by Lonza to fully and adequately staff the Lonza Facility with all managers, supervisors, engineers, technicians, inspectors, and other dedicated personnel necessary, and with sufficient technical expertise and reasonably acceptable to Genentech, to perform its obligations under this Agreement, the Tech Transfer Agreement and the Quality Agreement, including without limitation the implementation of the Manufacturing Process, manufacture, storage and quality testing of the Bulk Drug at the Lonza Facility. Without limiting any other provision of this Agreement, so long as such personnel remain employed by Lonza, Lonza will use Commercially Reasonable Best Efforts to provide that such individuals are available to perform the obligations, as appropriate, to be provided by Lonza hereunder.

ARTICLE 4.
TECHNOLOGY TRANSFER AND PROCESS IMPLEMENTATION

4.1 Technology Transfer and Manufacturing Process Implementation.

4.1.1 Process Description and Tech Transfer Agreement. The Parties acknowledge that in order to enable them to fulfill their respective obligations under this Agreement, they have entered into the Tech Transfer Agreement and, pursuant thereto, jointly developed a plan for the transfer of technology and implementation of the Manufacturing Process at the Lonza Facility. Pursuant to this Agreement and the Tech Transfer Agreement, Genentech shall disclose to Lonza the Manufacturing Process for the Bulk Drug and the Bulk Drug Specifications. The Tech Transfer Agreement sets forth the specific responsibilities of the Parties in connection with technology transfer and implementation of the Manufacturing Process at the Lonza Facility, and the modifications to the Lonza Facility needed to implement the Manufacturing Process at the Lonza Facility, including a timeline, budget and statement of work jointly developed by the Parties. The Tech Transfer Agreement includes reasonable milestones for the transfer of technology,

exchange of information, and implementation of the project, reasonable timelines for achieving such milestones, and criteria for assessing the progress and success of the project as it progresses.

4.1.2 Commercially Reasonable Best Efforts; Cooperation; Tech Transfer Agreement. Lonza shall use Commercially Reasonable Best Efforts to complete its responsibilities in a timely manner under and in accordance with the Tech Transfer Agreement and Section 4.1 of this Agreement. In addition, Lonza agrees to use Commercially Reasonable Best Efforts to cooperate with and assist Genentech in its efforts to perform its obligations under the Tech Transfer Agreement and Section 4.1 of this Agreement.

4.1.3 Delivery of Working Cell Bank. By not later than the applicable delivery deadline set forth in the Tech Transfer Agreement, Genentech shall deliver to Lonza the Working Cell Bank, which shall conform to Genentech's applicable release criteria, as set forth in Genentech's Working Cell Bank specifications.

4.2 Changes to Tech Transfer Agreement; Changes to the Manufacturing Process. Prior to the commencement of Commercial Production of Bulk Drug under this Agreement, and subject to Section 3.1.4 hereof, the JPT shall have the authority to modify or supplement attachments and exhibits to the Tech Transfer Agreement as necessary to ensure implementation of the Manufacturing Process in the Lonza Facility in a timely manner. In addition, Genentech may, in its sole discretion, modify the Manufacturing Process as it deems appropriate or useful to ensure implementation of the Manufacturing Process in the Lonza Facility in a timely manner. To the extent such modifications are directed to implementing Genentech’s Manufacturing Process (as such process existed as of the Effective Date) at the Lonza Facility, it is understood and agreed by the Parties that such modifications are contemplated by the Tech Transfer Agreement and the Quality Agreement and the payments set forth in Section 6.3 and 6.4 herein. To the extent Genentech elects to make any other modifications to Genentech’s Manufacturing Process, and such modifications would result in a material change and cost to the Parties to implement, such modifications shall be subject to the provisions of Article 8.

4.3 Facility Modifications and Improvements. Lonza shall use Commercially Reasonable Best Efforts to: (a) make facility modifications as required to conduct the Manufacturing Process at the Lonza Facility, and (b) procure, engineer, install, scale-up, test and validate the equipment and systems necessary to conduct the Manufacturing Process at the Lonza Facility, in each case as described in, and in accordance with, the Tech 'Transfer Agreement, in each as determined by Genentech in its reasonable discretion.

4.4 Initial Runs and Batches.

4.4.1 Development Runs. Lonza shall use Commercially Reasonable Best Efforts to perform Development Runs at such size and in such number sufficient to produce [*] as set forth in the Tech Transfer Agreement. Lonza will provide the Product resulting from such Successful Development Runs and Development Batches to Genentech, at no cost other than the cost specified in Section 6.4.1 and in accordance with the delivery terms set forth in Section 5.5 hereof; provided, Genentech shall have no obligation to pay Lonza for [*]. At Genentech's election, Genentech may make whatever further use of such Development Runs, including, without limitation, any Product therefrom, as it shall determine, or direct Lonza, at Lonza's cost, to dispose of the material from such Development Runs. It is understood that if Lonza commences a Development Run, and delivers 3 Successful Development Runs prior to finishing such commenced Development Run, Genentech will pay for such commenced Development Run (subject to not having to pay for more than four (4) Development Runs).

4.4.2 Validation and Qualification Batches. Once scale-up of the Manufacturing Process is completed at the Lonza Facility, and Genentech has reviewed and approved the deliverables specified in Section 4.4.1 above, Lonza shall use Commercially Reasonable Best Efforts to perform all required process validation described in Section 12.3 and shall perform Qualification Runs sufficient to produce, at commercial scale, [*] as set forth in the Tech Transfer Agreement in order to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the regulatory documents described in Section 4.6 hereof. Lonza shall provide the Product and Bulk Drug resulting from such Qualification Runs and Qualification Batches to Genentech, at no other costs than the cost specified in Section 6.4.2 (except as otherwise agreed by the Parties pursuant to Section 4.9 hereof) in accordance with the delivery terms set forth in Section 5.5 hereof; provided, Genentech shall have [*] Genentech may make whatever further use of such Qualification Batches, including, without limitation, any Product therefrom, as it shall determine appropriate.

4.5 Raw Materials and Suppliers.

4.5.1 Raw Materials. Genentech has developed specifications for the raw materials, used in the Manufacturing Process. The raw material specifications [*] for raw materials will be included in the Tech Transfer Agreement, which raw material specifications may be amended from time to time by Genentech at its reasonable discretion[*] for raw materials used in the manufacture of the Bulk Drug, then, during the Term, Genentech shall provide Lonza with [*]

4.5.2 Raw Materials Management and Safety Stock. Subject to Section 6.4, Lonza shall procure [*] maintain and store, such amounts of raw materials and components as required, including as agreed by the Parties an adequate supply of safety stock, for the Development Runs and Qualification Runs described in Section 4.4 above and the Commercial Runs described in Article 5. Lonza will provide such raw materials and components and such procurement and management services with no additional mark-up or administrative fees to Genentech; provided, to the extent Lonza is unable to procure such raw materials from the Approved Suppliers for the Development Runs and Qualification Runs, Genentech shall provide such raw materials and components to Lonza with no additional mark-up or administrative fees.

4.5.3 Raw Materials Testing. Lonza shall perform testing and evaluation of the raw materials as required by the applicable raw material specifications or Bulk Drug Specifications and cGMP, and otherwise in accordance with the Tech Transfer Agreement, the Quality Agreement and standard operating procedures to be agreed upon in writing by the Parties.

4.6 Regulatory Matters. Lonza shall use Commercially Reasonable Best Efforts to timely prepare, assist and enable Genentech to obtain and maintain all Regulatory Approvals that are required to manufacture Bulk Drug at the Lonza Facility and that are required to market and sell in the Territory the Product resulting from the Bulk Drug, including, without limitation, the preparation, filing and maintenance of supplements to any Lonza existing FDA licenses', and Lonza shall reasonably assist Genentech to timely prepare, assist and enable Genentech to obtain all Regulatory Approvals that are required to market and sell in the Territory the Product resulting from the Manufacturing Process as carried out at the Lonza Facility, including, without limitation, reasonably assisting with the preparation and review of the drafts of the chemistry, manufacturing and controls sections of the sBLA to be filed by Genentech with FDA. Lonza shall also reasonably assist Genentech in responding to requests and inquiries from the FDA prior to, during and after regulatory review periods, including without limitation, providing all data, records and reports requested by Genentech relevant to such review periods, and by attending meetings with such regulatory authorities to the extent Genentech requests for Lonza to participate given its unique knowledge or its status as manufacturer of Bulk Drug under this Agreement. Lonza personnel shall also facilitate pre-approval inspection of the Lonza Facility conducted by such regulatory authorities. The assistance to be provided by Lonza under this Section 4.6 shall be provided at no additional cost to Genentech, except as otherwise provided in Sections 4.9 and 5.8 hereof.

4.7 Target Dates.

4.7.1 Target Date for Facility Modification Completion. Lonza agrees to use Commercially Reasonable Best Efforts to complete the modifications specified under Section 4.3 and make the Lonza Facility ready and available by [*] for Lonza to perform Development Runs and manufacture Development Batches at such size and in such number as is set forth in the Tech Transfer Agreement, as determined by Genentech in its reasonable discretion (the "Phase A Completion"). If Phase A Completion is not achieved by [*], with respect to each Supplemental Batch Payment to be paid by Genentech pursuant to Section 6.4.3(b), such amount shall be reduced by an amount equal to [*] (i.e., amount to be paid shall equal to [*] and, if Phase A Completion is not achieved by [*], each Supplemental Batch Payment to be paid by Genentech pursuant to Section 6.4.3(b) shall be reduced by an additional amount equal to [*] (i.e. [*] equals a total of [*] (i.e., amount to be paid by Genentech shall equal to [*]

4.7.2 Target Date for 1st Successful Development Run. In addition to the foregoing, Lonza agrees to use Commercially Reasonable Best Efforts by [*] to manufacture at commercial scale and fill the first (1st) Successful Development Lot, as further defined in the Tech Transfer Agreement (the "Development Run Initiation").

4.7.3 Target Date for Commencement of Qualification Runs. In addition to the foregoing, Lonza agrees to use Commercially Reasonable Best Efforts by [*] to commence manufacture of the first (1st) Qualification

Batch in at least a [*] as determined by achievement of certain criteria (such criteria to be agreed upon by the Parties) specified in the Tech Transfer Agreement (the "Qualification Run Initiation").

4.7.4 Target Date for Successful Qualification Runs. In addition to the foregoing, Lonza agrees to use Commercially Reasonable Best Efforts by [*] to manufacture at commercial scale and deliver to Genentech [*] produced from [*] including all appropriate data, records and reports related thereof, as further described in the Tech Transfer Agreement (the "Phase B Completion"). It is understood and agreed by the Parties, that so long as Lonza delivers to Genentech samples from each of such Qualification Lots by the target date specified in Section 6.3.4, and uses its Commercially Reasonable Best Efforts to deliver to Genentech all appropriate data, records and reports related thereof as soon as possible thereafter (but in any event, no more than sixty (60) days after such target date) and such Qualification Lots are thereafter determined to be Successful, Lonza shall be deemed to have "delivered" such Successful Qualification Lots to Genentech by such target date.

4.7.5 Target Date for Enablement of sBLA Filing. In addition to the foregoing, Lonza agrees to use Commercially Reasonable Best Efforts to prepare, assist and enable Genentech to file the sBLA with the FDA by [*] as required in order to manufacture Bulk Drug at the Lonza Facility, including without limitation, assisting with the preparation and review of the drafts of the chemistry, manufacturing and control sections of the sBLA to be filed (the "sBLA Enablement").

4.7.6 Target Date for FDA Approval. Lonza agrees to use Commercially Reasonable Best Efforts to prepare, assist and enable Genentech (including, without limitation, those obligations of Lonza specified in Section 4.6) to obtain by [*] FDA approval for the manufacture of Bulk Drug at the Lonza Facility (the "FDA Approval").

4.7.7 Termination for Failure to Achieve Certain Target Dates. Without limiting the foregoing, if Phase B Completion is not achieved by [*], or if sBLA Enablement is not achieved by [*] or FDA Approval of the Lonza Facility is not received by [*], Genentech shall also have the right to terminate the Agreement in accordance with Section 20.2.3 hereof.

4.8 Manufacturing, Documentation. In accordance with the terms of the Tech Transfer Agreement, Genentech shall, by the relevant date that is set forth in the Tech Transfer Agreement as such date may be modified by the JPT, provide to Lonza the Manufacturing Documentation listed within exhibits and schedules to the Tech Transfer Agreement, and shall, thereafter, from time to time and in accordance with the timeline set forth in the Tech Transfer Agreement, provide to Lonza such additional Manufacturing Documentation as Lonza shall reasonably require in order to implement the Tech Transfer Agreement and the Manufacturing Process and otherwise perform its obligations under this Agreement. In accordance with the terms of the Quality Agreement and cGMP, Lonza shall maintain a process notebook which maintains a record of the Manufacturing Process as implemented at the Lonza Facility, including, without limitation, the process trend and variability data (the "Process Notebook"). Genentech shall have the right to review and copy any information in such Process Notebook at any time during the Term. Genentech's obligations under this Section 4.8 shall be subject to obligations to Third Parties as set forth in written agreements in effect prior to the Effective Date of this Agreement. In the event an obligation to a Third Party prohibits Genentech from rendering such assistance, Genentech shall promptly seek from such Third Party permission to render such assistance. Such Manufacturing Documentation and Process Notebook shall be the sole property of Genentech, and shall be treated in all respects as Genentech Confidential Information. The Process Notebook, including any copies or any portion thereof, shall be delivered to Genentech upon expiration or termination of this Agreement.

4.9 Product Substitution. Genentech shall have the right at any time prior to [*] to substitute for manufacture under this Agreement another product or products for the Bulk Drug; provided (i) such substitute product is a cell culture derived protein produced with the use of similar unit operations as are used for the Bulk Drug; and (ii) the Parties agree upon new dates, deadlines and costs set forth in this Agreement to the extent impacted by such product substitution.

ARTICLE 5.
RUNS; PRODUCTION AND SUPPLY; DELIVERIES

5.1 Commercial Production of Bulk Drug. [*] that comply with cGMP and the Bulk Drug Specifications, the Target Yield and the warranties in Section 7.1, and the execution and delivery by Lonza of the related Certificates of Compliance and Certificates of Testing, "Commercial Production" of Bulk Drug will commence under this Agreement, with the first Commercial Run performed after Phase B Completion and prior to FDA Approval. After Commercial Production has commenced, changes to the Manufacturing Process shall be made as set forth in Article 8 hereof and the Quality Agreement or as the Parties may otherwise agree in writing. Issues relating to quality of Product shall be resolved in accordance with the Quality Agreement.

5.2 Efforts.

5.2.1 Commercially Reasonable Best Efforts. Lonza shall use Commercially Reasonable Best Efforts to conduct Commercial Production and deliver Bulk Drug in the amounts and time frame specified in this Agreement.

5.2.2 Minimum Runs and Campaign Period. Notwithstanding anything to the contrary in this Article 5, but subject to the other terms of this Agreement, in each calendar year during the Term, Lonza shall make available the Lonza Facility during each Campaign and perform at least the number of Runs set forth in Exhibit A during such Campaign, as further defined as the "Campaign Minimum " and “Campaign Minimum Run” for such calendar quarter on Exhibit A attached hereto and incorporated herein. For purposes of this Article 5, the term "Runs" refers to Commercial Runs, and does not refer to Qualification Runs or Development Runs.

5.2.3 Pre-Campaign/Campaign Requirements. It is understood that Genentech is entering into this Agreement, the Tech Transfer Agreement and the Quality Agreement in reliance upon Lonza being fully prepared and able to conduct manufacturing of the Bulk Drug during each Campaign. In order to ensure such preparedness and ability, [*] such checklist to include without limitation, the following requirements: (i) that the Lonza Facility is compliant with all regional, national, federal, state and local regulations in the Territory; (ii) that the Lonza Facility is outfitted with all tools, equipment and utility services necessary to perform Commercial Production; (iii) that the Lonza Facility has been properly maintained and that any maintenance that is required to be performed on equipment and tools within the Lonza Facility has been performed prior to such Campaign; (iv) that the Lonza Facility is fully and adequately staffed with all supervisors, engineers, technicians, inspectors, and other dedicated personnel necessary, and with sufficient technical expertise and acceptable to Genentech, to perform Commercial Production, including any quality testing of Bulk Drug produced (in addition, the Parties shall mutually agree upon each of the primary and secondary Lonza key personnel to be assigned to perform the Commercial Production during each Campaign, and once agreed, Lonza may not change such assignment without Genentech’s mutual agreement); (v) that Lonza has adequate stock of raw materials on hand to perform all Runs required during such Campaign; and (vi) that the Lonza Facility is accessible [*]

5.2.4 Genentech Right of Review and Approval. In no event shall Genentech’s right to review and/or approve an activity hereunder obligate Genentech to do so, nor shall its exercise or failure to exercise such right constitute a basis of any claim by Lonza against Genentech.

5.3 Production and Supply.

5.3.1 Product Manufacturing Forecast. By not later than the Effective Date of this Agreement and thereafter on a calendar quarter by calendar quarter basis of each year, beginning on [*], for the remainder of the Term, Genentech shall provide to Lonza a rolling "Product Manufacturing Forecast" which shall commence with the first day of the next calendar quarter and establish, on a yearly basis, for the remainder of the Term, the dates on which Campaigns are to be conducted, the number of Runs to be performed and the quantity of Bulk Drug reasonably expected to be manufactured, released and supplied to Genentech, all within the ranges set forth in Exhibit A hereto (except as otherwise agreed pursuant to Section 5.7 hereof). The Product Manufacturing Forecast shall be used for joint planning purposes and shall be non-binding unless otherwise specified herein, and may be amended by the Parties from time to time as the Parties deem appropriate. Beginning [*] the anticipated commencement of Commercial Production (or such other date as agreed upon by the Parties in writing), each Product Manufacturing Forecast shall be binding for the first [*] of the next calendar quarter following such forecast, and non-binding for the remainder of the Term, as further described below. Beginning with the initial binding Product Manufacturing Forecast, the forecasts for Bulk Drug and Campaigns within the first [*] months of the next calendar quarter following each such rolling Product Manufacturing

Forecast shall constitute a Bulk Drug Commitment and shall be binding upon the Parties and cannot be changed except upon mutual written consent of the Parties. By way of example only, when the rolling Product Manufacturing Forecast for [*] is issued, the twelve (12)-month period covered by such forecast shall commence on [*], and shall end on [*], and shall be binding for the period [*]. The Bulk Drug Commitment shall include approximate harvest dates for each Commercial Run. Concurrent with each Product Manufacturing Forecast, Genentech shall issue to Lonza a written purchase order, consistent with the Bulk Drug Commitment for such Product Manufacturing Forecast, and such purchase order shall be binding on both Parties.

5.3.2 Weekly Meetings. The JPT shall participate in a weekly meeting (or at such frequency as otherwise mutually agreed), in person or via telephone, to review and discuss production, supply and logistics operations for the next three (3) month period, including: (i) the dates on which Campaigns shall occur, (ii) dates or approximate dates on which Runs will start and be performed; (iii) dates or approximate dates for Lonza's and Genentech's release of Bulk Drug; (iv) size or approximate size of Batches; (v) dates or approximate dates for delivery of Batches; (vi) destination for shipment of Batches; and (vii) status of Batches undergoing investigation, and related matters, and to issue and, as appropriate, update the Product Manufacturing Forecast.

5.4 Management of Product Manufacturing Forecast.

5.4.1 Delivery. Genentech and Lonza will work together in good faith to determine delivery dates and a shipping schedule for deliveries of Bulk Drug under this Agreement, and shall establish a written "Delivery Schedule" as a part of the Product Manufacturing Forecast and the related Bulk Drug Commitment.

5.4.2 Delivery Dates. For each Run, the delivery date respectively set forth in the Delivery Schedule will be the "Delivery Date" for such Run, unless the Parties agree on an alternative delivery date; provided, however, that for purposes of Section 9.1 (a)(ii) hereof, the "Delivery Date" for any particular Bulk Drug shall be later of the actual date on which such Bulk Drug is delivered to Genentech's Designated Carrier at Lonza's Facility in accordance with Section 5.5 hereof, or the actual date of delivery to Genentech of the records specified in Section 10.2.1 for such Bulk Drug (e.g., Batch Records, Lonza's Release Documentation, Certificate of Testing, Certificate of Compliance, etc.).

5.4.3 Purchase Quantities. Except as otherwise set forth in this Agreement (including, without limitation, upon mutual agreement of the Parties under Section 4.9 or Section 5.8 hereof, Genentech shall purchase all Bulk Drug that complies with and conforms to cGMP, the Bulk Drug Specifications, the Target Yield and the warranties set forth in Section 7.1 up to the applicable Campaign Maximum set forth in Exhibit A hereto (except as otherwise agreed pursuant to Section 5.7 hereof).

5.4.4 Shortages; Shortfalls; Delivery Delays. If at any time during the Term, Lonza is unable to fulfill the Bulk Drug Commitments on the related Delivery Date(s), then Lonza shall (1) immediately notify Genentech in writing as to the reason for the shortfall, shortage and/or delay, and provide an indication of the likely duration of the shortfall, shortage and/or delay, and (2) at Genentech's written request, use Commercially Reasonable Best Efforts to provide Genentech with additional Commercial Runs to meet outstanding Bulk Drug Commitments under this Agreement, including, without limitation, extending the then existing Campaign and/or scheduling and conducting an additional Campaign within the next [*] in order to make-up such shortfall, shortage or delay. In addition, Lonza shall also promptly notify Genentech in writing when any such shortfall, shortage and/or delay is over. It is understood and agreed that nothing herein this Section 5.4.4 shall release Lonza from its obligation to promptly supply Bulk Drug to Genentech and/or their respective designee, as appropriate, to meet such Bulk Drug Commitments.

5.4.5 Manufacturing Success Rate. If at any time during the Term, Lonza is unable to meet the Annual Minimum Success Rate and/or Target Yield for a calendar quarter (as further described on Exhibit B attached hereto and incorporated herein): (i) at Genentech’s request, Lonza shall discuss in good faith with Genentech a reduction in the Purchase Price for all Commercial Batches accepted by Genentech in accordance with Section 5.4.6 for such calendar quarter (the determination of such reduction to be based upon the actual success rate achieved over such calendar quarter, including without limitation the actual Target Yield achieved in each Commercial Lot produced in such calendar quarter), and (ii) Genentech shall have the right to terminate the Agreement in accordance with Section 20.2.4 hereof. Notwithstanding anything to the contrary, nothing herein shall obligate Genentech to accept any Runs that do not conform to the cGMP, the Bulk Drug Specifications, the Target Yield and the warranties in Section 7.1.

5.4.6 Acceptance of Bulk Drug. Lonza shall deliver to Genentech samples of all Batches manufactured under this Agreement, as and when Batches are manufactured, and otherwise in accordance with the Quality Agreement and applicable standard operating procedures approved by both Parties. Lonza shall also provide the related Batch Record and other Batch documentation described in the Quality Agreement for each Batch of Bulk Drug. Upon receipt of samples of a particular Batch of Bulk Drug together with the related Batch Record and other Batch documentation (as set forth in the Quality Agreement or as otherwise reasonably requested by Genentech), Genentech shall perform release testing and review the Batch Record and other Batch documentation for each Batch, in good faith, and, in the absence of an investigation for said Batch pursuant to the Quality Agreement or Section 9.1 hereof, such testing and review shall be completed within [*] after Genentech's receipt of samples of such Batch together with the related Batch Record and other Batch documentation. Any investigation shall be initiated and conducted in accordance with Genentech's applicable standard operating procedure. Subject to Genentech's rights to make claims under Article 9 hereof, a Batch shall be deemed to have been accepted by Genentech on the date (the "Acceptance Date") on which Lonza receives written notice from Genentech that such Batch has been released by Genentech pursuant to applicable release testing standard operating protocols as described in the Quality Agreement.

5.5 Delivery Terms. Lonza shall deliver Bulk Drug, suitably packed in agreed upon shipping containers, to Genentech's [*] at which time title to and risk of loss for the Bulk Drug shall transfer to Genentech. Genentech shall have the right to designate the carrier. Genentech shall undertake and arrange for shipment of Bulk Drug within [*] after the Acceptance Date related thereto. Lonza shall provide storage for such Bulk Drug at no charge during this period. Prior to shipping any Bulk Drug, Genentech shall obtain all appropriate approvals and consents of any governmental authority necessary for the transportation or shipment of such Bulk Drug. Lonza shall comply with all applicable laws and regulations regarding the packaging of Bulk Drug for shipment. [*] Bulk Drug resulting from Development Runs and Qualification Runs (see Sections 4.4.1 and 4.4.2 hereof), and Non-Conforming Bulk Drug (see Section 9.4) shall also be subject to the delivery terms set forth in this Section 5.5. Genentech shall procure, at Genentech's cost, and provide to Lonza sufficient quantities of freeze tanks for shipment of Bulk Drug from Lonza's Facility to Genentech Designated Carrier. Lonza shall maintain such freeze tanks in compliance with the terms of the Quality Agreement. [*] Such freeze tanks shall be deemed to be "Portable Equipment" and shall be subject to Section 15.2 hereof.

5.6 Storing, Packaging and Shipping. Lonza shall store, package, label and ship the Bulk Drug according to the Bulk Drug Specifications and according to packaging procedures mutually agreed upon by Genentech and Lonza in writing.

5.7 Additional and New Capacity at the Lonza Facility.

5.7.1 Additional Capacity Made Available In Calendar Year 2004. If at any time during the [*] additional capacity becomes available at the Lonza Facility for commercial production, Genentech shall [*] to utilize some or all of such additional capacity for Commercial Production, for so long as such additional capacity is available during the Term, [*] to Genentech as provided for under this Agreement.

5.7.2 Additional Capacity Made Available After Calendar Year 2004. If at any time in any year after the [*] and during the Term, additional capacity becomes available at the Lonza Facility for commercial production, Genentech shall [*] to utilize some or all of the first [*] Runs of such additional capacity, and [*]to utilize some or all of any Runs in excess of such first [*] Runs of such additional capacity, for Commercial Production, for so long as such additional capacity is available during the Term, and in each case, [*]to Genentech as provided for under this Agreement.

5.7.3 New Capacity. Each and every time in any year during the Term, if new capacity becomes available at the Lonza Facility for commercial production, as a result of Lonza installing additional bioreactors at the Lonza Facility (other than that capacity specified in the Tech Transfer Agreement), Genentech [*]

5.7.4 Notice. Lonza shall promptly notify Genentech in writing upon any such additional or new capacity becoming available, and provide Genentech with all information reasonably useful for Genentech to make a decision regarding such additional or new capacity.

(a) With respect to any additional capacity subject to Genentech's [*] Genentech shall have [*] days following its receipt of all such information to review such information and provide written notification to Lonza regarding [*]

(b) With respect to any additional or new capacity subject to Genentech's [*] (i) if such additional or new capacity will not be available until [*] after such notice from Lonza, Genentech shall have [*] days following its receipt of all such information to review such information and provide written notification to Lonza regarding its decision to negotiate with respect to such additional or new capacity, or (ii) if such additional or new capacity will be available within [*]of such notice from Lonza, Genentech shall have [*] days following its receipt of all such information to review such information and provide written notification to Lonza regarding its decision to[*] with respect to such additional or new capacity. With respect to any additional or new capacity subject to [*], during said [*] or [*] day period, as applicable, Lonza shall be free to talk to any Third Party, provided Lonza does not enter into a written agreement with any Third During regarding such additional or new capacity until after the end of said [*] or [*] day period, as applicable.

5.7.5 With respect to that additional (or new) capacity which Genentech receives notice of pursuant to Section 5.7.4 and is subject to:

(a) Genentech's [*] if written notice is given that Genentech does not want to accept such additional capacity, or written notice is not given by Genentech within said [*] day period, Genentech [*] such additional capacity (or, as applicable, that portion thereof that it specifies in such written notice that it does not want to accept);

(b) Genentech's [*], if written notice is given that Genentech does not want to accept such additional or new capacity, or written notice is not given by Genentech within said [*] or [*] day period, as applicable, Genentech will have [*] for such additional or new capacity (or, as applicable, that portion thereof that it specifies in such written notice that it does not want [*]

and in each case, Lonza will be free to provide such additional or new capacity to any Third Party, subject to Section 5.7.6, and as long as the terms of such additional or new capacity are not [*] to such Third Party than those last offered to [*], without first offering to enter into a written agreement with Genentech on such terms.

5.7.6 [*]. It is understood and agreed to by the Parties, if any existing capacity or new capacity becomes available at the Lonza Facility during the Term, use of such capacity would first be subject to the provisions of Section 5.7.5, and then subject to the provisions of this Section 5.7.6. [*]

(a) Genentech Right of Last Refusal on Existing Capacity. Lonza agrees that during the Term, Lonza shall not enter into a written agreement to use any existing capacity at the Lonza Facility to manufacture for itself or any Affiliate or Third Party, any [*] Product, without first providing written notice of and offering to enter into a written agreement with Genentech on such terms. If, at any time(s) during the Term, Lonza receives and is ready to accept a bona-fide written offer from a Third Party or Affiliate, negotiated in good faith and at arms-length and which offer contains all material terms, to use any existing capacity at the Lonza Facility to manufacture an [*] Product, Lonza shall provide written notification to Genentech of such offer and all information reasonably useful for Genentech to make a decision regarding such capacity (including without limitation, a copy of the agreed upon terms of such offer, redacted as necessary to remove the name of the Third Party and the identity of the [*] Product). Genentech shall have thirty (30) days following its receipt of all such information to review such information and provide written notification to Lonza regarding its decision to accept such capacity. If Genentech provides written notice to Lonza within such thirty (30) day period of its acceptance of such capacity, Genentech shall have the right to use such capacity to manufacture Bulk Drug for so long as such existing capacity is available during the Term and under the same terms and conditions of this Agreement [*] shall prevail with respect to such capacity). If written notice is given that Genentech does not want to accept such additional capacity, or written notice is not given by Genentech within said thirty (30) day period, Genentech will have waived its right to accept such capacity, and Lonza will be free to provide such capacity to such Third Party as long as the terms of the written agreement with such Third Party are not [*] to such Third Party than the terms last offered to [*], without first offering to enter into a written agreement with Genentech on such terms.

(b) Exclusivity on New Capacity.

(i) If Lonza elects to build any new capacity at the Lonza Facility, Lonza agrees that during the Term, Lonza shall not use such new capacity to manufacture, either for commercial supply or clinical supply, for itself or any Affiliate or Third Party, any [*],Product. Notwithstanding the foregoing, and subject to the other provisions of this Agreement, this Section 5.7.6(b) does not prohibit Lonza from manufacturing the Product for ultimate sale by Roche outside the United States and Canada in accordance with the terms of this Agreement, or for Roche as otherwise agreed upon in writing by the Parties.

(ii) Subject to the foregoing, if, at any time(s) during the Term, Lonza receives a bona-fide written offer from a Third Party or Affiliate, negotiated in good faith and at arms-length and which offer contains all material terms, to use any new capacity at the Lonza Facility to manufacture an [*] Product, Lonza may provide written notification to Genentech of such offer and request that Genentech accept and use such capacity for manufacture of Genentech Products. Concurrent with such notice, Lonza shall provide to Genentech all information reasonably useful for Genentech to make a decision regarding such capacity (including without limitation, a copy of the agreed upon terms of such offer, redacted as necessary to remove the name of the Third Party and the identity of the [*] Product).

(iii) Genentech agrees to consider in good faith each such written request by Lonza for Genentech to accept and use such capacity, and, in considering such request, Genentech shall take into account the current business relationship of the Parties and the product life cycle stage of its Product.

(iv) Subject to the foregoing, Genentech may, at its sole discretion, either elect or reject such request to use such capacity, and (1) if Genentech elects to accept such request to use such capacity, Genentech may use such capacity for so long as such new capacity is available during the Term, and on terms and conditions [*]to Genentech as provided for under this Agreement ([*] of this Agreement), or (2) if Genentech rejects such request to use such capacity, such capacity shall remain subject to Section 5.7.6(b)(i).

(c) Definition of [*] Products. As used herein, [*]. To the extent any product is substituted for the Product pursuant to Section 4.9, such obligations under this Section 5.7.6 shall apply as well to any protein(s) or peptide(s) (including any fragment thereof) whose mechanism of action is initiated by binding to the target that is the subject of such substituted product.

5.8 Regulatory Approval for Outside the United States. Any time following Phase B Completion, Genentech may request that Lonza seek EMEA, MHWJ, or other Regulatory Approval to enable Bulk Drug to be sold outside of the United States by Genentech or its designee, including without limitation, Roche and/or Zenyaku Kogyo Co. Ltd. Upon such request, the JPT will meet to discuss timelines, activities and responsibilities necessary to obtain such Regulatory Approval. The Parties understand that Roche is the license holder for the Product in Europe, and shall discuss Roche's role in such project; provided, however, that the Agreement shall remain between the Parties, and Roche shall not be a Third Party beneficiary hereunder unless otherwise agreed to in writing by the Parties. The supply, purchase and payment provisions of this Agreement would not be affected by a decision to seek Regulatory Approval outside the United States for the Product hereunder unless otherwise agreed to in writing by the Parties, and Genentech would continue to purchase the Bulk Drug Commitment in accordance with the terms of this Agreement, at least up to the applicable Campaign Maximum set forth in Exhibit A hereto.

5.9 Sale of Lonza Facility.

5.9.1 Right of First Notice. If at any time(s) during the Term, Lonza elects to sell the Lonza Facility, including without limitation an election to solicit a Third Party, or an election to consider a solicitation or other inquiry received from a Third Party, to purchase the Lonza Facility, on each such occasion, Lonza shall promptly provide written notice to Genentech thereof, and with such notice shall provide to Genentech all information reasonably useful for Genentech to make a reasonably informed bid with respect to such proposed sale (but in any event, no less than the same information that Lonza provides to any Third Party considering a bid with respect to such proposed sale). Genentech shall have ninety (90) days to review such information and provide written notification to Lonza regarding its decision to purchase the Lonza Facility, and/or whether its needs additional information regarding such sale. During such ninety (90) day period Lonza shall be free to talk to any Third Party with respect to such proposed sale of the Lonza Facility, provided Lonza does not enter into a written agreement with any Third Party regarding such proposed sale of the Lonza Facility until after the end of such ninety (90) day period.

5.9.2 Effect of Notice. If written notice is given that Genentech desires to purchase the Lonza Facility, the Parties shall negotiate in good faith the terms thereof. If written notice is given that Genentech does not want to purchase the Lonza Facility, or written notice is not given by Genentech within said ninety (90) day period, Genentech will have waived its right to negotiate in good faith with Lonza and to submit a bid for the Lonza Facility and Lonza shall be free to sell the Lonza Facility without restriction to any Third Party; provided, Lonza consummates such sale within one (1) year of such written notice by Lonza to Genentech under Section 5.9.1. Any final decision to sell the Lonza Facility will be based on economic and such other considerations as determined by, and solely at the discretion of, Lonza Inc's shareholders.

5.9.3 Limitations. It is understood and agree that such right of first notice only applies with respect to the sale of the Lonza Facility, and not with respect to any such sale that is incidental to a proposed sale of Lonza Group Ltd.

ARTICLE 6.
PAYMENTS

6.1 Execution Fee. Genentech shall pay Lonza [*] within [*] business days of the Effective Date.

6.2 [Intentionally left blank]

6.3 Milestone Payments. For each Milestone I through VI set forth in this Section 6.3 that is completed by the deadline respectively described below, Genentech shall pay the related milestone, within [*]business days of receipt of a correct, undisputed invoice, which may be delivered on or after the date earned:

6.3.1 Completion of Milestone I: Phase A Completion:

(a) If Phase A Completion is achieved by [*]Genentech shall pay Lonza [*] or

(b) If Phase A Completion is not achieved until after [*] but before [*], Genentech shall pay Lonza [*] or

(c) If Phase A Completion is not achieved until after [*] but before [*]Genentech shall pay Lonza [*].

6.3.2 Completion of Milestone II: Development Run Initiation. If Development Run Initiation is achieved by [*], Genentech shall pay Lonza [*].

6.3.3 Completion of Milestone III: Qualification Run Initiation. If Qualification Run Initiation is achieved by [*], Genentech shall pay Lonza [*]

6.3.4 Completion of Milestone IV: Phase B Completion:

(a) If Phase B Completion is achieved by [*], Genentech shall pay Lonza [*] or

(b) If Phase B Completion is not achieved until after [*], but before [*], Genentech shall pay Lonza [*]

6.3.5 Completion of Milestone V: sBLA Enablement. If sBLA Enablement is achieved by [*], Genentech shall pay Lonza [*]

6.3.6 Completion of Milestone VI: FDA Approval: If FDA Approval for the Lonza Facility is achieved on or before [*] (or in the event sBLA Enablement is achieved prior to [*], but Genentech elects to file the sBLA at a later date, then [*]after the date of such filing), Genentech shall pay Lonza [*].

6.4 Batch Pricing; Invoicing.

6.4.1 Development Batches. For each Development Batch [*]manufactured by not later than [*]and in compliance with this Agreement, and conformance to cGMP, the Bulk Drug Specifications, and the warranties in Section 7.1, Genentech shall pay Lonza an amount equal to [*] per Batch and, subject to Section 4.5, the Acquisition Cost of raw materials used to manufacture such Batch. Such amount shall be the Purchase Price for such Development Batches.

6.4.2 Qualification Batches. For each Successful Qualification Batch [*] manufactured by not later than [*]and in compliance with this Agreement and conformance to cGMP, the Bulk Drug Specifications, the Target Yield, and the warranties provided in Section 7.1 hereof, Genentech shall pay Lonza an amount equal to [*] per Batch and, subject to Section 4.5, the Acquisition Cost of raw materials used to manufacture each such Batch. Such amount shall be the Purchase Price for such Qualification Batches.

6.4.3 Commercial Batches. Except as otherwise expressly set forth in this Agreement, including, without limitation, in Article 8 and Section 9.1 hereof:

(a) For each Successful Commercial Batch (up to the Campaign Maximum in a particular Campaign) manufactured in compliance with this Agreement and in conformance with cGMP and the Bulk Drug Specifications, the Target Yield, and the warranties provided in Section 7.1 hereof, Genentech shall pay Lonza an amount equal to [*]. Such amount shall be the Purchase Price for such Commercial Batches.

(b) In addition to the foregoing, subject to Section 4.7.1, with respect to each such Successful Commercial Batch under 6.4.3(a) above, up to a maximum of [*] such Successful Commercial Batches, Genentech shall pay Lonza an amount equal to [*] (the "Supplemental Batch Payment"). It is understood and agreed, that no such payment shall be due for any Successful Commercial Batches in excess of such [*] Successful Commercial Batches, including without limitation any additional Batches purchased during the Term, including any extension thereof.

(c) In addition to the foregoing, Genentech shall reimburse Lonza, subject to Section 4.5, [*] the Acquisition Cost of the raw materials utilized to produce such Successful Commercial Batches (up to the Campaign Maximum in a particular Campaign).

(d) In addition, Lonza shall also be entitled to receive: (i) a one-time additional payment of (i) [*] upon delivery to Genentech of the [*] Successful Commercial Batch in [*], and (ii) a one-time additional payment of [*] upon delivery to Genentech of the [*] Successful Commercial Batch in [*] which such additional amounts shall be payable upon Genentech's final release of the [*] Commercial Batch in such calendar year. For the avoidance of doubt, such amounts shall in no event be paid more than once each, and only on achievement of such milestone in [*]

6.4.4 Invoicing Genentech for Batches. For amounts owed under:

(a) Sections 6.4.1 and 6.4.2, invoices may be issued on or after the related Acceptance Date; and

(b) Section 6.4.3, invoices may be issued on or after the related Acceptance Date.

Such invoices shall reference the Acceptance Date, the Batch delivered and the total Purchase Price. In addition, for invoices issued with respect to Section 6.4.2(c), such invoices shall also reference a complete list of the Successful Commercial Batches produced, shipped and accepted by Genentech during such calendar year. Amounts due under undisputed correct invoices shall be due and payable in U.S. currency within thirty (30) days after receipt of such invoice.

6.5 Payment Method. All payments due hereunder shall be made by wire transfer from a bank in the United States in immediately available funds to a bank in the United States designated by the Party to receive payment. All payments hereunder shall be made in U.S. dollars. [*]

Genentech's Designated U.S. Bank:

[*]

Lonza's Designated U.S. Bank:

[*]

6.6 Commercial Audit. For at least three (3) years after final payment under this Agreement (or for such longer period of time as may be required by applicable laws and regulations), Lonza shall maintain complete and accurate books, records, documents, and other evidence of costs, expenses and allowances pertaining to this Agreement and/or the Tech Transfer Agreement and the Facility Modifications and Services Costs (for purposes of this Section 6.6, hereinafter collectively called "Records") to the extent and in such detail as will properly reflect all costs and expenses incurred by Lonza in connection with this Agreement and/or the Tech Transfer Agreement. Genentech, acting through its independent public accountants of recognized national standing selected by Genentech and reasonably acceptable to Lonza, shall have a right to examine and audit such Records once per Campaign, upon at least twenty (20) days' prior written notice.

ARTICLE 7.
MANUFACTURER PRODUCT WARRANTIES

7.1 Product Warranties by Lonza. Lonza hereby warrants to Genentech that the Bulk Drug, at the time of Delivery to Genentech's Designated Carrier, shall:

(a) conform to the Bulk Drug Specifications;

(b) be manufactured in compliance with the requirements of cGMP;

(c) be manufactured in compliance with the requirements of all applicable material national, state and local laws, ordinances and governmental rules and regulations of the U.S.;

(d) complies with Lonza's standard operating procedures;

(e) complies with Lonza's standard operating procedures (as developed by Lonza and Genentech and approved by Genentech based on the Genentech standard operating procedures provided by Genentech to Lonza hereunder, in accordance with the Quality Agreement); and

(f) be transferred free and clear of any liens or encumbrances of any kind to the extent arising through or as a result of the acts or omissions of Lonza, its Affiliates or their respective agents.

7.2 Lonza Facility. Lonza hereby warrants that it owns or lawfully controls the Lonza Facility, and that, provided the Manufacturing Process is successfully implemented in accordance with the Tech Transfer Agreement, it has sufficient manufacturing capacity to enable Lonza to manufacture Bulk Drug throughout the Term in quantities sufficient to fulfill, in each calendar year, the Campaign Minimums and Campaign Minimum Runs for such year as set forth in Exhibit A hereto, in accordance with this Agreement. Lonza hereby covenants that it will use Commercially Reasonable Best Efforts to ensure that the Lonza Facility shall be maintained in accordance with cGMP and in such condition as will allow Lonza to manufacture the Bulk Drug in compliance with and conformance to cGMP and the Bulk Drug Specifications.

7.3 OTHER THAN AS SET FORTH IN THIS ARTICLE 7 AND ARTICLE 16 HEREOF, ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE HEREBY EXPRESSLY DISCLAIMED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 8.
SPECIFICATION AND MANUFACTURING — PROCESS CHANGES

8.1 Specification and Manufacturing - Process Changes. Except as otherwise expressly set forth to the contrary in the Quality Agreement, in the event that (i) Genentech is required, or desires, to change the Bulk Drug Specifications or the Manufacturing Process Lonza shall use Commercially Reasonable Best Efforts to accommodate such request, subject to the following:

(a) Genentech shall promptly advise Lonza in writing of any such change(s), and provide information reasonably necessary for Lonza to evaluate the effect of such change(s), and Lonza' shall promptly advise Genentech as to scheduling changes, if any, which may result from such change(s). The notification and approval procedure shall be in accordance with standard operating procedures (i.e., change control procedures) agreed upon by the Parties from time to time. The Parties shall hold a JPT meeting in a timely manner with appropriate advisors invited to discuss such changes as appropriate.

(b) Prior to implementation of any such material change(s) to the Bulk Drug Specifications or Manufacturing Process, the Parties agree to negotiate in good faith in an attempt to reach agreement on (i) the new Purchase Price (higher or lower) for any Bulk Drug manufactured under this Agreement by Lonza which embodies such material change, giving due consideration to the effect of such material change on Lonza's direct manufacturing costs for Bulk Drug, and (ii) any other amendments to this Agreement which may be necessitated by such material changes.

(c) Prior to implementation of any such change(s), Lonza will provide Genentech with an estimate of the reasonable and necessary expenses that would be incurred by Lonza as a result of the implementation of any such change(s) to the Bulk Drug Specifications or Manufacturing Process, including, but not limited to, its validation and analytical development costs, and capital expenditure costs. If such change(s) are implemented, Genentech will reimburse Lonza for the reasonable and necessary expenses as agreed upon in advance and incurred by Lonza as a result of any such change(s) to the Bulk Drug Specifications or Manufacturing Process, including, but not limited to, reimbursing Lonza for its validation and analytical development costs and capital expenditure costs.

(d) Lonza shall use Commercially Reasonable Best Efforts to promptly accommodate changes described in Section 8.1 hereof in light of Lonza's facilities and resource constraints and current operations. Lonza shall cooperate with Genentech in good faith to implement all agreed upon changes to the Bulk Drug Specifications or Manufacturing Process in accordance with the agreed upon schedule. During the pendency of Lonza implementing any such changes to the Manufacturing Process or Bulk Drug Specifications, Lonza shall, at Genentech's written request, produce and Genentech shall purchase Bulk Drug in accordance with the terms of the Agreement.

(e) If any such changes to the Bulk Drug Specifications or Manufacturing Process renders obsolete or unusable any raw materials, components or supplies used to manufacture the Bulk Drug, and to the extent such materials may not be either returned to the appropriate vendor for a credit or utilized by Lonza for its other manufacturing operations, Genentech shall purchase from Lonza, at Lonza's Acquisition Cost, that amount of inventory of such raw materials, components or supplies, as the case may be, so rendered obsolete or unusable, not to exceed the amount of such raw materials, components or supplies which would have been required for Lonza to manufacture and supply the total quantity of Bulk Drug specified in Bulk Drug Commitments outstanding under this Agreement.

(f) The notification and formal approval procedure for those changes to the Bulk Drug Specifications or Manufacturing Process approved by the Parties under this Section shall be in accordance with the Quality Agreement and standard operating procedures (i.e., change control procedures) agreed upon in writing by Genentech and Lonza from time to time.

8.2 Procedure for Specification or Manufacturing Process Changes by Lonza. Notwithstanding anything to the contrary in this Agreement (including Section 3.1.4), the Quality Agreement and/or the Tech Transfer Agreement, Lonza shall not change the Bulk Drug Specifications or the Manufacturing Process except with Genentech's prior written consent, which consent Genentech may grant in its sole discretion.

8.3 Vendor or Supplier Changes. Notwithstanding anything to the contrary in this Agreement (including Section 3.1.4), the Quality Agreement and/or the Tech Transfer Agreement, Lonza shall not change any vendor or supplier of raw materials or analytical reagents used in the manufacture or testing of Bulk Drug except with Genentech's prior written consent.

ARTICLE 9.
CLAIMS

9.1 Notice of Claims. In the event that any Bulk Drug is Non-Conforming Bulk Drug, Genentech may reject the same by giving written notice thereof to Lonza:

(a) within seventy (70) days after the later of Genentech's receipt of samples of such Batch or the related Batch Record and other Batch documentation specified in Section 10.2.1 (e.g., Batch Records, Lonza's Release Documentation, Certificate of Testing, Certificate of Compliance, etc.), Genentech will communicate in writing to Lonza their acceptance or rejection of the Batch. If the decision is to reject the Batch, Genentech will have an additional five (5) days to write up and communicate to Lonza its notice of rejection (for a total of 75 days) ; and

(b) in the case of a latent defect, within one-hundred and twenty (120) days after discovery of such latent defect, but in no event later than one (1) year after delivery to Genentech's Designated Facility, which notice shall specify the manner in which such Bulk Drug fails to conform to any warranty and shall be accompanied by any test results or reports evidencing such non-conformity.

Alternatively, rather than initially issuing a notice of rejection under Section 9.1(a) or (b) above, Genentech may give written notice to Lonza within the applicable time period set forth in this Section 9.1 of a Genentech decision to investigate whether a potentially Non-Conforming shipment should be rejected. Within thirty (30) days following such notice to investigate, Genentech shall provide to Lonza, for Lonza’s review and comment, a written plan for investigating and resolving such potentially Non-Conforming shipment, which investigation shall be completed in accordance with the procedures set forth in the Quality Agreement.

9.2 No Lonza Liability. If it is determined by agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that either (i) there is no nonconformity, in which case Genentech shall pay to Lonza the Purchase Price for such Bulk Drug, or (ii) there is nonconformity but the nonconformity was not caused by Lonza (or its agents), in which case Lonza shall have no liability to Genentech with respect thereto, and Genentech shall pay to Lonza the Purchase Price for such Bulk Drug.

9.3 Lonza Liability; Replacement of Product. If it is determined by agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that the nonconformity was caused by Lonza (or its agents), at Genentech's written request, Lonza shall as soon as practicable use Commercially Reasonable Best Efforts to replace such Non-Conforming Bulk Drug with conforming Bulk Drug, at no additional, cost to Genentech except for payment of the Purchase Price for the replacement conforming Bulk Drug, which shall be payable as follows: if Genentech previously paid the Purchase Price for the Non-Conforming Bulk Drug, then Lonza shall promptly and in any event within thirty (30) days credit such amount to Genentech on the next invoice (or, at Genentech's option, Genentech may set off such amount against amounts owed to Lonza under this Agreement), and Genentech shall pay the Purchase Price for the replacement conforming Bulk Drug; and, if Genentech did not previously pay the Purchase Price for the Non-Conforming Bulk Drug, then Genentech shall pay the Purchase Price for the replacement conforming Bulk Drug; provided, however, Genentech shall have no obligation to pay Lonza for replacement Conforming Bulk Drug which is not delivered by a date acceptable to

Genentech (such date to be mutually agreed in writing by the parties following Genentech's written request to Lonza to replace such Non-Conforming Bulk Drug).

9.4 Cooperation in Investigations, Disposition of Non-Conforming Bulk Drug. If Genentech desires to make a claim against Lonza with respect to and reject a Batch of Non-Conforming Bulk Drug pursuant to Section 9.3, Genentech agrees that it shall not dispose of or allow such Bulk Drug to be disposed of without written prior notification to Lonza. Disposition of Non-Conforming Bulk Drug shall be determined in accordance with the provisions of the Quality Agreement.

ARTICLE 10.
MANUFACTURING AUDITS; CERTIFICATE OF COMPLIANCE; AND REGULATORY MATTERS

10.1 Manufacturing Audits. Genentech shall have the right to perform, directly or through its representatives, cGMP compliance audit [*] pre-approval inspection audits, For Cause Audits, and additional follow-up audits Genentech reasonably believes is necessary as a result of the findings of any of the foregoing audits, all in accordance with the audit provisions set forth in the Quality Agreement. During such audits, personnel of Genentech or its representatives shall have access only to all public areas (including cafeteria's) and those areas that are directly related to the performance of Lonza's obligations under this Agreement, including the manufacture, testing, storage and shipping of Bulk Drug. No more than a reasonable number of representatives shall be permitted on Lonza's premises for any such audit.

10.2 Certificates; Manufacturing Issues; Records.

10.2.1 Certificates; Manufacturing Issues. As soon as possible after manufacture and, unless otherwise agreed by Genentech, in any event by not later than the date of each shipment of Bulk Drug, Lonza shall furnish to Genentech the Batch Records and Lonza's Release Documentation described in the Quality Agreement, including, without limitation, a Certificate of Testing, a Certificate of Compliance and a summary (in a format to be agreed upon by Genentech and Lonza) of any deviations or investigations that occurred during the manufacturing or testing of the Bulk Drug that is part of such shipment. The provisions set forth in the Quality Agreement regarding deviations shall control whether a deviation results in Non-Conforming Bulk Drug.

10.2.2 Records. Lonza shall maintain all of its manufacturing and analytical records, all records of shipments of Bulk Drug and all validation data relating to Bulk Drug for the time periods required by applicable laws and regulations of all regional, national, federal, state and local regulatory agency in the jurisdictions where the Product will be sold. Lonza agrees that, in response to any complaint, or in the defense by Genentech of any litigation, hearing, regulatory proceeding or investigation relating to Bulk Drug, Lonza shall make available to Genentech such Lonza employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections.

10.3 Complaints. Genentech shall have sole responsibility for reporting any complaints relating to the Product to the FDA and any other regulatory authorities, including, but not limited to, complaints relating to the manufacture of the Product and adverse drug experience reports. Genentech shall maintain complaint files in accordance with cGMP. Lonza shall provide Genentech with a copy of any complaints received by Lonza with respect to the Product in accordance with the Quality Agreement and standard operating procedures to be agreed upon by Genentech and Lonza from time to time. Genentech shall have responsibility for responding to all complaints, and for promptly providing Lonza with a copy of any responses to complaints relating to the manufacture of the Product. Lonza shall use Commercially Reasonable Best Efforts to respond to requests from Genentech for information in Lonza's possession that is necessary for Genentech to respond to complaints arising out of the manufacture of the Bulk Drug.

10.4 Regulatory Correspondence.

10.4.1 Notification to Other Parties of Regulatory Correspondence. Each Party shall immediately and within at least three (3) business days notify the other Party in writing of, and shall provide the other Party with

copies of, any correspondence and other documentation received or prepared by such Party in connection with any of the following events: (i) receipt of a regulatory letter, Warning Letter, or similar item, from the FDA or any other regulatory authority directed to the manufacture, packaging, and storage of Bulk Drug, by Lonza or in connection with any general cGMP inspections applicable to any Lonza Facility to the extent associated with Lonza's activities under this Agreement; (ii) any recall, market withdrawal or correction of any Batch of Bulk Drug or resulting Finished Product; and (iii) any regulatory comments related to the manufacture of Bulk Drug or resulting Finished Product requiring a response or action by a Party.

10.4.2 Regulatory Correspondence Requiring a Lonza Response. In the event Lonza receives any regulatory letter or comments from any regional, national, federal, state or local regulatory authority in the Territory directed to its manufacture of Bulk Drug requiring a response or action by Lonza, including, but not limited to, receipt of a Form 483 (Inspectional Observations) or a Warning Letter, Genentech will, to the extent within its control or possession, promptly provide Lonza with any data or information required by Lonza in preparing any response related to Lonza's manufacture of Bulk Drug and will cooperate fully with Lonza in preparing such response. Lonza shall provide Genentech with a copy of each such response (redacted to remove information not related to the manufacture of Bulk Drug or Lonza's other obligations under this Agreement) for Genentech's review and comment prior to Lonza's submission of its detailed written response. Lonza shall give all due consideration to any Genentech comments to each such proposed Lonza response provided Genentech timely responds. Likewise, in the event Genentech receives any regulatory letter or comments from any regional, national, federal, state or local regulatory authority in the Territory directed to the manufacture of Bulk Drug at the Lonza Facility requiring a response or action by Genentech, including, but not limited to, receipt of a Form 483 (Inspectional Observations) or a Warning Letter, Lonza will, to the extent within its control or possession, promptly provide Genentech with relevant data or information sufficient for Genentech to prepare any response related to the manufacture of Bulk Drug and will cooperate fully with Genentech in preparing such response. Genentech shall provide Lonza with a copy of each such response (redacted to remove information not related to the manufacture of Bulk Drug at Lonza's Facility or Genentech's obligations under this Agreement) for Lonza's review and comment prior to Genentech's submission of its detailed written response. Genentech shall give all due consideration to any Lonza comments to each such proposed Genentech response provided Lonza timely responds.

10.5 Inspections; Non-Compliance; Failure to Manufacture.

10.5.1 Inspections. In the event the Lonza Facility is inspected, or Lonza is notified that the Lonza Facility will be inspected, by representatives of any regional, national, federal, state or local regulatory agency in the Territory directed to Lonza's manufacture of Bulk Drug, Lonza shall notify Genentech within twenty-four (24) hours after receipt of notice of such inspection, and shall supply Genentech with copies of any correspondence or portions of correspondence which relate to Bulk Drug. Genentech may send, and upon the request of Lonza shall send, representatives to the Lonza Facility to participate in any portion of such inspection which is directed to Bulk Drug.

10.5.2 Non-Compliance; Failure to Manufacture. In the event that any regional, national, federal, state or local regulatory agency in the Territory shall determine, as a result of an inspection described in Section 10.5.1 above, that Lonza is not in compliance with applicable laws or regulations or otherwise not in compliance with cGMP with respect to the manufacture of Bulk Drug, Lonza shall at its expense use Commercially Reasonable Best Efforts to cure any such non-compliance as soon as practicable.

ARTICLE 11.
RECALLS

11.1 Recalls. Genentech shall notify Lonza promptly (and in any event within three (3) business days of receipt of written notice) if any batch of Bulk Drug or resulting Finished Product is the subject of a recall, market withdrawal or correction. Genentech shall (i) bear the cost of and be responsible for conducting all recalls, market withdrawals or corrections of Bulk Drug or Finished Product, (ii) remain obligated to pay Lonza the Purchase Price for the Bulk Drug recalled or used to make such recalled Finished Product (as long as it is not Non-Conforming Bulk Drug), and (iii) reimburse Lonza for its direct out-of-pocket expenses related to the recall, if any. Notwithstanding the foregoing, to the extent such recall, market withdrawal or correction was caused by Lonza's breach of any of its warranties set forth in Article 7 hereof, Lonza shall credit Genentech for all of the Purchase Price for the Bulk Drug recalled or used to make such recalled Finished Product and shall reimburse Genentech for all of Genentech's reasonable out-of-pocket expenses directly related to the recall, if any. For the avoidance of doubt such expenses shall not, except

as provided in Section 17.4, include any Consequential Damages. As between the Parties, Genentech or its agent shall make all decisions regarding, and in all events shall have sole authority for, conducting any recalls, market withdrawals or corrections with respect to the Product in the Territory.

ARTICLE 12.
QUALITY ASSURANCE; QUALITY CONTROL; VALIDATION; STABILITY

12.1 Responsibility for Quality Assurance and Quality Control. Responsibility for quality assurance and quality control of Bulk Drug shall be allocated between Genentech and Lonza as set forth in the Quality Agreement and in standard operating procedures agreed upon in writing by Genentech and Lonza from time to time. In general, (a) Lonza shall be responsible for performing certain in-process testing and selected acceptance testing on the Bulk Drug as set forth in the Tech Transfer Agreement and the Quality Agreement, and (b) Genentech shall be responsible for all final acceptance testing and authorizing final release of all Bulk Drug to the market.

12.2 Validation of Lonza Facility; Utilities and Equipment. Lonza shall maintain cGMP validation status of the Lonza Facility, as well as the utilities and equipment used in the manufacture of Bulk Drug at the Lonza Facility, and shall make relevant validation reports applicable thereto (redacted to remove information not related to the manufacture of Bulk Drug) available to Genentech for review at Genentech's reasonable request.

12.3 Validation of Bulk Manufacturing Process. In accordance with the requirements of and timelines set forth in the Tech Transfer Agreement and Quality Agreement, Genentech shall provide Lonza with Manufacturing Documentation related to the validation of the Manufacturing Process, as further described therein, including, without limitation, drafts of the product comparability protocol and the process validation protocol related to the Manufacturing Process. Lonza shall be responsible for performing all required process validation at the Lonza Facility and Genentech shall review and approve all process validation protocols and reports. A Process Qualification Plan (as defined in the Quality Agreement) to be developed by Lonza and approved by Genentech will identify additional process validation related to the technology transfer to Lonza, if required, at commercial scale. Lonza shall provide Genentech with copies of documentation related to the validation of the Manufacturing Process, as implemented by Lonza, and validation reports applicable thereto, to Genentech, at Genentech's reasonable request, on a frequency and in a format to be agreed upon by Lonza and Genentech.

12.4 Change Control. Any changes to the Lonza Facility, utilities, equipment or processes used by Lonza in its performance under this Agreement, including those relating to the manufacturing, storage, testing, shipping and cleaning procedures that are used by Lonza in the manufacture of Bulk Drug under this Agreement, shall occur pursuant to change control procedures agreed upon by Lonza and Genentech and as set forth in the Quality Agreement.

12.5 Stability. Genentech shall conduct all necessary stability testing to comply with cGMP and other applicable regulatory guidelines. Such stability testing shall include testing to validate the lead times for shipment, the shelf life of Bulk Drug and the Bulk Drug Specifications applicable to shipment, storage and handling of Bulk Drug. Lonza shall prepare all stability samples, and shall sublot stability samples and package and ship stability samples to Genentech, all in accordance with timelines, protocols and procedures agreed upon by Lonza and Genentech and set forth in the Quality Agreement.

ARTICLE 13.
MANUFACTURER'S OBLIGATIONS AS MANUFACTURER

13.1 Control of Working Cell Bank. Lonza shall maintain all portions of the Working Cell Bank that it receives in safe and secure storage under its control in the Lonza Facility at Portsmouth, New Hampshire, and shall not permit the transfer of the Working Cell Bank to any Lonza Affiliate or any Third Party that is not specifically authorized in advance and in writing by Genentech. Lonza shall comply with all applicable regulatory requirements relating to general safety and compliance in handling the Working Cell Bank and any raw materials and components used in manufacturing Product and Bulk Drug.

13.2 Manufacturing Capabilities. Lonza shall at all relevant times throughout the Term use Commercially Reasonable Best Efforts consistent with the terms of this Agreement to (a) own or lawfully control all the necessary plant, equipment and facilities, and (b) have sufficient numbers of appropriately qualified personnel, in each case to enable Lonza to manufacture Bulk Drug in accordance with the Bulk Drug Specifications and in quantities sufficient to fulfill its obligations to supply Bulk Drug under this Agreement.

13.3 Compliance with Law. Lonza shall perform all work and services under this Agreement in conformance with cGMP and in conformance with the substantive requirements of all applicable material regional, national, state and local laws, ordinances and governmental rules or regulations in the Territory, and shall have all applicable licenses and permits required to perform the work and services hereunder, the absence of which would materially adversely affect the marketability of the Bulk Drug.

13.4 Lonza Facility. Lonza will use Commercially Reasonable Best Efforts to ensure that the Lonza Facility shall be maintained in accordance with cGMP and in such condition as will allow Lonza to manufacture the Bulk Drug in accordance with the Bulk Drug Specifications.

13.5 Storage Facilities. Lonza shall provide sufficient and suitable cGMP storage facilities that meet the Bulk Drug Specifications for storage of Bulk Drug and raw materials.

13.6 Raw Materials. Lonza shall maintain an adequate inventory of raw materials necessary to meet the Bulk Drug Commitment. Lonza shall only use the raw materials [*] for manufacture of Bulk Drug under this Agreement.

13.7 Subcontracting. Lonza shall not subcontract any of its obligations hereunder without the prior written consent of Genentech.

13.8 Regulatory Documentation.

13.8.1 Lonza shall provide Genentech in a timely manner with a copy of any Lonza manufacturing and control records for Bulk Drug which are required for any Genentech regulatory filings with respect to the Product, which records shall be in Lonza's standard formats unless otherwise agreed upon by the Parties.

13.8.2 Lonza shall provide Genentech promptly after the end of each annual reporting period for the Product (as calculated consistent with appropriate regulations and guidelines) with such information as is reasonably requested in writing by Genentech for the preparation of the annual report with respect to the manufacturing and control of the Product for such annual reporting period. Thereafter, Genentech shall provide to Lonza at least fifteen (15) days prior to Genentech's filing with the respective regulatory authorities a copy of such Genentech annual report, and Genentech shall take into consideration any Lonza comments to such annual report with respect to the manufacture of Product.

13.9 Manufacturing Data. Lonza shall collect data on the yield from each Batch, as well as the date of manufacture of each such Batch and make reports of the same available to Genentech in the form of a monthly manufacturing status report in Lonza's standard format or in such other format as may be agreed by the Parties. Lonza shall retain such manufacturing data in accordance with the requirements of applicable laws, rules and regulations.

13.10 Retention and Reserve Samples. Lonza shall isolate, identify and, subject to Section 20.3 hereof, retain retention and reserve samples of all raw materials and in-process production steps used in the production of Bulk Drug as may be required by standard operating procedures to be agreed upon in writing by Lonza and Genentech from time to time.

13.11 Analytical Testing. Except as otherwise contemplated by this Agreement or expressly set forth in the Quality Agreement, Lonza shall not perform any analytical testing on Bulk Drug unless agreed to by Lonza and Genentech.

13.12 Accurate Documentation. Each Party shall use diligent efforts to ensure all records and documentation provided to the other Party in connection with the manufacture of Bulk Drug shall be accurate in all material respects.

13.13 Insurance.

13.13.1 Insurance. During the term of this Agreement, and thereafter for the period of time required below, Lonza shall maintain:

(i) **Commercial General Liability** insurance, including contractual liability, in the minimum amount of [*] each occurrence combined single limit for bodily injury and property damage ("CGL") with an annual aggregate of [*]. This insurance shall include completed operations coverage; and

(ii) **Products Liability** insurance**,** including contractual liability, with a minimum limit of [*]each occurrence combined single limit for bodily injury and property damage with an annual aggregate of [*] ("Products Liability").

13.13.2 Special Requirements.

(a) Genentech shall be named as additional insureds under the above insurance policies.

(b) The CGL and Products Liability insurance policies shall be under a "claims-made" policy form and the CGL insurance coverage shall be maintained by Lonza for at [*] following termination of this Agreement, and the Products Liability insurance, for [*] following termination of this Agreement.

(c) The CGL insurance shall provide coverage for Bulk Drug in Lonza's care, custody and control.

(d) Each of the above insurance policies shall be primary insurance as respects Lonza's participation under this Agreement.

(e) All of the above insurance coverage shall be maintained with an insurance company or companies having an A.M. Best's rating of "A-VII" or higher.

13.13.3 Notice of Insurance. Within thirty (30) days from the execution of this Agreement, Lonza shall provide Genentech a certificate insurance reflecting the above requirements. Renewal certificates shall continue to be provided throughout the term of this Agreement, and in case of cancellation or material change, a thirty (30) day notice shall be provided to Genentech.

ARTICLE 14.
LICENSES

14.1 License Grant to Genentech of Rights Existing as of the Effective Date. Lonza, on behalf of itself and its Affiliates, hereby grants to Genentech and Genentech's Affiliates a non-exclusive, royalty-free license under Lonza Confidential Information, and under patent rights, if any, owned or controlled by Lonza or its Affiliates as of the Effective Date, to make (and have made), use, sell, offer for sale and import Product in the Territory, to the extent they relate to (i) the Manufacturing Process in effect as of the Effective Date or at anytime during the Term, (ii) the Product of the Manufacturing Process described in (i) above, or (iii) the importation, use, sale or offer for sale of the Product of the Manufacturing Process described in (i) above. This license shall apply with respect to any Product manufactured by or for Genentech under this Agreement with the Manufacturing Process described in this Section 14.1. Genentech shall have the right to grant sublicenses of the rights granted under this Section 14.1 to Product licensees and contract manufacturers of Product, in all or part of the Territory.

14.2 License Grant to Genentech of Rights Obtained after the Effective Date; Option to Grant Sublicenses.

14.2.1 In the event that Lonza or its Affiliates obtains any patent rights after the Effective Date (whether by acquisition, in-licensing, or independent development) that relate to (i) the Manufacturing Process in effect as of the Effective Date or at anytime during the Term, (ii) the Product of the Manufacturing Process described in (i)

above, or (iii) the importation, use, sale or offer for sale of the Product of the Manufacturing Process described in (i) above, Lonza, on behalf of itself and its Affiliates, hereby grants to Genentech and Genentech's Affiliates a non-exclusive, royalty-free license under such patent rights to make (and have made), use, sell, offer for sale and import Product in the Territory.

14.2.2 Option to Grant Sublicenses. Lonza also hereby grants to Genentech an option to obtain the right to grant sublicenses to any Third Party under any rights granted under Section 14.2.1 above. If Genentech exercises such option, Lonza agrees to negotiate in good faith with Genentech commercially reasonable terms under which Genentech would obtain such sublicense rights.

14.3 No Implied Licenses. Lonza acknowledges and agrees that no rights or licenses, implied or otherwise, are granted to Lonza by Genentech related to the manufacture of Product under this Agreement. This Agreement does not grant any right or license to Lonza, under any intellectual property rights of Genentech, or otherwise. No other right or license is to be implied or inferred from any provision of this Agreement or by the conduct of the Parties.

14.4 Survival. The obligations of the Parties set forth in this Article 14 shall survive the expiration or termination of this Agreement and shall be binding upon and inure to the benefit of the successors and assigns of the Parties.

ARTICLE 15.
OWNERSHIP OF INTELLECTUAL PROPERTY, MATERIALS AND EQUIPMENT

15.1 Inventorship, Existing Confidential Information, and Inventions.

15.1.1 Inventorship. Inventorship shall be determined in accordance with the rules of inventorship of the United States of America. As between the Parties, (i) each Party shall solely own any and all inventions or discoveries that are conceived or reduced to practice solely by such Party or its employees or agents in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, and (ii) the Parties shall jointly own inventions or discoveries that are conceived or reduced to practice jointly by or on behalf of the Parties in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement. The Parties hereby agree that neither Party shall be considered an "employee or agent" of the other Party.

15.1.2 Existing Confidential Information. As between the Parties, Genentech shall own all Genentech Confidential Information existing as of the Effective Date, and Lonza shall own all Lonza Confidential Information existing as of the Effective Date; provided, however, that the foregoing shall not limit Genentech' ownership of, or ability to use, the Cell Line, Master Cell Bank, Working Cell Bank, and/or the Product, including, without limitation, aspects of Lonza Confidential Information that result in or contribute to modifications to said Cell Line, Master Cell Bank, Working Cell Bank, and/or the Product in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, either by Genentech in an authorized manner under said agreements or by Lonza.

15.1.3 Inventions. Notwithstanding Section 15.1.1, as between the Parties: (a) Genentech shall own all rights, including without limitation, all intellectual property rights, in and title to the biological materials described as the Cell Line, the Master Cell Bank, and/or the Working Cell Bank, the Manufacturing Process and/or the Product, and any and all improved or enhanced versions of the foregoing that are created by either Party from their use thereof or in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, including, without limitation, any derivatives or variants of the foregoing created by either Party from their use thereof or in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, uses of such biological materials and methods of manufacture using such biological materials; and (b) Lonza hereby assigns to Genentech its entire interest in any and all patentable inventions, patentable and non-patentable, made from their use thereof or in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, solely by Lonza or its employees or agents, or jointly by the employees and/or agents of each Party, and all intellectual property rights therein.

15.1.4 Survival. The terms of this Section 15.1 shall survive the expiration or termination of this Agreement, and shall be binding upon and inure to the benefit of the successors and assigns of the Parties. The Parties will continue to reasonably cooperate with each other to perfect the rights granted in this Section.

15.2 Ownership of Equipment.

15.2.1 Genentech shall own all right, title and interest in and to any and all equipment, materials, facilities improvements and other assets purchased by Genentech and provided to Lonza for use under this Agreement, including, without limitation, the Portable Equipment specified in Section 5.5 (collectively, the "Genentech Equipment"), free and clear of any right or claim of Lonza. All Genentech Equipment shall be delivered in good working condition by Genentech and maintained in good repair by Lonza.

15.2.2 Lonza shall own all right, title and interest in and to any and all equipment, materials, facilities improvements and other assets purchased by Lonza for use under this Agreement (collectively, the "Lonza Equipment"), free and clear of any right or claim of Lonza. All Lonza Equipment shall be maintained in good repair by Lonza.

15.2.3 If Lonza fails to timely arrange for the removal of the Genentech Equipment from the Lonza Facility, Genentech shall send written notice requesting such removal. If such removal has not occurred within thirty (30) days of such notice, then Genentech shall be entitled to hire a qualified Third Party at Lonza's reasonable expense to enter the Lonza Facility with written notice at least two (2) business days in advance and remove such Genentech Equipment, which shall be removed in a reasonable manner without damage to the Lonza Facility. For clarification purposes, removal of the Genentech Equipment shall not in and of itself be considered damage to the Lonza Facility.

ARTICLE 16.
REPRESENTATIONS AND WARRANTIES

16.1 Genentech. Genentech hereby represents and warrants to Lonza that:

16.1.1 To Genentech's knowledge as of the Effective Date: (a) Genentech is free to supply to Lonza the Working Cell Bank, Genentech Confidential Information (including, without limitation, the Manufacturing Documentation), and all information to be supplied by Genentech to Lonza under the Tech Transfer Agreement; (b) there is no suit pending against Genentech in the Territory that alleges patent infringement by the manufacture or sale of the Product; and (c) Genentech has not received written notice alleging infringement of a Third Party patent by the manufacture or sale of the Product; and

16.1.2 Genentech has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations under this Agreement.

16.2 Lonza. Lonza hereby represents and warrants to Genentech that:

16.2.1 To Lonza's knowledge as of the Effective Date, Lonza is free to supply the Lonza Confidential Information to Genentech;

16.2.2 Lonza has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations under this Agreement;

16.2.3 Lonza owns or lawfully controls the Lonza Facility, and, to the best of its knowledge after reasonable inquiry, has a sufficient number of employees with such expertise and experience as is necessary or appropriate to produce Bulk Drug in accordance with the terms hereof and in quantities sufficient to fulfill the Campaign Minimums and Campaign Minimum Runs set forth in Exhibit A hereof;

16.2.4 To Lonza's knowledge as of the Effective Date, there is no additional capacity available for commercial production at the Lonza Facility, and Lonza has not entered into written agreements with any Third Party to

conduct commercial production that would result in Lonza not being able to conduct the commercial production it has committed to Genentech; and

16.2.5 To Lonza's knowledge as of the Effective Date, there are no patents owned or controlled by Lonza relating to the (i) the Manufacturing Process in effect as of the Effective Date, (ii) the Product of the Manufacturing Process described in (i) above, or (iii) the importation, use, sale or offer for sale of the Product of the Manufacturing Process described in (i) above.

ARTICLE 17.
INDEMNIFICATION

17.1 Indemnification.

17.1.1 Indemnification by Genentech. Subject to and except to the extent of any indemnification from Lonza pursuant to Section 17.2 below, Genentech shall indemnify, defend and hold Lonza, its Affiliates, and their respective directors, officers, and employees harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses), (collectively, the "Liabilities") to the extent such Liabilities arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of [*]

17.1.2 Indemnification by Lonza. Lonza shall indemnify, defend and hold Genentech, and its Affiliates, directors, officers, and employees harmless from and against all Liabilities to the extent such Liabilities arise out of or result from [*]

17.2 Indemnification Procedures.

17.2.1 Identification of Indemnitor and Indemnitee. An "Indemnitor" means Genentech with respect to Section 17.1 hereof, and Lonza with respect to Section 17.2 hereof. An "Indemnitee" means any of Lonza, its Affiliates, and their respective directors, officers, and employees with respect to Section 17.1 hereof, and any of Genentech, and its respective Affiliates, directors, officers and employees with respect to Section 17.2 hereof.

17.2.2 Indemnification Procedures. An Indemnitee which intends to claim indemnification under Section 17.1 or 17.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, and employees intend to claim such indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, and employees to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, such settlement does not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein in order for the Indemnitor to exercise such rights. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

17.3 Survival of Indemnification Obligations. The provisions of this Article 17 shall survive the termination or expiration of this Agreement

17.4 Disclaimer of Consequential Damages. Except for claims arising from (i) the intentional misuse or misappropriation of the other Party's Confidential Information, (ii) any willful breach by Lonza of its obligation hereunder to perform, in no event shall either Party be liable to the other Party for incidental, indirect, special, punitive or consequential damages arising from or related to breach of this Agreement, including, without limitation, any claims for damages based upon lost profits for sales to Third Parties (collectively, "Consequential Damages").

ARTICLE 18.
CONFIDENTIALITY

18.1 Confidentiality Obligations.

18.1.1 Lonza Confidentiality Obligations. Lonza shall not disclose Genentech Confidential Information to any Third Party other than:

(a) its employees who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to perform their duties in carrying out Lonza's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement,

(b) contractors who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to provide direction to Lonza or Genentech regarding their respective obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or

(c) regulatory authorities, for example, the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

18.1.2 Genentech Confidentiality Obligations. Genentech shall not disclose any Lonza Confidential Information to any Third Party (including, without limitation, Roche) other than:

(a) employees, consultants, agents or contractors of Genentech or Genentech's Affiliates who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to perform their duties in carrying out Genentech's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or in order to provide direction to Genentech regarding the subject matter of this Agreement, including, but not limited to, production, testing, storage or quality of the Product or regulatory or compliance issues related to the Product, or

(b) regulatory authorities, for example, the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

18.2 Terms of Agreement. Subject to Sections 18.4 and 19.1 hereof, and except for any disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with national, federal or state laws or regulations (including the rules and regulations of any national stock exchange on which such Party's securities are traded), neither Party shall, without the prior written consent of the other Party, disclose in any manner to any Third Party the terms and conditions of this Agreement; provided that this Section 18.2 shall not prohibit the disclosure of this Agreement by Genentech to Roche (including any successor or assignee thereof).

18.3 Exclusions. The obligations of confidentiality and nonuse applicable hereunder to Lonza with respect to Genentech Confidential Information and to Genentech with respect to Lonza Confidential Information shall not apply to any information which:

(a) at the time of disclosure, is known publicly or thereafter becomes known publicly through no fault of the recipient, its Affiliates or agents;

(b) becomes available to the recipient from a Third Party which is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from the disclosing Party;

(c) was developed by the recipient independently of information obtained from the disclosing Party as evidenced by written records;

(d) was already known to the recipient before receipt from the disclosing Party, as shown by its prior written records, provided that such information was not acquired directly or indirectly from the disclosing Party; or

(e) is released with the prior written consent of the Party that had originally disclosed such information to the other Party hereunder.

In determining whether or not the disclosing Party's Confidential Information has entered the public domain, the obligations of confidentiality shall no longer apply to only that portion of said Confidential Information that has become public, and portions remaining confidential shall retain their status as Confidential Information.

18.4 Notification of Mandatory Disclosure.

18.4.1 Notification and Consultation. In the event that a Party (in such case, the "Notifying Party") believes it is required by applicable statute or regulation (including the rules and regulations of any national stock exchange on which such Party's securities are traded), or by judicial or administrative process to disclose any part of the other Party's (in such case, the "Notified Party") Confidential Information which is disclosed to it under this Agreement, the Notifying Party shall (i) promptly notify the Notified Party of each such requirement and identify the documents so required thereby, so that the Notified Party may seek an appropriate protective order or other remedy and/or waive compliance by the Notifying Party with the provisions of this Agreement, and (ii) consult with the Notified Party on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

18.4.2 Limited Disclosure. If, in the absence of such a protective order or such a waiver by the Notified Party of the provisions of this Agreement, the Notifying Party is nonetheless required by mandatory applicable law to disclose any part of the Notified Party's Confidential Information which is disclosed to it under this Agreement, the Notifying Party may disclose such Confidential Information without liability under this Agreement, except that the Notifying Party shall furnish only that portion of the Confidential Information which is legally required.

18.5 No Licenses Maintenance of Confidentiality; Non-use Obligations.

18.5.1 No Licenses. Except as expressly provided in Articles 14 and 15 hereof, no right or license, either express or implied, under any intellectual property right is granted under this Agreement, the Tech Transfer Agreement, or the Quality Agreement, by virtue of the disclosure of Confidential Information under this Agreement, the Tech Transfer Agreement, or the Quality Agreement, or otherwise.

18.5.2 Maintenance of Confidentiality. Each Party shall use reasonable and customary precautions to safeguard the other Party's Confidential Information, including ensuring that all employees, consultants, agents or contractors who are provided access to such Confidential Information are informed of the confidential and proprietary nature of such Confidential Information and have contractual confidentiality and nonuse obligations that are at least as restrictive as those contained in this Agreement.

18.5.3 Non-use Obligations. Genentech Confidential Information shall not be utilized by Lonza for any purpose other than performing its obligations under this Agreement, the Tech Transfer Agreement, or the Quality Agreement, without first obtaining Genentech's prior written consent to each such utilization. Lonza Confidential Information shall not be utilized by Genentech except as set forth in this Agreement, the Tech Transfer Agreement, or the Quality Agreement, or except for the limited purpose of production, testing, storage or quality of the Product or regulatory or compliance issues related to the Product, without first obtaining Lonza's prior written consent to each such utilization.

18.5.4 Equitable Relief. Each Party agrees that the other Party and their respective Affiliates would be irreparably injured by a material breach of the confidentiality and nonuse provisions of this Agreement by the breaching Party or by its employees or the employees of its Affiliates, consultants, agents or contractors, that monetary remedies would be inadequate to protect the other Party against any actual or threatened material breach of the provisions of this Article 18 by the breaching Party or by its employees or the employees of its Affiliates, consultants, agents or contractors, and, without prejudice to any other rights and remedies otherwise available to the other Party, the breaching Party agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief,

including injunctive relief and specific performance, in the other Party's favor without proof of actual damages. It is further understood and agreed that no failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

18.6 Survival of Confidentiality Obligations. The provisions of this Article 18 shall survive the termination or expiration of this Agreement.

18.7 Termination of Certain Prior Agreements. This Agreement supersedes all previous agreements between the parties relating hereto, including without limitation the Confidential Disclosure Agreement between the Parties dated July 1, 2003, the Agreement for Funding Purchase of Long Lead Time Equipment of November 19, 2003 and the Material Transfer Agreement of November 24, 2003. All Confidential Information exchanged between the Parties under such previous agreements shall be deemed Confidential Information under this Agreement (either Genentech Confidential Information or Lonza Confidential Information, as the context requires) and shall be subject to the terms of this Agreement.

18.8 No Disclosure of Unrelated Information. Neither Party shall disclose confidential information to the other Party that is not reasonably necessary for performance of a Party's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, including but not limited to manufacturing processes for other products, marketing plans and clinical development plans. Notwithstanding the foregoing, nothing in this provision shall limit the confidentiality and non-use obligations and rights herein.

ARTICLE 19.
PRESS RELEASES;USE OF NAMES

19.1 Press Releases. Following the Effective Date, the Parties shall agree upon a joint press release to announce the execution of this Agreement together with a corresponding Question & Answer outline for use in responding to inquiries about the Agreement. Such joint press release shall be made on or before December 25, 2003, the timing of which such announcement shall be mutually agreed by the Parties. Following the publication of such joint press release, each Party shall be entitled to make or publish any public statement consistent with the contents of such joint press release and Question & Answer outline without the need for further approval by the other. Except as set forth in the preceding sentences of this Section, no press release, publicity or other form of public written disclosure related to this Agreement shall be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing. This Section shall not apply to any disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with regional, national, federal or state or local laws or regulations in the Territory (including the rules and regulations of any national stock exchange on which such Party's securities are traded).

19.2 Use of Names. No Party shall make use of the name of any other Party in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party; provided, however, either Party may include the other Party on a general list of business partners or collaborations.

ARTICLE 20.
TERM; TERMINATION

20.1 Term; Option to Extend. Unless sooner terminated pursuant to the terms of this Agreement, the term of this Agreement (the "Term") shall commence on the Effective Date and shall continue until [*]; provided, however, Genentech shall have the one time right, at its sole discretion, upon written notice to Lonza prior [*], to extend the Term for an additional period of [*]. During any such extension, all terms of this Agreement, the Tech Transfer Agreement and the Quality Agreement shall apply. As used herein “Term” shall mean the initial Term, including any extension thereof.

20.2 Termination.

20.2.1 Material Breach. This Agreement may be terminated in its entirety by either Party (the "Nonbreaching Party") upon written notice thereof to other Party (the "Breaching Party") in the event of a material breach by the Breaching Party which is not cured within [*] days after receipt of written notice from the Nonbreaching Party to the Breaching Party, specifying in reasonable detail the nature of such breach, or such longer period of time if the Breaching Party delivers a certificate that such material breach is not reasonably capable of being cured within such [*] days and that the Breaching Party is working diligently to cure such breach, but in no event shall the time for curing such breach exceed an additional [*]days. Notwithstanding the foregoing, if the material breach referred to in this Section 20.2.1 arises out of or consists of the failure to pay Lonza amounts due under this Agreement in accordance with the terms hereof, there shall be a single period of [*]days after notice of breach within which Genentech shall have the right to cure such default by making payment in full of the amount then due and payable. In the event such breach is not cured within such cure period, this Agreement shall terminate as set forth in the Nonbreaching Party's notice of breach and in accordance with the terms of this Article; provided, however, that this Agreement shall not be terminated prior to the end of such cure period. During the period in which Lonza is attempting to cure any Lonza material breach, Genentech shall have no obligation to purchase Product.

20.2.2 Withdrawal of Product**.** Genentech may terminate this Agreement in its sole discretion, upon thirty (30) days prior written notice to Lonza, in the event the BLA for the Product is withdrawn.

20.2.3 Permissive Termination. Genentech may terminate this Agreement at any time for any reason, upon twelve (12) months prior written notice to Lonza.

20.2.4 Failure to Timely Achieve Key Milestones or Targeted Performance Criteria. Genentech may, in its sole discretion, terminate this Agreement in its entirety upon [*]days prior written notice to Lonza, if (i) Phase A Completion is not achieved [*] (ii) Phase B Completion is not achieved [*], (iii) if the sBLA Enablement is not achieved by [*], (iv) FDA Approval is not received by the later of [*], in the event sBLA Enablement is achieved [*], (v) the Pre-Campaign/Campaign Requirements for a particular [*] are not met in [*] (unless such non-compliance with such requirements is cured within the period specified in Section 5.2.3 [*], and/or (vi) the Campaign Minimum Runs, Annual Minimum Success Rate and/or Target Yield for a [*] are not met in such [*].

20.2.5 Change of Control. In the event of a Change of Control of Lonza, Genentech shall have the one time right, exercisable within [*] after such Change of Control (upon thirty (30) days prior written notice to Lonza (or its successor)), to terminate this Agreement. As used herein "Change of Control" means the merger, consolidation, sale of substantially all of the assets or similar transaction or series of transactions, as a result of which Lonza's shareholders before such transaction or series of transactions, own less than fifty percent (50%) of the total number of voting securities of the surviving entity immediately after such transaction or series of transactions.

20.3 Consequences of Termination.

20.3.1 Payment of Amounts Due; Cumulative Remedies. Expiration or termination of this Agreement for any reason shall not exempt any Party from paying to any other Party any amounts owing to such Party at the time of such expiration or termination. Except as expressly stated otherwise herein, remedies under this Agreement are cumulative, and nothing in this Agreement shall prevent any Party, in the case of a material breach (after expiration of applicable cure period and notice periods), from terminating this Agreement and seeking to enforce its rights under this Agreement.

20.3.2 Termination of Bulk Drug Commitment.

(a) Upon termination of this Agreement in its entirety by Genentech pursuant to Section 20.2.1 (Lonza Material Breach) hereof, Genentech may, in its discretion, cancel, in whole or in part, any Runs that were scheduled to be initiated on or after the effective date of such termination. Likewise, upon termination of this Agreement in its entirety by Lonza pursuant to Section 20.2.1 (Genentech Material Breach) hereof, Lonza may, in its discretion, cancel, in whole or in part, any Runs that were scheduled to be initiated on or after the effective date of such termination. Runs that are in process [*] as of the effective date of any such termination shall not be cancelled without the mutual agreement of the Parties, and the Agreement shall continue to survive with respect to those in-process Runs.

(b) Upon the issuance of a notice of termination of this Agreement pursuant to Section 20.2.2 (Withdrawal of Product) or Section 23.4 (Termination for Force Majeure Event) hereof, all Runs which were scheduled to be initiated after the date on which the notice of termination was issued shall be automatically cancelled. Runs that are in process at the [*] on the date on which the notice of termination was issued shall not be cancelled without the mutual agreement of the Parties, and the Agreement shall continue to survive with respect to those in-process Runs.

(c) Upon the termination of this Agreement pursuant to Section 20.2.3 (Permissive Termination), Genentech may, in its discretion, cancel, in whole or in part, any Campaign's and Runs scheduled during such [*] period (as defined in the current Product Manufacturing Forecast); provided, in the event of any such cancellation, if the amounts paid by Genentech to Lonza during such [*] period for Successful Commercial Batches produced from such Campaigns and Runs amounts to less than [*] Genentech agrees to pay Lonza the balance of such amount within [*]days following the effective date of termination of this Agreement (i.e., [*] less the amounts paid for such Successful Commercial Batches).

(d) Upon the termination of this Agreement pursuant to Section 20.2.4 (Failure to Timely Achieve Key Milestones or Targeted Performance Criteria) or Section 20.2.5 (Change of Control), Lonza shall immediately stop all Bulk Drug manufacturing hereunder, other than completing testing and release of Bulk Drug that has been fully manufactured as of the date of termination. Bulk Drug that has been fully manufactured as of the date of termination but for which testing and release has not been completed shall remain subject to the terms of this Agreement, and the Agreement shall continue to survive with respect to such Bulk Drug.

20.3.3 Raw Materials. Subject to Lonza's obligation upon receipt of a notice of termination to place no further orders for raw materials, intermediates or packaging components except as may be necessary for completion of any portion of Lonza's services hereunder that are not immediately terminated:

(a) Upon expiration of this Agreement or termination of this Agreement pursuant to Section 20.2.1 (Genentech Material Breach) hereof, Genentech shall purchase from Lonza, at the request of Lonza, at Lonza's Acquisition Cost, all remaining usable raw materials, intermediates and packaging components acquired and paid for by Lonza for the manufacture and packaging of Bulk Drug under this Agreement (provided such materials and/or intermediates have a shelf life remaining of at least six (6) months); or

(b) Upon termination of this Agreement pursuant to Section 20.2.2 (Withdrawal of Product), or Section 20.2.3 (Permissive Termination), Section 20.2.4 (Failure to Timely Achieve Key Milestones or Targeted Performance Criteria), Section 20.2.5 (Change of Control) or Section 23.4 (Termination for Force Majeure Event) hereof, Genentech may purchase from Lonza, at the request of Lonza, at Lonza's Acquisition Cost, all remaining usable raw materials, intermediates and packaging components acquired and paid for by Lonza for the manufacture and packaging of Bulk Drug under this Agreement.

Notwithstanding the foregoing, Genentech shall not be obligated to purchase an amount of such raw materials, intermediates and packaging components in excess of the amount reasonably necessary to fulfill the outstanding Bulk Drug Commitment for Bulk Drug that are outstanding at the time of such termination plus a reasonable safety stock.

20.3.4 Return of Materials and of Genentech Confidential Information, Transfer of Genentech Equipment. Upon expiration or termination of this Agreement, unless otherwise directed by Genentech, Lonza shall promptly (i) return or, at Genentech's election, destroy all quantities of the Cell Line, Master Cell Bank, and Working Cell Bank received by Lonza under this Agreement, the Tech Transfer Agreement or the Quality Agreement, with any such destruction to be certified in writing to Genentech by an authorized Lonza officer, (ii) return all Genentech Confidential Information to Genentech, and (iii) return to Genentech all retention and reserve samples being held by Lonza pursuant to Section 13.8 hereof. In addition, if requested by Genentech, Lonza shall transfer the Genentech Equipment to Genentech in accordance with Section 15.2 hereof.

20.3.5 Return of Lonza Confidential Information. Upon expiration or termination of this Agreement, and at Lonza's written request, Genentech shall promptly return all Lonza Confidential Information to Lonza.

20.3.6 Accrued Rights. Except as otherwise expressly set forth herein, any termination or expiration of this Agreement shall be without prejudice to any right which shall have accrued to the benefit of either Party and shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein or, if no period is provided therein, then such obligations shall remain in full force and effect indefinitely.

ARTICLE 21.
ASSIGNMENT

21.1 Assignment. This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party; provided, however, Genentech may assign its interest under this Agreement, without the prior written consent of Lonza, (a) to an Affiliate, so long as Genentech unconditionally guarantees the obligations of such Affiliate or (b) to a successor of Genentech's business by reason of merger, sale of all or substantially all of its assets or other form of acquisition. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

ARTICLE 22.
DISPUTE RESOLUTION

22.1 Exclusions. Section 22.2 below shall not apply to any disputes arising under Article 18 (Confidentiality) or Section 24.9 (Non-Competition).

22.2 Dispute Resolution.

22.2.1 Disputes. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement that relates to a Party's rights and/or obligations under this Agreement. Unless otherwise specifically recited in this Agreement, disputes among members of each operating committee will be resolved as recited in this Section 22.2. In the event of the occurrence of such a dispute, any Party may, by written notice to the other Parties, have such dispute referred to their respective officers designated below, or their respective designees, for attempted resolution by good faith negotiations within five (5) days after such notice is received. Such designated officers are as follows:

For Genentech – [*]

For Lonza – [*]

In the event the designated officers, or their respective designees, are not able to resolve such dispute within such five (5)-day period, or such other period of time as the Parties may mutually agree in writing, either Party may, by written notice to the other, invoke the following provisions of this Section 22.2 hereinafter.

22.2.2 Arbitration. The Parties agree that, except as otherwise set forth in Section 22.1 above or Section 22.2.4 or 22.2.5 below, any dispute, controversy or claim arising out of or relating to this Agreement, the Tech Transfer Agreement, or the Quality Agreement (other than issues regarding disposition of Bulk Drug, which shall be resolved in accordance with the terms of the Quality Agreement), or the breach, termination, or invalidity thereof, shall be resolved through binding arbitration. If a dispute arises between the Parties, and if such dispute cannot be resolved pursuant to Section 22.2.1 above, such dispute shall be finally resolved by binding arbitration administered by the American Arbitration Association (unless otherwise agreed in writing by the Parties) in accordance with its Commercial Arbitration Rules (unless otherwise agreed in writing by the Parties), except as modified herein. Each Party shall select one arbitrator and the two (2) arbitrators so selected shall choose a third arbitrator to resolve the dispute. A reasoned arbitration decision shall be rendered in writing within thirty (30) days of the conclusion of arbitration and shall be binding and not be appealable to any court in any jurisdiction. Such arbitration shall be concluded within six (6) months following the filing of the initial request for arbitration. The prevailing Party may enter

such decision in any court having competent jurisdiction. Unless otherwise mutually agreed upon by the Parties, the arbitration proceedings shall be conducted at San Francisco, California, or such other location as may be agreed in writing by the Parties. The Parties agree that they shall share equally the cost of the arbitration filing and hearing fees, and the cost of the mediator/arbitrator. Each Party must bear its own attorneys' fees and associated costs and expenses. NOTWITHSTANDING THE FOREGOING TIME PERIODS IN THIS SECTION 22.2.2, THE PARTIES AND ARBITRATOR SHALL USE ALL DILIGENT EFFORTS TO COMPLETE ANY ARBITRATION OF A CLAIM OR DISPUTE DESCRIBED IN SECTION 3.1.4(C), 3.1.4(D) OR SECTION 17.4 WITHIN THIRTY (30) DAYS OF APPOINTMENT OF THE ARBITRATOR TO RESOLVE THE DISPUTE, AND TO COMPLETE ANY ARBITRATION OF SUCH CLAIM OR DISPUTE WITHIN NINETY (90) DAYS AFTER THE FILING OF THE INITIAL REQUEST FOR ARBITRATION.

22.2.3 Jurisdiction. For the purposes of this Article 22, the Parties agree to accept the jurisdiction of the federal courts located in the Northern District of California for the purposes of enforcing awards entered on behalf of Genentech pursuant to this Article 22 and for enforcing the agreements reflected in this Article, or to a state court in such jurisdiction if the applicable rules of civil procedure preclude federal court jurisdiction.

22.2.4 Determination of Patents and Other Intellectual Property. Notwithstanding the foregoing, any dispute relating to the determination of validity of a Party's patents or other issues relating to a Party's intellectual property shall be submitted exclusively to the federal court located in the jurisdiction of the defendant, or to a state court in such jurisdiction if the applicable rules of civil procedure preclude federal court jurisdiction, and the Parties hereby consent to the jurisdiction and venue of such courts.

22.2.5 Claims involving Consequential Damages. The Parties agree that, with respect to any willful breach by Lonza of its obligation hereunder to perform, for which Genentech intends to seek Consequential Damages from Lonza, prior to invoking the provisions of Section 22.2.2 to resolve such dispute, controversy or claim, the following provisions shall apply:

(a) Genentech shall provide Lonza with [*] days written notice of such breach specifying in reasonable detail the nature of such breach and a statement that Genentech intends to seek Consequential Damages from Lonza for such breach. If Lonza does not deliver to Genentech a written plan for curing such breach and cure such breach within such [*] day period, or such longer period of time if Lonza delivers to Genentech a certificate that such breach is not reasonably capable of being cured within [*] days and that Lonza is using all Commercially Reasonable Best Efforts to cure such breach as soon as possible, but in no event shall the time period for curing such breach exceed an additional [*] days, at the end of such period, Genentech may seek to have such dispute finally resolved by binding arbitration in accordance with Section 22.2.2 above.

(b) If Genentech files a request for binding arbitration of such dispute, Genentech shall provide Lonza with written copy of such filing including a statement that Genentech intends to seek Consequential Damages from Lonza for such breach.

(c) To the extent the arbitrator in its written decision awards Genentech any Consequential Damages, Lonza shall have the right, at its discretion, to elect to [*] in lieu of paying to Genentech such Consequential Damages; such election to be made by Lonza in writing to Genentech within five (5) days of the arbitrator's written notice to the Parties of such final decision. In the event of such election: (i) [*] and (ii) Genentech hereby waives any Consequential Damages awarded in such written decision of such arbitrator. If written notice is given by Lonza that it does not wish to make such election, or written notice is not given to Genentech by Lonza within such five (5) day period, Genentech shall be free to enter such decision in any court having competent jurisdiction.

ARTICLE 23.
FORCE MAJEURE

23.1 Effect of Force Majeure Event. No Party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due under this Agreement) occasioned by any reason beyond the control and without the fault or negligence of the Party affected thereby, including an act of God, fire,

act of government or state, war, civil commotion, insurrection, embargo, an infectious virus which cannot be detected by testing and which causes a shutdown for a substantial period of a large portion of the Lonza Facility that was used for the manufacture of the Product due to contamination despite Commercially Reasonable Best Efforts by Lonza to prevent such occurrence, prevention from or hindrance in obtaining energy or other utilities, a market shortage of raw materials or necessary components (but only to the extent that Lonza has otherwise complied with the safety stock requirements specified in Section 4.5), or labor disputes of whatever nature (a "Force Majeure Event"). Nothing in this Section 23.13 shall, however, release such Party from using its Commercially Reasonable Best Efforts to avoid or remove all such causes. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement.

23.2 Notice of Force Majeure. Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under this Agreement. Each Party further agrees to use Commercially Reasonable Best Efforts to correct the Force Majeure Event as quickly as practicable and to give the other Party prompt written notice when it is again fully able to perform such obligations.

23.3 Annual Minimum Campaign and Annual Minimum Runs. If a Force Majeure Event prevents Lonza from manufacturing Bulk Drug under this Agreement in any calendar year, the parties shall in good faith discuss and Lonza shall use Commercially Reasonable Best Efforts to schedule and conduct an additional Campaign within the next six (6) months following correction of such Force Majeure Event in order to make-up such shortfall, shortage or delay and/or increase proportionately the Annual Minimum Campaign and Annual Minimum Runs in the subsequent calendar year.

23.4 Target Dates and Milestones. It is understood and agreed that nothing herein this Article 23 shall entitle Lonza, or obligate Genentech, to extend any of the target dates specified in Section 4.7 and/or the dates for completion of milestones set forth in Section 6.3.

23.5 Termination. Genentech may terminate this Agreement if Lonza is unable to perform pursuant to this Article 23 for a period of six (6) months.

ARTICLE 24.
MISCELLANEOUS

24.1 Notices. Other than notices within the jurisdiction of the respective Project Team Leaders, which shall be given to those individuals, any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with the original promptly sent by any of the foregoing manners), to the addresses or facsimile numbers of the other Parties set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to Genentech: Corporate Secretary
Genentech, Inc.
I DNA Way
South San Francisco, CA 94080
Fax: (650) 952-9881
Phone: (650) 225-1672

with a copy to: Senior Vice President of Product Operations
Genentech, Inc.
1 DNA Way, MS 53
South San Francisco, CA 94080
Fax: (650) 225-5007
Phone: (650) 225-3978

with a copy to:	Vice President of Business & Commercial Development Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 Phone: (650) 225-3705 Fax: (650) 225-3009
If to Lonza:	Lonza Biologics, Inc. Chief Operating Officer 101 International Drive Portsmouth, New Hampshire 03801 Fax: (603) 610-5050 Phone: (603) 610-4899
with a copy to:	Lonza Biologics, Inc. Legal Advisor 101 International Drive Portsmouth NH 03801 Fax: (603) 610-5050 Phone: (603) 610-5295
with a copy to:	Corporate Legal Counsel Lonza Group Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland

24.2 Applicable Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal substantive laws of the State of California, without reference to the choice of law doctrine of such state.

24.3 Headings. The table of contents and all headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement.

24.4 Exhibits. All exhibits referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

24.5 Severability. Each Party hereby expressly agrees that it has no intention to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or any Party hereto, in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as enforcement of the remainder does not violate the Parties' overall intentions in this transaction.

24.6 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall hold itself out to Third Parties as purporting to act on behalf of, or serving as the agent of, the other Party.

24.7 Waiver. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

24.8 Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

24.9 [This Section intentionally left blank.]

24.10 Harmful Products. During the Term, Lonza agree that it shall not manufacture, either for commercial supply or clinical supply, for itself or any Affiliate or Third Party, any compound or composition of matter (including without limitation any viruses, antibiotics, or microplasmas) which may put at risk Lonza's efforts to obtain and maintain Regulatory Approval of the Lonza Facility and/or to manufacture Bulk Drug in accordance with the terms of this Agreement. In addition, Lonza agrees not to use any form of penicillin or cephalosporin in the Manufacturing Process utilized at the Lonza Facility, without Genentech's prior written consent.

24.11 Non-Solicitation. The Parties recognize that each Party has a substantial interest in preserving and maintaining confidential its Confidential Information hereunder. Each Party recognizes that certain of the other Party's employees, including those engaged in manufacturing, validating and testing Product, may have access to such Confidential Information of the other Party. The Parties therefore agree not to knowingly solicit or otherwise induce or attempt to induce for purposes of employment, any employees from the other Party involved in the manufacturing, validating or testing of any Product during the Term and for a period of two years thereafter.

24.12 Injunctive Relief. Lonza agrees that Genentech would be irreparably injured by a material breach by Lonza or its employees of Lonza's obligations under Article 4 and/or Article 5, and that monetary remedies would be inadequate to protect Genentech against any actual or threatened material breach of the provisions of such Articles by Lonza or by its employees, and, without prejudice to any other rights and remedies otherwise available to Genentech, Lonza agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief, including injunctive relief and specific performance, in Genentech's favor without proof of actual damages. It is further understood and agreed that no failure or delay by Genentech in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

24.13 Entirety; Amendments. This Agreement, including any exhibits attached hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof (i.e., purchase and supply of Bulk Drug), and no terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless it is hereafter made in writing and signed by each of the Parties. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any purchase order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein. In the event of a conflict between this Agreement, the exhibits hereto, the Tech Transfer Agreement or the Quality Agreement, the terms of this Agreement shall control (except, with respect to issues of quality control, other than as specified in Section 3.1.4(c) of this Agreement, the terms of the Quality Agreement shall control). This Agreement may be amended and supplemented only by a written instrument signed by each of the Parties.

24.14 Preference. Unless otherwise specifically provided for in the Quality Agreement and/or Tech Transfer Agreement, the terms of this Agreement shall prevail in the event of a conflict between this Agreement and any of the aforementioned agreements.

[the remainder of this page intentionally blank]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

GENETECH, INC.

By: /S/ Arthur D. Levinson
Name: Arthur D. Levinson
Title: Chairman and CEO

LONZA BIOLOGICS, INC.

By: /S/ Markus Gemuend
Name: Markus Gemuend
Title: Chief Executive Officer

LONZA BIOLOGICS, PLC

By: /S/ Markus Gemuend
Name: Markus Gemuend
Title: Chief Executive Officer

Exhibit A
Annual Minimums***

Calendar Year	Campaign Minimum*	Campaign Minimum Runs**
[*]		

*Unless otherwise mutually agreed by the Parties, Lonza shall conduct the Campaign in each year in [*] Any Runs started during a Campaign shall be completed, [*]

**When used in this Exhibit, the term "Runs" for purposes of defining the term [*] shall mean commencement of a fermentation start of the Manufacturing Process at the [*], with the intent to progress through the [*] and [*], harvest, recovery, quality testing and release.

***[*] it is understood and agreed that the Campaign Minimums and Campaign Minimum Runs shall be adjusted accordingly to account for such [*]

Campaign Maximums

Calendar Year	Successful Commercial Batches
[*]	

Exhibit B
Annual Minimum Success Rate

Calendar Year	Minimum Successful Commercial Lots
[*]	[*]of Annual Minimum Runs
[*]	[*]of Annual Minimum Runs
[*]	[*]of Annual Minimum Runs
[*]	[*]of Annual Minimum Runs

Exhibit C
Target Yield

1. The initial Target Yield is [*] with a standard deviation of +/- [*]. The initial Target Yield is based on [*] data obtained by Genentech [*]for manufacture of the Bulk Drug (adjusted for the Lonza Facility).

2. Following completion of all Successful Development Runs (as determined in accordance with the Tech Transfer Agreement), the JPT shall review and revise as necessary the initial Target Yield based on (i) the [*] data obtained by Genentech [*] for manufacture of the Bulk Drug and (ii) the [*] data obtained by the Parties from the Successful Development Runs.

3. Following completion of all Successful Qualification Lots (as determined in accordance with the Tech Transfer Agreement), the JPT shall review and revise as necessary the current Target Yield based on (i) such [*] data obtained by Genentech [*] for manufacture of the Bulk Drug and (ii) the [*] data obtained by the Parties from the Successful Development Runs and (iii) the [*] data obtained by the Parties from the Successful Qualification Lots. Such Target Yield shall be the Target Yield for Commercial Production of the Bulk Drug for the remainder of the Term, unless otherwise agreed by the Parties in writing. It is understood that based on the current BLA for the Product, the final Target Yield must be within [*]of the initial Target Yield.

EXHIBIT 10.32

TOLL MANUFACTURING AGREEMENT

By and Between

WYETH,
Acting through its Wyeth Pharmaceuticals Division

and

GENENTECH, INC.

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TOLL MANUFACTURING AGREEMENT

This TOLL MANUFACTURING AGREEMENT (the "Agreement") is made effective as of September 15, 2004 (the "Effective Date"), by and between Wyeth, a Delaware corporation acting through its Wyeth Pharmaceuticals Division having its principal place of business at Five Giralda Farms, Madison, New Jersey 07940 ("Wyeth"), and Genentech, Inc., a Delaware corporation, having its principal place of business at One DNA Way, South San Francisco, California 94080 ("Genentech"). Wyeth and Genentech may each be referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Genentech markets and sells a certain proprietary biological pharmaceutical product known as Herceptin, and Genentech desires to obtain additional supply of commercial quantities of Herceptin bulk drug substance.

WHEREAS, Wyeth has experience and expertise necessary to perform the manufacturing and related services needed to supply Herceptin bulk drug substance, and Wyeth owns a facility that, with some modifications, would be suitable for production of commercial quantities of Herceptin bulk drug substance.

WHEREAS, Genentech desires to retain Wyeth on a nonexclusive basis, to convert Raw Materials (as defined below) into commercial quantities of Herceptin bulk drug substance, and Wyeth desires to perform such services, all on the terms and conditions set forth in this Agreement.

WHEREAS, on August 11, 2004 the Parties entered into a Letter of Intent (the "LOI") contemplating their entry into this Agreement and the other Transaction Agreements (as defined below) and preliminary activities relating to the Technology Transfer (as defined below) have been initiated by the Parties pursuant thereto.

WHEREAS, on even date herewith, Wyeth and Genentech are entering into a Quality Agreement for the purpose of further effectuating the intent of the Parties hereunder.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1.
DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement.

1.1 "Affiliate" means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity voting stock or general partnership or managing membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, resolution or otherwise, provided, however, that the term "Affiliate" shall not include subsidiaries or other entities in which a Party or its Affiliates owns a majority of the ordinary voting power necessary to elect a majority of the board of directors or other governing body but is restricted from electing such majority by contract or otherwise until such time as such restrictions are no longer in effect. Notwithstanding the foregoing, Roche shall not be considered an Affiliate of Genentech for purposes of this Agreement.

1.2 "Batch" or "Lot" means the quantity of Product produced from a single Run, and refers to a Commercial Batch or Lot, a Development Batch or Lot, a Pilot Batch or Lot and/or a Qualification Batch or Lot, as the context requires. A given Run may result in more than one sub-batch or sub-lot due to splitting into tanks downstream in the Manufacturing Process, but all such sub-batches or sub-lots shall still constitute the same Batch or Lot.

1.3 "Batch Records" means the documentary evidence (electronic or hard copy) of all activities required to manufacture, process, test, label, store and package a Batch.

1.4 "Bill of Materials" means (i) a list of all Raw Materials (including Specialized Raw Materials) and Genentech Proprietary Materials required to complete a Run and (ii) the corresponding quantities (including appropriate amounts of wastage) of such Raw Materials (including an allocable portion of Raw Materials used for multiple Runs (e.g., resins)) and Genentech Proprietary Materials required to complete a Run.

1.5 "Calendar Year" or "CY" means a one (1) year period commencing on January 1st and ending on December 31st.

1.6 "cGMP" means both the regulatory requirements for current good manufacturing practices promulgated by the FDA under the FD&C Act, 21 C.F.R. Sections 210, 211 and 600 et *seq*. and under the PHS Act, 21 C.F.R. Sections 600-610 and the ICH Guideline for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, as the same may be amended from time to time.

1.7 "Cell Line" means the proprietary Genentech Chinese Hamster Ovary cell line that expresses the Product.

1.8 "Centrifuge" means the [*] Centrifuge that has been purchased by Genentech [*] for use in the Manufacturing Process at the Facility, [*]

1.9 "Certificate of Analysis" means, as further specified in the Quality Agreement, with respect to each Batch, a document prepared by Wyeth: (a) listing tests performed by Wyeth, specifications, and test results, and (b) certifying the accuracy of the foregoing. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this Agreement.

1.10 "Certificate of Compliance" means, as further specified in the Quality Agreement, with respect to each Batch, a document prepared by Wyeth: (a) listing the manufacturing date, unique Batch number, and quantity of Product in such Batch, and (b) certifying that such Batch was manufactured in accordance with the Manufacturing Documentation, cGMP, the Product Specifications existing as of the time of the inoculation of the [*] bioreactor for such Batch and the warranties set forth in Section 7.1. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement.

1.11 "Commercial Batch" or "Commercial Lot" means a Batch or Lot produced from a Commercial Run.

1.12 "Commercial Production" means the operation of the Facility after sBLA Filing with [*] of its capacity dedicated to running the Manufacturing Process to manufacture Product that is or is expected to be (following FDA Approval) commercially saleable.

1.13 "Commercial Run" means a Run that is initiated after achievement of PAI Readiness for the purpose of manufacturing Product that is or is expected to be (following FDA Approval) commercially saleable.

1.14 "Commercially Reasonable Diligent Efforts" means: [*] Notwithstanding the foregoing, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, such Party would not be deemed to have failed to use its Commercially Reasonable Diligent Efforts in performing the adversely affected obligations.

1.15 "Commercially Reasonable Efforts" of a Party means those efforts and resources normally used by such Party with respect to a biopharmaceutical product owned by such Party or to which such Party has similar

rights and that is of similar market potential at a similar stage in the development or life of such product. Notwithstanding the foregoing, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, such Party would not be deemed to have failed to use its Commercially Reasonable Efforts in performing the adversely affected obligations.

1.16 "Commissioning" means those activities occurring after Mechanical Completion that are intended to verify that the Facility (and equipment and systems therein) meet pre-established design specifications, installation and operational requirements. Commissioning typically precedes and supports Qualification and includes Factory Acceptance Test ("FAT"), Site Acceptance Test ("SAT"), and full-scale wet-testing ("Water Dummy Runs") in order to provide reasonable assurance of the successful Qualification of the equipment, systems, and Facility.

1.17 "Completed Development Run" means a Development Run for which Product has been processed through the final purification step and filled and frozen in a Vessel according to the instructions, procedures and requirements described in the Manufacturing Documentation established for said procedures; provided, however, that a Development Run need not be processed through the high temperature short (residence) time skid ("HTST Skid") to be considered a Completed Development Run.

1.18 "Completed Qualification Run" means a Qualification Run for which Product has been processed through the final purification step and filled and frozen in a Vessel according to the instructions, procedures and requirements described in the Manufacturing Documentation established for said procedures.

1.19 "Confidential Information" means Genentech Confidential Information and/or Wyeth Confidential Information, as the context requires.

1.20 "Control" or "Controlled" means possession of the ability to grant a license or sublicense without violating (a) any law or governmental regulation applicable to such license or sublicense or (b) the terms of an agreement with a Third Party.

1.21 "Conversion Fee" means the conversion fee to be paid by Genentech to Wyeth for Product as determined in accordance with the terms of this Agreement.

1.22 "Development Batch" means a Batch or Lot produced from a Development Run. Development Batches are intended for testing only and are not saleable.

1.23 "Development Run" means a Run that (i) is used for Commissioning the Facility, testing equipment, Manufacturing Process demonstration, confirmation of some or all of the Manufacturing Process steps, finalizing Manufacturing Documentation, and training, as further described in Section 4.6 hereof. Development Runs may also be referred to as "Engineering Runs" or "Trial Runs".

1.24 "Excluded Patents" means [*] as those terms are defined on Exhibit A hereto, as well as any other Patent Rights owned or Controlled by Genentech that are not required for Wyeth to perform its obligations under the Transaction Agreements in accordance with the terms and conditions thereof.

1.25 "Facility" means one or more of the following, as the context requires: the [*] at Wyeth's commercial manufacturing facility located at Andover, Massachusetts and, to the extent used by Wyeth in the Manufacturing Process or the storage of Product hereunder, the Utilities, the Warehouse and the QC Laboratory.

1.26 "Facility Modifications and Services Costs" means all costs and expenses incurred by Wyeth (including, without limitation, Wyeth's internal labor and material costs) for the modifications needed to implement the Manufacturing Process at Wyeth's Andover, Massachusetts facility, including, without limitation, design and engineering services, equipment and/or Utilities installed at or necessary for the operation of the Facility (or any part thereof) or used to modify the Facility (or any part thereof) in accordance with the Technology Transfer Project Plan.

1.27 "Facility Validation" means validation of the Facility, including manufacturing equipment and

systems, computer systems, testing equipment and including non-Product specific processes such as sterilization, all as required by and in accordance with the Quality Agreement.

1.28 "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as the same may be amended from time to time.

1.29 "FDA" means the United States Food and Drug Administration, or any successor agency thereto.

1.30 "Finished Product" means Product that has been formulated, compounded, filled into containers, labeled and placed in final commercial packaging.

1.31 "For Cause Audit" means a non-routine audit of the Facility required and conducted by Genentech's quality compliance organization due to the existence of an Operational Issue that Genentech reasonably believes in good faith may result in a significant quality or cGMP deficiency.

1.32 "Genentech Confidential Information" means the Manufacturing Documentation and all technical and other information, whether patented or unpatented, relating to the Genentech Proprietary Materials, the Manufacturing Process, the Technology and/or the Product, Genentech processes, methods, operations, technologies, forecasts and business information, in the case of each of the foregoing that (a) are disclosed or supplied to Wyeth by or on behalf of Genentech pursuant to this Agreement and/or the Quality Agreement, (b) Wyeth may first become aware through the presence of its employees or agents at Genentech offices or facilities or at other facilities (other than Wyeth's facilities) that manufacture the Product for Genentech or (c) is Genentech Data generated hereunder. The foregoing may include, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results, business and scientific plans and information, designs, algorithms, software and facility layout and schematics. Notwithstanding the foregoing, "Genentech Confidential Information" shall not include any information that: (i) at the time of disclosure, is known publicly or thereafter becomes known publicly through no breach of this Agreement by Wyeth, its Affiliates or agents; (ii) becomes available to Wyeth from a Third Party which is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from Genentech under obligations of confidentiality; (iii) was developed by Wyeth independently of information obtained from Genentech as evidenced by competent proof; (iv) was already known to Wyeth before receipt from Genentech, as shown by competent proof, provided that such information was not acquired directly or indirectly from Genentech under obligations of confidentiality; or (v) is released with the prior written consent of Genentech. In determining whether or not Genentech's Confidential Information has entered the public domain and is therefore no longer falls within the definition of Genentech Confidential Information, only that portion of said Genentech Confidential Information that has become public shall cease to be within the definition of Genentech Confidential Information, and any information remaining confidential (including, without limitation, the organization of such information, the existence of such public information within the Genentech Confidential Information or information regarding the relationships between individual pieces of Genentech Confidential Information and information that is in the public domain) shall retain their status as Genentech Confidential Information.

1.33 "Genentech Data" means (i) those elements of Manufacturing Data that pertain to the Manufacturing Process, the conduct of the Manufacturing Process at the Facility, the Genentech Proprietary Materials, the Raw Materials or the Product (ii) those elements of other data generated by Wyeth in the performance of its obligations hereunder that pertain to the Manufacturing Process, the conduct of the Manufacturing Process at the Facility, the Genentech Proprietary Materials, the Raw Materials or the Product (iii) data generated by Genentech hereunder that pertain to the Manufacturing Process, the conduct of the Manufacturing Process at the Facility, the Genentech Proprietary Materials, the Raw Materials, the Product or (iv) information generated by Genentech that pertains to any equipment, processes, algorithms or software installed or used in the Facility, in the case of each the foregoing, excluding the Wyeth Data.

1.34 "Genentech Proprietary Materials" means the Cell Line, Master Cell Bank, Working Cell Bank and all Genentech proprietary reagents, reference standards and assays required to implement the Technology Transfer, utilize the Technology, conduct the Manufacturing Process and/or manufacture Product, all in accordance with the Manufacturing Documentation, and as each is further defined in Exhibit B to the Technology Transfer Project Plan.

"Genentech Proprietary Materials" shall also include any other proprietary materials of Genentech provided to Wyeth hereunder that are identified in writing by Genentech as "proprietary" at the time of delivery.

1.35 "GMP Commissioning" means the acceptance of the Facility by Genentech for cGMP activities as required by and in accordance with the Quality Agreement.

1.36 "Herceptin" means those pharmaceutical formulations containing the Product, currently marketed by Genentech in the United States and currently marketed by Roche outside of the United States each as the commercial product Herceptin.

1.37 "Manufacturing Data" means either or both, as the case requires: (i) all data and information (including the Batch Records) related to the conduct of the Manufacturing Process at the Facility that is generated by Wyeth in the performance of its obligations hereunder from the Effective Date through the date of achievement of PAI Readiness and that would be necessary or useful for Genentech to complete the filing of the sBLA with the FDA, including without limitation data related to the Commissioning and validation of the Facility, and/or (ii) all data and information (including the Batch Records) related to the manufacture of Product at the Facility that is generated by Wyeth in the performance of its obligations hereunder following achievement of PAI Readiness and that would be necessary or useful for Genentech to comply with all laws and regulations pertaining to the manufacture, use, storage or sale of Product manufactured by Wyeth under this Agreement.

1.38 "Manufacturing Documentation" means all documents and records describing or otherwise related to the Manufacturing Process or any part of the Manufacturing Process provided to Wyeth by or on behalf of Genentech under this Agreement or the Quality Agreement, including, without limitation, documents and records consisting of or containing process descriptions, requirements and specifications, process flow diagrams ("PFDs"), piping and instrumentation diagrams ("P&IDs") for Genentech's facilities, Genentech's facility layout schematics, equipment and instrumentation specifications, software logic and requirements specifications, bills of materials, raw material, in-process, and final Product specifications, process trend and variability data, validation protocols and reports, process development reports, batch records, and standard operating procedures ("SOPs"), including, without limitation, SOPs for Raw Material handling, manufacturing operations, equipment operation, Raw Material, in-process, and final Product quality control testing, quality assurance, validation, storage, and shipping.

1.39 "Manufacturing Process" means the [*] production process for the conversion of certain Genentech Proprietary Materials using the Raw Materials into Product and testing of such Product, [*] and is to be used by Wyeth pursuant to this Agreement for the manufacture of Product, [*], as such process may be changed from time to time in accordance with this Agreement.

1.40 "Master Cell Bank" [*]

1.41 "Mechanical Completion" means that the Facility is ready for Commissioning, Qualification and validation according to criteria established by the TOC for those activities. For the Facility to be considered mechanically complete, (i) all equipment (except the HTST skid) and Programmable Logic Controller/Supervisory Control And Data Acquisition ("PLC/SCADA") software required to implement the Manufacturing Process must be installed, tagged, and adjusted, (ii) mechanical and hydrostatic testing on said equipment (except the HTST skid) must be complete, and (iii) all applicable documentation must be compiled and complete. An element of Mechanical Completion shall be that the Manufacturing Execution System ("MES") software is available as required to support Commissioning.

1.42 "Non-Conforming Product" means Product that fails to conform to any of the warranties set forth in Section 7.1 hereof as of the Warranty Date.

1.43 "Non-Portable Equipment" means the Genentech Equipment (as defined in Section 15.2 hereof), excluding any Portable Equipment and the Centrifuge. Components of the Non-Portable Equipment, such as valves, pumps, agitators and filter housings, shall also be deemed Non-Portable Equipment. Non-Portable Equipment also includes the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment.

1.44 "Operational Issue" means an issue, concern or problem related to or arising from the implementation or conduct of the Technology Transfer Project and/or the Manufacturing Process at the Facility or at any of Genentech's facilities that might or does adversely impact (i) the operation of the Facility, (ii) the conduct of the Manufacturing Process by Wyeth, or (iii) the manufacture of Product hereunder, with respect to each of the foregoing, including, without limitation, any contamination, regulatory or quality control issues, problems or concerns, materials shortages, any issues, concerns or problems that may arise from the performance of the obligations under this Agreement and/or the Quality Agreement.

1.45 "PAI" means the pre-approval inspection of the Facility that will be conducted by the FDA prior to FDA Approval.

1.46 "PHS Act" means the Public Health Service Act, Biological Products, as amended, as the same may be amended from time to time.

1.47 "Party" or "Parties" means Wyeth and/or Genentech, as the context requires.

1.48 "Patent Rights" means all United States and foreign issued patents and patent applications, including, but not limited to, provisionals, divisionals, continuations, continuations-in-part (to the extent the claims in such continuation-in-part application are directed to subject matter specifically described in such prior patent application), and patents issuing therefrom, reissues, reexaminations, substitutions, renewals, restorations, additions, registrations, and foreign counterparts thereof, as well as extensions and supplementary protection certificates based thereon.

1.49 "Pilot Batch" means a Batch produced from a Run that is completed through the [*] bioreactor, and which is subsequently harvested [*] and purified at the laboratory scale using an appropriate small scale laboratory model of the Manufacturing Process. For a Batch to be considered a Pilot Batch the Batch must be completed [*] and provide sufficient quantities of samples to enable the Parties to complete analytical testing [*]. A Pilot Batch may be processed through the final purification step at the laboratory scale.

1.50 "Portable Equipment" means the portable equipment described with particularity in the Technology Transfer Project Plan and referred to in Sections 5.7 hereof, including, without limitation, the related documentation regarding the design, validation, operation, calibration, and maintenance of such equipment. The Portable Equipment is a part of the Genentech Equipment, as defined in Section 15.2 hereof. Components of the Portable Equipment, such as valves, pumps, agitators and filter housings, shall also be deemed Portable Equipment.

1.51 "Pre-existing Defect" means a defect in (i) any Raw Material delivered to Wyeth by [*] Genentech or (ii) any Genentech Proprietary Material delivered to Wyeth by Genentech, where such defect, in the case of either (i) or (ii), could not have been detected by Wyeth performing those manufacturing steps and testing procedures to be performed by Wyeth as required by the Manufacturing Documentation.

1.52 "Product" means the bulk form of Genentech's proprietary biological drug substance anti-Her-2 antibody (as more particularly described in Genentech's BLA for Herceptin STN: BL 103792, including any successor filing thereto with the FDA, and any supplements to or amendments to any of the foregoing) which has been (i) manufactured by Wyeth pursuant to this Agreement, and (ii) purified to a concentrated form from one or more Batches by Wyeth pursuant to this Agreement.

1.53 "Product Specifications" means the specifications developed by Genentech for Product, including, without limitation, testing methods and acceptance criteria for each Batch, a copy of which shall be attached to the Quality Agreement prior to the start of Development Runs, as such specifications may be amended from time to time in accordance with Article 8 hereof, including, without limitation, such amendments as may be required to obtain and/or maintain FDA Approval.

1.54 "QC Laboratory" means either or both the laboratory facilities located in Wyeth's Andover, Massachusetts commercial manufacturing facility or any Third Party laboratory facilities approved by Genentech in accordance with Section 13.5, in each case to the extent that they are required for Wyeth to perform the testing of all

Raw Materials and in-process and finished Product in accordance with the Transaction Agreements.

1.55 "Qualification" means establishing documented evidence that a piece of equipment or a manufacturing process operates within predetermined parameters consistently and reproducibly, and that such piece of equipment or manufacturing process is capable of producing Product that consistently meets all applicable quality specifications. Qualification may refer to Installation Qualification ("IQ"), Operational Qualification ("OQ"), and Performance Qualification ("PQ") as those terms have been generally defined by the FDA and the pharmaceutical industry.

1.56 "Qualification Batch" or "Qualification Lot" means a Batch or Lot produced from a Qualification Run. Each Qualification Batch is intended to produce Product that is or is expected to be (following FDA Approval) commercially saleable.

1.57 "Qualification Run" means a Run conducted (i) to demonstrate and document the consistency and reproducibility of the Manufacturing Process at the Facility, (ii) to establish the comparability of the Product manufactured therefrom to Herceptin manufactured by Genentech as required by the FDA and (iii) to support licensure of both the Facility and the Manufacturing Process at the Facility under the sBLA. Each Qualification Run must be produced from an inoculation of the [*], all in accordance with cGMP and the Manufacturing Documentation.

1.58 "Quality Agreement" means the quality agreement entered into by and between the Parties of even date herewith that references this Agreement and relates to Wyeth's manufacture of the Product hereunder, as amended from time to time.

1.59 "Regulatory Agency" means any applicable supranational, national, federal, state or local regulatory agency, department, bureau or other governmental entity of any country or jurisdiction in the Territory having responsibility in such country or jurisdiction for any Regulatory Approval of any kind in such country or jurisdiction, and any successor agency or authority thereto.

1.60 "Regulatory Approval" means any approvals, licenses, registrations or authorizations of any Regulatory Agency necessary for the manufacture and sale of the Product in each regulatory jurisdiction in which the Product will be sold.

1.61 "Raw Materials" means those materials set forth on the Bill of Materials attached to the Technology Transfer Project Plan that are used in the Manufacturing Process, including, but not limited to, chemicals, reagents, chromatography resins, and specialty filters.

1.62 "Roche" means Roche Holdings, Inc., a Delaware corporation, and its "Affiliates" (as hereinafter defined) other than Genentech and Genentech's subsidiaries. Subject to the foregoing, with respect to Roche, "Affiliates" means any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with Roche Holdings, Inc.; and, for purposes of this definition, the term "control" means direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, resolution or otherwise.

1.63 "Run" means a single fermentation run of the Manufacturing Process commencing at the [*] at the Facility and progressing through, as applicable, [*] harvest, recovery, purification, freezing and quality testing and release, and refers to a Commercial Run, Development Run and/or Qualification Run, as the context requires; [*]

1.64 "Run Start" [*]

1.65 "sBLA" means the supplemental biologics license application to be submitted to the FDA to permit the licensure of the Facility to manufacture the Product using the Manufacturing Process, any equivalent successor filing thereto with the FDA, and any supplements or amendments to any of the foregoing.

1.66 "Sourcing Date" means the date that the FDA approves the sBLA.

1.67 "Specialized Raw Materials" means that subset of Raw Materials that are identified as such on the Bill of Materials attached to the Technology Transfer Project Plan and that require higher levels of inventory planning and control due to shortage of supply, long supplier lead times and criticality to Product quality. Examples include chromatography resins and certain media components.

1.68 "Successful" means, subject to Section 5.7, with respect to a single Qualification Run or Commercial Run, or a single Batch or Lot produced from such a single Qualification Run or Commercial Run, conformance of that Run to all elements of: (i) the quality requirements of this Agreement, the Technology Transfer Project Plan and the Quality Agreement; (ii) the Product Specifications as they exist at the time of the inoculation [*] bioreactor for such Batch (or such earlier time as may be appropriate in the event that there are any modifications to those portions of the Manufacturing Process occurring prior to the inoculation [*] bioreactor or which require changes to the materials used (or specifications therefor) prior to the inoculation [*] (bioreactor); and (iii) all applicable United States laws and regulations. For the avoidance of doubt, a Successful Batch will be or is expected to be (following FDA Approval) saleable following the Sourcing Date.

1.69 "Success Rate" means, with respect to a particular campaign or a specified period of time, the ratio of the number of Successful Batches produced during such campaign or period of time by the Party in question over the number of Run Starts made during such campaign or period of time by the Party in question.

1.70 "Technology" means the Manufacturing Process, assays, quality control analyses, specifications, transportation and storage requirements, and other know-how and information provided by Genentech to Wyeth (including, without limitation, the Manufacturing Documentation) and which is required to reproducibly manufacture, test, store and transport Product: (i) in compliance with cGMP; (ii) in conformity with the applicable Product Specifications; (iii) in compliance with Genentech's approved sBLA; and (iv) which meets the protocols for analytical comparability and bioequivalency of Product, which protocols shall be developed by Genentech and subject to agreement of the Parties.

1.71 "Technology Transfer" means the transfer of all technology, information, documentation, equipment, materials, tools, and technical assistance between the Parties (including the transfer of Technology from Genentech to Wyeth) in order to implement the Manufacturing Process at the Facility and obtain FDA Approval for manufacture of commercial quantities of the Product at the Facility under the sBLA. Technology Transfer shall also include such additional assistance as Genentech will provide to Wyeth pursuant to the terms hereof, including without limitation, the transfer of the Technology and technical assistance by Genentech to Wyeth and the transfer of information by Wyeth to Genentech hereunder necessary for the transfer of Technology to Wyeth and the implementation of the Manufacturing Process at the Facility in order to and as required to start up and operate the Facility. Technology Transfer will be considered to begin as of the effective date of the LOI and to be complete as of the Sourcing Date.

1.72 "Technology Transfer Project" means the activities conducted by or under the authority of the Parties under the Technology Transfer Project Plan in order to complete the Technology Transfer.

1.73 "Technology Transfer Project Plan" means a written description of the Technology Transfer, as the same may be amended from time to time by mutual written agreement of the Parties, that includes, but is not limited to, the objective, scope, approach, functional strategies, resources, roles and responsibilities, statement of work, activities, deliverables, milestones, schedule and success criteria. The Technology Transfer Project Plan will also incorporate by reference more detailed functional plans as needed (e.g., the Master Validation Plan, Comparability Plan, GMP Commissioning Plan, etc.). The Technology Transfer Project Plan is hereby incorporated into this Agreement by reference. The initial Technology Transfer Project Plan has been exchanged between the Parties as of the Effective Date and describes the understanding of the Parties (as of the Effective Date) regarding the transfer of Technology and implementation of the Manufacturing Process, test methods and testing at the Facility, and the modifications to the Facility needed to implement the Manufacturing Process at the Facility, as jointly developed by the Parties.

1.74 "Termination Fee" means that amount payable by Genentech to Wyeth in accordance with Section 21.8 hereof as a result of the termination of this Agreement in accordance with Section 21.8.

1.75 "Territory" means the United States and those countries set forth on Exhibit B hereto.

1.76 "Third Party" means any party other than Genentech, Wyeth and their respective Affiliates.

1.77 "Transaction Agreements" means this Agreement and the Quality Agreement, including any attachments and exhibits thereto and any amendments to the foregoing mutually agreed upon in writing by the Parties.

1.78 "United States" or "U.S." means the United States of America, its territories and possessions, and the Commonwealth of Puerto Rico.

1.79 "Utilities" means the utilities and other service hook-ups related to the Facility, QC Laboratory or Warehouse to the extent that they are necessary for Wyeth perform its obligations under the Transaction Agreements.

1.80 "Vessel" means a portable, [*] that is supplied to Wyeth by Genentech to store and ship Product to Genentech at a controlled temperature.

1.81 "Warehouse" means the shared cGMP storage facilities at Wyeth's Andover, Massachusetts manufacturing facility to the extent that they are used by Wyeth to handle, store, ship and receive Raw Materials, Genentech Proprietary Materials, Vessels and Product, all in accordance with the terms and conditions of the Transaction Agreements.

1.82 "Working Cell Bank" or "WCB" means [*]

1.83 "Wyeth Confidential Information" means all technical and other information, whether patented or unpatented, relating to the Facility and/or Wyeth processes, methods, operations, technologies, forecasts and business information that (a) are disclosed or supplied to, or used by Wyeth in the performance of its obligations or exercise of its rights under this Agreement, the Technology Transfer Project Plan and/or the Quality Agreement, or (b) Genentech may first become aware of through the presence of its employees or agents at Wyeth offices or at the Facility or any other Wyeth facility, or (c) is Wyeth Data generated hereunder. The foregoing may include, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results and business and scientific plans and information and facility layout and schematics. Notwithstanding the foregoing, "Wyeth Confidential Information" shall not include any information that: (i) at the time of disclosure, is known publicly or thereafter becomes known publicly through no breach of this Agreement by Genentech, its Affiliates or agents; (ii) becomes available to Genentech from a Third Party that is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from Wyeth under obligations of confidentiality; (iii) was developed by Genentech independently of information obtained from Wyeth as evidenced by competent proof; (iv) was already known to Genentech before receipt from Wyeth, as shown by competent proof, provided that such information was not acquired directly or indirectly from Wyeth under obligations of confidentiality; or (v) is released with the prior written consent of Wyeth. In determining whether or not Wyeth's Confidential Information has entered the public domain and therefore no longer falls within the definition of Wyeth Confidential Information, only that portion of said Wyeth Confidential Information that has become publicly known shall cease to be within the definition of Wyeth Confidential Information, and any information remaining confidential (including, without limitation, the proprietary use or organization of such public information, the existence of such public information within the Wyeth Confidential Information or the relationship between individual pieces of Wyeth Confidential Information and such public information) shall retain its status as Wyeth Confidential Information.

1.84 "Wyeth Data" means (i) those elements of the Manufacturing Data that solely pertain to the Facility, the operations of the Facility or the processes, algorithms, software or equipment in the Facility, (ii) those elements of other data generated by Wyeth in performance of its obligations hereunder that solely pertain to the Facility, the operations of the Facility or the processes, algorithms, software or equipment in the Facility or (iii) those elements

of the data generated by Genentech hereunder that solely pertain to the Facility, the operations of the Facility or the processes, algorithms, software or equipment in the Facility.

1.85 "Wyeth Equipment" means the equipment listed in the Technology Transfer Project Plan, including all components thereof (i.e., pipes, valves, pumps, agitators and other related equipment), already owned or leased or to be acquired by Wyeth and installed at the Wyeth Facility for the purposes of implementing the Manufacturing Process, and the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment, as such list may be amended from time to time according to the provisions in this Agreement and the Technology Transfer Project Plan.

Each of the following definitions are found in the body of this Agreement, or elsewhere, as indicated below:

Defined Term	Section
[*]	4.3.6
"Acceptance"	5.6
"Acceptance Date"	5.6
"Actual Cost"	4.9.6(b)
"Agreement"	Preamble
"Annual Maximum Purchase Commitment"	5.4
[*]	4.9.1
"Asserting Party"	19.4.3
"Bonus Run Completion"	5.1
"Bonus Runs"	5.1.1
"Breaching Party"	21.2
"Budgeted Costs"	4.9.6(a)
[*]	Exhibit A
"CGL"	17.3.1
"Change of Control"	21.8.1
"Cure Period"	21.2
"Delivery Schedule"	5.5.2
"Designated Carrier"	5.8
[*]	4.9.1
"Development Run Completion"	4.3.2
"Dual Use Improvement Option"	15.1.3(g)(ii)
"Effective Date"	Preamble
"ESC" or "Executive Steering Committee"	3.1.1(a)
"Excessive Use"	4.9.6
"Exchange Act"	21.8.1
"FAT"	1.16
"FDA Approval"	4.3.8
"Facility Data"	14.1.2
"Fermentation Run Starts"	4.7.1
"Force Majeure Event"	24.1
"GAAP	4.9.5
"Genentech"	Preamble
"Genentech Equipment"	15.2.1
"Genentech Financial Records"	6.10(c)
"Genentech Indemnified Parties"	17.1.2
"Genentech Proprietary Materials"	1.3.4
"Herceptin Improvements"	15.1.3
"HTST Skid"	1.1.7
"Indemnitee"	17.2.1
"Indemnitor"	17.2.1
"Initial Qualification Run Completion"	4.3.3
"Intentional Breach	18.1

"JPST" or "Joint Project Sub-Teams"	3.1.2(b)(ii)
"JPT" or "Joint Project Team"	3.1.2(a)
"JQT" or Joint Quality Team	3.1.4(a)
"Lead Quality Representative"	Quality Agreement
"Liabilities"	17.1.1
"Licensed Parties"	14.2
"MES"	1.41
"Mechanical Completion"	4.3.1
"Milestone Payment"	6.4
"Nonbreaching Party"	21.2
"Nonsuit"	14.2
"Notified Party"	19.3.1
"Notifying Party"	19.3.1
"PAI Readiness"	4.3.6
"Permitted Use of Genentech Confidential Information	15.1.3(e)
"P&IDs"	1.38
"Portable Equipment"	5.7
"PFDs"	1.38
"Production Plan"	5.5.1
"PLC/SCADA	1.41
"Projected Usage"	4.9.5
"Project Team Leader"	3.1.5
"Raw Material Specifications"	4.9.1
"Release"	5.6
"sBLA Data Delivery"	4.3.5
"sBLA Filing"	4.3.7
"SEC"	19.2
"SAT"	1.16
"Standard Bill of Materials Cost"	4.9.2
"Standard Cost"	4.9.5
"SOPs"	1.38
"Start Fee"	6.7.1
"Success Fee"	6.7.2
"Successful Qualification Batch Delivery"	4.3.4
"Target Date"	4.3
"Target Resolution Date"	3.2.2
"Technical Issues"	3.1.2(a)
"TOC" or "Technical Operations Committee"	3.1.2(a)
"Term"	21.1
"warning letter"	Quality Agreement
"Warranty Date"	7.1
"Water Dummy Runs"	1.16
"Wyeth"	Preamble
"Wyeth Entities"	21.8.1
"Wyeth Financial Records"	6.10(b)
"Wyeth Indemnified Parties"	17.1.1
"Wyeth Production Records"	6.10(a)
"Wyeth Release Documentation"	Quality Agreement
"Wyeth Trade Secret"	14.3

ARTICLE 2.
COMMITMENT TO MANUFACTURE; DEDICATED FACILITY

2.1 Commitment to Manufacture. Subject to the terms and conditions set forth in this Agreement, during the Term: (a) Genentech shall retain Wyeth as a non-exclusive manufacturer of Product; (b) Wyeth shall dedicate [*]

portion of the Facility exclusively to enable the Technology Transfer and to conduct the Manufacturing Process; (c) Wyeth shall dedicate adequate time and/or capacity at the Warehouse and QC Laboratory to enable the Technology Transfer and to conduct the Manufacturing Process; (d) Wyeth shall use its Commercially Reasonable Efforts to deliver Product meeting the warranties set forth in Section 7.1 hereof to Genentech for use by Genentech in completing the manufacture (e.g., filling, finishing and packaging) of its Herceptin product to be sold by Genentech in the United States or supplied by Genentech to Roche and its Affiliates for sale elsewhere in the Territory; and (e) Genentech shall purchase all such Product from Wyeth (subject to Section 5.4, up to the Annual Maximum Purchase Commitment).

2.2 Exclusive Use of Facility. All activities conducted by Wyeth related to the manufacture of Product hereunder shall be conducted solely at the Facility. Wyeth shall use no other facility, other than the Facility, for the handling and storing of all Raw Materials, Genentech Proprietary Materials, Vessels and all Successful Batches awaiting shipment to Genentech, and Wyeth shall use its Commercially Reasonable Efforts to maintain the Warehouse such that during the Term it meets the applicable specifications for storage of Genentech Proprietary Materials, Vessels, Product and Raw Materials. Wyeth shall use no facility other than the QC Laboratory for testing of all Raw Materials, Genentech Proprietary Materials and in-process and finished Product without the prior written consent of Genentech.

ARTICLE 3.
MANAGEMENT OF PROJECT

3.1 Management.

3.1.1 Executive Steering Committee.

(a) Formation. Within fifteen (15) days after the Effective Date, the Parties will establish an Executive Steering Committee (the "ESC") to provide oversight and decision-making support to the TOC and JPT (as those acronyms are defined below) and to manage Product manufacturing at the Facility. The ESC will be composed of two (2) representatives appointed by each of Wyeth and Genentech, with one (1) representative from each of Wyeth and Genentech having oversight for Quality. All such representatives will be officers of Genentech or Wyeth (or, in the case of Wyeth, any operating division of Wyeth or any of its Affiliates involved in the manufacture of the Product hereunder); provided, however, that no such representative shall also serve as a Party's representative on either the TOC or the JPT or be a Party's designated executive officer for dispute resolution pursuant to Section 23.2.1. Either Party may replace any or all of its representatives at any time upon prior written notice to the other Party. The ESC will meet at least once each Calendar Quarter, or as otherwise agreed by the ESC or as necessary to make determinations as required of it under Section 4.8.2 and 5.1.1 in a prompt and timely manner, and will operate by unanimous decision of its members, except as expressly set forth herein. If the ESC is unable to unanimously resolve a dispute regarding any issue presented to it, such dispute shall be resolved in accordance with Article 23.

(b) Function. In particular, the ESC is responsible for performing the following functions:

(i) Overseeing and monitoring the Technology Transfer and implementation of the Manufacturing Process at the Facility, and any changes to the foregoing approved or recommended by the TOC under Article 8;

(ii) Establishing and overseeing the governance structure for the manufacture of Product at the Facility;

(iii) Settling disputes or disagreements that are unresolved by an operating committee formed pursuant to the Transaction Agreements unless otherwise indicated in this Agreement;

(iv) making determinations as required of it under Sections 4.8.2 and 5.1.1 in a prompt and timely manner; and

(v) Performing such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.1.2 Technical Operations Committee.

(a) Formation. Within fifteen (15) days after the Effective Date, the Parties will establish a Technical Operations Committee (the "TOC") which is a Director-level, cross-functional body responsible for providing technical guidance and decision-making support to the Joint Project Team (the "JPT") (as described below), regarding manufacturing, process sciences, quality control or regulatory affairs issues (collectively, "Technical Issues") arising in the transfer of Technology and implementation of the Manufacturing Process and commercial manufacturing of Product at the Facility. The TOC will be composed of an equal number of at least three (3) representatives appointed by each of Wyeth and Genentech. Each Party will have one (1) vote on all matters within the TOC's technical purview. Such representatives will include Technical Product Managers/Leads, Directors of Quality Assurance and Regulatory, Director of Manufacturing, or other individuals with expertise and responsibilities in the same areas of manufacturing, process sciences, quality control or regulatory affairs. Either Party may replace any or all of its representatives at any time upon written notice to the other Party. The TOC will meet at least once every two (2) calendar months, or as otherwise agreed by the TOC, as directed by the ESC or as required by the Transaction Agreements. The TOC will operate by unanimous decision of its members, except as expressly set forth herein. If the TOC is unable to resolve a dispute regarding any issue presented to it, such dispute shall be resolved in accordance with Section 3.1.6 below. Members of the JPT or the ESC shall not serve on the TOC.

(b) Function. In particular, the TOC is responsible for performing the following functions:

(i) Providing technical guidance on the overall Technology Transfer and manufacturing strategy for the manufacture of Product at the Facility, including strategies for licensure of the Facility for manufacture of Product;

(ii) Providing strategic and technical guidance to the JPT and the Joint Project Sub-Teams (the "JPST") (as described below), including reviewing and approving changes to the Technology Transfer Project Plan;

(iii) Conducting stage reviews as required by the Technology Transfer Project Plan with the JPT at appropriate milestones or completion of a sequence of events to ensure the Technology is being implemented appropriately and to review and approve (a) deliverables, and (b) next steps recommended by the JPT;

(iv) Reviewing and approving any requested changes to the Product Specifications, testing methods, Manufacturing Process, the Facility or the equipment used to manufacture Product, all in accordance with Article 8;

(v) Settling disputes or disagreements that are unresolved by the JPT; and

(vi) Surfacing disputes or disagreements to the ESC.

3.1.3 Joint Project Team.

(a) Formation. Within fifteen (15) days after the Effective Date, the Parties will establish a Joint Project Team (the "JPT"). The JPT shall be composed of an equal number of up to eight (8) representatives from the manufacturing, process sciences, quality control or regulatory affairs areas appointed by each of Wyeth and Genentech, and will be led by the Project Team Leaders from each of Wyeth and Genentech in accordance with Section 3.1.5 below. Project managers appointed by each of Wyeth and Genentech will support the JPT. Each representative will have one (1) vote on all matters within the JPT's purview, except such project managers, who will have no vote. To ensure continuity of information sharing and consistency of decision-making, each Party shall appoint its lead representative from each of the JPSTs to sit on the JPT and such other individuals with expertise and responsibilities in the same areas of manufacturing, process sciences, quality control or regulatory affairs as each

Party deems necessary. Either Party may replace any or all of its representatives on the JPT at any time upon written notice to the other Party. The JPT will operate by unanimous decision of its members, except as expressly set forth herein. If the JPT is unable to resolve a dispute regarding any issue presented to it, such dispute shall be resolved in accordance with Section 3.1.6 below.

(b) Function. In particular, the JPT is responsible for performing the following functions:

(i) Determining the overall Technology Transfer and manufacturing strategy for the manufacture of Product at the Facility, including strategies for licensure of the Facility for the Product;

(ii) Planning, reviewing, monitoring, guiding, and managing the overall Technology Transfer Project and implementation of the Manufacturing Process per the Technology Transfer and manufacturing strategy;

(iii) Coordinating the activities of the Parties to ensure successful Technology Transfer, including providing timely decisions to the JPSTs and managing the technical aspects of the implementation of the Manufacturing Process;

(iv) Reporting to and consulting with the TOC, and keeping the ESC periodically informed of the progress of the Technology Transfer Project, status of Technical Issues and Operational Issues and implementation of the Manufacturing Process;

(v) Scheduling and conducting project and technical reviews with the TOC to solicit guidance on resolution of Technical Issues and Operational Issues;

(vi) Surfacing disputes or disagreements to the TOC and/or ESC, as appropriate;

(vii) Establishing, overseeing and managing the JPSTs;

(viii) Reviewing and recommending (to the TOC) changes to (a) the Technology Transfer Project Plan and (b) the Manufacturing Process and Facility changes recommended by the JPSTs; and

(ix) Settling disputes or disagreements that are unresolved by the JPSTs.

3.1.4 Joint Project Sub-Teams.

(a) Formation. The JPT will establish JPSTs for manufacturing, process sciences, quality control or regulatory affairs areas, and the following functional areas: quality, process, QC/analytical, supply chain management, and regulatory. Each JPST may establish additional sub-teams responsible for specific technical areas who report to the respective JPST, for example the process JPST may establish separate cell culture and recovery sub-teams. The Joint Quality Team established under the Quality Agreement (the "JQT") shall be one of the JPSTs. Each JPST will be responsible for planning, organizing, managing, conducting, and completing the Technology Transfer steps and activities assigned to the particular JPST by the JPT. Each JPST representative will have one (1) vote on all matters within its purview and all decisions made by each JPST will require unanimous consent of all representatives. Either Party may replace any of its representatives on any JPST at any time upon written notice to the other Party. JPST members will be listed in the Technology Transfer Project Plan, but in general each JPST will be comprised of an equal number of representatives from the appropriate functional disciplines of Genentech and Wyeth.

(b) Function. In particular, the JPSTs are responsible for performing the following functions:

(i) Planning, reviewing, monitoring, guiding, and managing the functional activities of the Technology Transfer Project and implementation of the Manufacturing Process;

(ii) Coordinating the functional activities of the Parties to ensure successful Technology Transfer;

(iii) Reporting to and keeping the JPT periodically informed of the progress of the functional activities for the Technology Transfer Project;

(iv) Developing and reviewing functional recommendations with the JPT; and

(v) Surfacing disputes or disagreements to the JPT.

3.1.5 Appointment of Project Team Leader. Within fifteen (15) days after the Effective Date, each Party shall appoint a Project Team Leader (each, a "Project Team Leader") to act as the primary contact for such Party in connection with matters related to the implementation of the Manufacturing Process, in connection with activities to be performed under the Technology Transfer Project Plan and/or Commercial Production of the Product (as described in Articles 4 and 5 below). Each such Project Team Leader, unless otherwise mutually agreed, shall serve as the Genentech and Wyeth functional leaders of the JPT. The initial Project Team Leaders are:

Genentech: [*]

Wyeth: [*]

Notwithstanding anything to the contrary in this Article 3, the ESC shall have the right (i) to approve the appointment of the Project Team Leader of both Parties and (ii) to require a Party to replace its Project Team Leader, upon the ESC's request, and to review and approve the new Project Team Leader.

3.1.6 Decision-making.

(a) All decisions of the ESC, the TOC and the JPT, except as expressly set forth herein (including without limitation Sections 3.1.6(c) and (d) below), shall be made by the unanimous agreement of all of its members or their designated representatives, and shall be reflected in written meeting reports which summarily address topics discussed, delegation of work, schedules and decisions of such committee or team. Such written reports shall be subject to approval by the authorized representatives of the Parties; provided, however, that no operating committee herein may amend or waive any provision of this Agreement, including, without limitation, the Target Dates set forth in Section 4.2, the Milestones set forth in Section 6.3 or the financial terms set forth in Article 6, it being understood that this Agreement may be amended, and any provision of this Agreement may be waived, only by a written agreement signed by authorized officers of each Party that specifically states that the Parties are amending or waiving this Agreement.

(b) In the event that the JPT is unable, despite the good faith efforts of all members, to resolve within seven (7) business days a disputed issue that is within the purview of the JPT, the disputed issue shall be referred immediately by the JPT to the TOC. In the event the TOC is unable to resolve the disputed issue within an additional seven (7) business days, the disputed issue will be referred to the ESC. If the dispute cannot be resolved by the ESC within an additional ten (10) business days, the matter will be handled in accordance with Article 23 hereof.

(c) Notwithstanding anything to the contrary in this Agreement and/or the Quality Agreement, with respect to any disagreement over issues relating to quality, such issues shall be resolved as follows: each Party's Lead Quality Representative (as defined in the Quality Agreement) on the JPT, or their respective designees, will in good faith attempt to mutually resolve such disagreements in a timely fashion (but in any event, in no more than seven (7) business days after such issue is referred to the JPT). If the dispute cannot be resolved by the ESC within an additional (10) business days, the matter with be resolved in accordance with the dispute resolution provisions of Article 23 hereof.

(d) Subject to the foregoing provisions of this Section 3.1.6, the Project Team Leaders (or their respective designees) will in good faith attempt to mutually resolve in a timely fashion any

disagreement with respect to the implementation of the Manufacturing Process which could reasonably affect Product quality (including any procurement, engineering, installation, scale-up, testing and validation of the equipment and systems and other modifications to the Facility required to implement the Manufacturing Process) and the manufacture of the Product, including without limitation the related management processes and operations, control of production planning and scheduling, prioritization decisions, allocation of resources, timing of in-process testing, oversight of auxiliary facilities (e.g., in-process tests that need to be conducted at the labs), all start-up, registration and troubleshooting decisions, and any other matters relating to manufacturing the Product.

3.2 Resolution of Operational Issues.

3.2.1 Identification of Operational Issues. Either Party shall have the right to raise an Operational Issue that it has identified or otherwise believes exists by having its Project Team Leader contact the other Party's Project Team Leader with a reasonably detailed description of the issue. Accordingly, each Party shall have the right to initiate the resolution process set forth below upon its good faith determination of or good faith belief in the existence of an Operational Issue.

3.2.2 Resolution of Operational Issues. Once an Operational Issue has been identified to the JPT through notice by either or both Project Team Leaders, the Project Team Leaders shall assign appropriate members of the JPT and/or the JPSTs to investigate, confirm and resolve any such Operational Issue(s) if such issue is not already the subject of such efforts; provided, however, that this resolution process excludes Batch-specific deviations and any quality disposition decisions related to specific Batches. Operational Issues that are deviations linked to specific Batches and the disposition of Product will be resolved in accordance with the procedures established pursuant to the Quality Agreement and will not be subject of the timeframes or decision-making process for resolution of Operational Issues under this Section 3.2.2. The resolution process for all other Operational Issues will require the Parties to work together in good faith to identify and solve any Operational Issue(s) that may arise during the Term in a timely and collaborative manner. This resolution process will also include a mutually agreed target period for resolution of each Operational Issue, such period not to exceed ninety (90) days from the date such Operational Issue is communicated in writing to the JPT or such longer period that (i) is reasonably necessary to resolve the Operational Issue and (ii) has been approved in writing by the ESC, such approval not to be unreasonably withheld or delayed by either Party's representatives on the ESC (in each case, the last day of such target period for resolution of an Operational Issue shall be referred to as the "Target Resolution Date"). If an Operational Issue is preventing substantial performance by either Party under this Agreement and remains unresolved for more than thirty (30) days after the Target Resolution Date, Genentech shall have the right to terminate this Agreement in accordance with Section 21.6. In addition, if an Operational Issue is preventing substantial performance by either Party under this Agreement and remains unresolved for more than sixty (60) days after the Target Resolution Date, Wyeth shall also have the right to terminate this Agreement in accordance with Section 21.6. The Parties agree and acknowledge that the existence of and/or a failure to resolve an Operational Issue in accordance with this Section 3.2 in and of itself shall not be deemed to be a breach of this Agreement; provided, however, that if a Party has failed to comply with the terms and conditions of this Section 3.2 and/or the terms and conditions of this Agreement in relation to an Operational Issue or resolution of an Operational Issue, a breach of this Agreement may have occurred. Subject to Sections 4.5 and 4.6 and Article 8, each Party shall be responsible for any costs and expenses incurred by it relating to the resolution of any Operational Issue.

3.3 Genentech Personnel at the Facility.

3.3.1 Prior to Commercial Production. Pursuant to and as set forth in greater detail in the Technology Transfer Project Plan and Quality Agreement, in order to expedite the Technology Transfer and to coordinate, expedite and guide the Development Runs and Qualification Runs, Genentech shall have the right to have [*] Genentech personnel [*] with operational expertise and another with quality expertise) on-site at the Facility on a full-time basis during all operational hours prior to the start of Commercial Production; provided, however, that Genentech shall use its Commercially Reasonable Efforts to assign the same [*] individuals to represent Genentech for the duration of such period so as to minimize the total number of Genentech personnel that are on-site at Wyeth's facility during such period. In addition, Wyeth shall use its Commercially Reasonable Efforts to accommodate up to [*] additional Genentech personnel to be present in the Facility on a periodic or part-time basis; provided, however, that, absent Wyeth's request, Genentech shall use its Commercially Reasonable Efforts to

minimize the total number of different Genentech personnel that are on-site at the Facility for the duration of such period so as to minimize the impact of their presence in the Facility on Wyeth's operations. Subject to Wyeth's approval, not to be unreasonably withheld or delayed, Genentech shall have the right to designate a reasonable number of additional Genentech personnel on-site at the Facility on a periodic or part-time basis at all times prior to the start of Commercial Production. All such personnel will coordinate closely with Wyeth in order to minimize the impact of their presence on other Wyeth operations. Unless otherwise agreed by Wyeth, such Genentech personnel shall have access only to those portions of Wyeth's Andover facility (including the Facility) reasonably related to the Technology Transfer, implementation of the Manufacturing Process, as well as cafeterias, designated office space and public areas. All Genentech personnel at the Facility shall comply with all Wyeth policies and procedures. In the event any Genentech personnel assigned to the facility fail to comply with any applicable Wyeth policy or procedure, Genentech, upon Wyeth's request, shall immediately replace such personnel.

3.3.2 After Commencement of Commercial Production. As further described in the Quality Agreement, Genentech shall have the right to have [*] Genentech personnel [*] with operational expertise and another with quality expertise) on-site at the Facility on a full-time basis during all operational hours following the start of Commercial Production to coordinate, expedite and guide the Commercial Runs and Wyeth's performance of its obligations under this Agreement; provided, however, that Genentech shall use its Commercially Reasonable Efforts to assign the same [*] individuals to represent Genentech for the duration of such period so as to minimize the total number of Genentech personnel that are on-site at Wyeth's facility during such period. In addition, Wyeth shall use its Commercially Reasonable Efforts to accommodate up to [*] additional Genentech personnel to be on-site at the Facility on a periodic or part-time basis; provided, however, that, absent Wyeth's request, Genentech shall use its Commercially Reasonable Efforts to minimize the total number of different Genentech personnel that are on-site at the Facility for the duration of such period so as to minimize the impact of their presence in the Facility on Wyeth's operations. Subject to Wyeth's approval, such approval not to be unreasonably withheld or delayed, Genentech shall have the right to designate a reasonable number of additional Genentech personnel to be present at the Facility during Commercial Production on a periodic or part-time basis. Unless otherwise agreed by Wyeth, such representatives of Genentech shall have access to all areas of the Facility as are relevant to the manufacture, storage and/or quality testing of the Product, as well as cafeterias, designated office space and public areas. All Genentech personnel at the Facility shall comply with all Wyeth policies and procedures. In the event any Genentech personnel assigned to the Facility fail to comply with any applicable Wyeth policy or procedure, Genentech, upon Wyeth's request, shall immediately replace such personnel.

3.3.3 Personnel Accommodations. With respect to any Genentech personnel assigned by Genentech to be present at the Facility, Wyeth shall provide at Wyeth's cost: (a) reasonable access to the Facility during all operational hours; (b) adequate on-site offices (at least one (1) dedicated office for the Genentech Project Team Leader, and such other offices or workstations for other Genentech personnel as are reasonably required by the Genentech personnel and to the extent available in excess of Wyeth's own needs), reasonable access to conference rooms (as necessary for meetings), parking facilities and toilet facilities; (c) reasonable access to and use of telephone, internet (but not Wyeth's intranet), facsimile and photocopying services; and (d) such other reasonable and customary business accommodations for such Genentech personnel as are necessary to perform any activities relating to the manufacture, storage and/or quality testing of the Product at the Facility.

3.3.4 Confidentiality. Genentech shall not assign any of its employees or representatives to visit or otherwise be present in any of Wyeth's facilities unless such employees or representatives are legally obligated to maintain the confidentiality of and limit their use of all Wyeth Confidential Information that is disclosed to them, or to which they otherwise have access to while in Wyeth's facilities or while otherwise performing any of Genentech's obligations or exercising any of Genentech's rights under any of the Transaction Agreements, under terms and conditions no less restrictive than those set forth in this Agreement. Genentech shall be responsible for the breach of any of the confidentiality or limitation of use obligations under this Agreement by any of its employees or representatives and shall take all actions necessary to prevent such breach or to remedy any such breach that occurs.

3.4 Wyeth Personnel at Genentech's Facilities.

3.4.1 During Fall 2004 Campaign. In order to expedite the implementation of the Technology Transfer and to heighten Wyeth's understanding of the Manufacturing Process, Wyeth shall have the right to have

[*] Wyeth personnel on-site at [*]. These personnel may be on-site during all operational hours of Genentech's Fall 2004 campaign of the Manufacturing Process; provided, that such personnel shall not be allowed in such facility earlier than four (4) weeks after the beginning of such campaign. Wyeth shall use its Commercially Reasonable Efforts to minimize the total number of Wyeth personnel that are on-site at [*] provided, that Wyeth shall not assign more than [*] different individuals to be on-site at such facility during the campaign. All such Wyeth personnel shall coordinate closely with Genentech in order to minimize the impact of their presence in the facility on Genentech's operations. Unless otherwise agreed by Genentech, such Wyeth personnel shall have access only to those portions of [*] reasonably related to the conduct of the Manufacturing Process, as well as cafeterias, designated office space and public areas, and shall comply with all applicable Genentech policies and procedures. In the event any Wyeth personnel assigned to the facility fail to comply with any applicable Genentech policy or procedure, Wyeth, upon Genentech's request, shall immediately replace such personnel.

3.4.2 Personnel Accommodations. With respect to any Wyeth personnel assigned by Wyeth to be present at the [*] in accordance with this Section 3.4.2, Genentech shall provide at Genentech's cost: (a) reasonable access to the [*] during the times that the Manufacturing Process is being run; (b) adequate on-site offices (as reasonably required by the Wyeth personnel and to the extent available in excess of Genentech's own needs), reasonable access to conference rooms (as necessary for meetings), parking facilities and toilet facilities; (c) reasonable access to and use of telephone, internet (but not Genentech's intranet), facsimile and photocopying services; and (d) such other reasonable and customary business accommodations as the Wyeth personnel may request.

3.4.3 Confidentiality. Wyeth shall not assign any of its employees or representatives to visit or otherwise be present in any of Genentech's facilities unless such employees or representatives are legally obligated to maintain the confidentiality of and limit their use of all Genentech Confidential Information that is disclosed to them, or to which they otherwise have access to while in Genentech's facilities or while otherwise performing any of Wyeth's obligations or exercising any of Wyeth's rights under any of the Transaction Agreements, under terms and conditions no less restrictive than those set forth in this Agreement. Wyeth shall be responsible for the breach of any of the confidentiality or limitation of use obligations under this Agreement by any of its employees or representatives and shall take all actions necessary to prevent such breach or to remedy any such breach that occurs.

3.5 No Relationship of Employees, Etc.

3.5.1 Genentech acknowledges and agrees that nothing in Section 3.3 shall be deemed to create any employment, agency or independent contractor relationship between Wyeth and any Genentech personnel, and that any Genentech personnel assigned to the Facility shall at all times remain employees of Genentech and as such, shall remain subject to the benefit plans and policies of Genentech and shall not be eligible to participate in any Wyeth benefit plan or policy. Genentech also acknowledges and agrees that it shall be responsible for all compensation payable to such personnel and for any tax payments or withholding with respect to such personnel. Genentech shall be liable for and shall defend, indemnify and hold Wyeth harmless from and against all actions taken by Genentech's personnel or any government agency or entity with respect to such Genentech personnel at Wyeth's Andover facility.

3.5.2 Wyeth acknowledges and agrees that nothing in Section 3.4 shall be deemed to create any employment, agency or independent contractor relationship between Genentech and any Wyeth personnel, and that any Wyeth personnel assigned to the [*] shall at all times remain employees of Wyeth and as such, shall remain subject to the benefit plans and policies of Wyeth and shall not be eligible to participate in any Genentech benefit plan or policy. Wyeth also acknowledges and agrees that it shall be responsible for all compensation payable to such personnel and for any tax payments or withholding with respect to such personnel. Wyeth shall be liable for and shall defend, indemnify and hold Genentech harmless from and against all actions taken by Wyeth's personnel or any government agency or entity with respect to such Wyeth personnel at the [*]

ARTICLE 4.
TECHNOLOGY TRANSFER;
MANUFACTURING PROCESS IMPLEMENTATION AND OPERATION

4.1 Technology Transfer and Manufacturing Process Implementation. The Parties have jointly developed a Technology Transfer Project Plan that establishes the process and timeline for the transfer of Technology from Genentech to Wyeth and the implementation of the Manufacturing Process at the Facility. Pursuant to the LOI, the Parties have commenced, and pursuant to this Agreement, the Parties shall continue to transfer the Manufacturing Process for the Product and the Product Specifications to Wyeth. The Technology Transfer Project Plan sets forth the specific responsibilities of the Parties in connection with Technology Transfer and implementation of the Manufacturing Process at the Facility. The Technology Transfer Project Plan includes reasonable milestones for the transfer of Technology, exchange of information, and implementation of the Technology Transfer Project, reasonable schedules for achieving such milestones, and criteria for assessing the progress and success of the project as it progresses. Each Party shall be solely responsible for its own internal labor and overhead costs incurred in connection with the Technology Transfer Project.

4.2 Commercially Reasonable Diligent Efforts; Cooperation. Wyeth shall use its Commercially Reasonable Diligent Efforts to meet those Wyeth obligations arising under the Transaction Agreements prior to the Sourcing Date in a timely manner and in accordance with the terms and conditions hereof; provided that Wyeth's responsibilities during the Technology Transfer are limited to Wyeth's obligations under the Transaction Agreements. In addition, Wyeth shall use its Commercially Reasonable Diligent Efforts to cooperate with and assist Genentech in its efforts to perform Genentech's obligations arising under the Transaction Agreements prior to the Sourcing Date. Genentech shall use its Commercially Reasonable Diligent Efforts to meet those Genentech obligations arising under the Transaction Agreements prior to the Sourcing Date in a timely manner and in accordance with the terms and conditions thereof; provided that Genentech's responsibilities during the Technology Transfer are limited to Genentech's obligations under the Transaction Agreements. Furthermore, Genentech is not responsible for and does not promise or guarantee to address issues not directly related to the Technology or the Technology Transfer. In addition, Genentech shall use Commercially Reasonable Diligent Efforts to cooperate with and assist Wyeth in its efforts to perform Wyeth's obligations arising under the Transaction Agreements prior to the Sourcing Date. [*]

4.3 Target Dates. Each Party shall use its Commercially Reasonable Diligent Efforts to complete each of the following activities by the associated target date (each, a "Target Date"):

4.3.1 Mechanical Completion. The Target Date to complete the purchase, construction and installation of all equipment required in the Facility in order to manufacture the Product and to complete the Facility modifications (except installation of the HTST Skid), all in accordance with the Technology Transfer Project Plan ("Mechanical Completion") shall be [*]

4.3.2 Development Run Completion. The Target Date to complete the manufacture at commercial scale of [*] Development Runs in accordance with both Section 4.6 and the Technology Transfer Project Plan ("Development Run Completion") shall be [*]

4.3.3 Initial Qualification Run Completion. The Target Date to manufacture at commercial scale [*] Completed Qualification [*] ("Initial Qualification Run Completion") shall be [*].

4.3.4 Successful Qualification Batch Delivery. The Target Date for Wyeth to complete the disposition, according to the Quality Agreement, of [*] Successful Qualification Batches [*] including all appropriate data, records and reports related thereto, all in accordance with both Section 4.8 and the Technology Transfer Project Plan ("Successful Qualification Batch Delivery") shall be [*]

4.3.5 sBLA Data Delivery. The Target Date for Wyeth to complete the delivery to Genentech of both (i) all Manufacturing Data and Manufacturing Documentation generated through completion of all Qualification Batches needed to satisfy sBLA filing requirements described in the Technology Transfer Project Plan and Section 4.3.4 and (ii) Wyeth's review of and comment on all sBLA sections received on or before [*] ("sBLA

Data Delivery") shall be [*]

4.3.6 PAI Readiness. The Target Date to complete the manufacture at Commercial scale of [*] Successful Qualification Batches [*] including Wyeth Qualification Batch disposition according to the Quality Agreement and all appropriate Manufacturing Data and Manufacturing Documentation related thereto, all in accordance with both Section 4.8 and the Technology Transfer Project Plan (collectively, "PAI Readiness") shall be [*]

4.3.7 sBLA Filing. The Target Date for Genentech to file the sBLA with the FDA ("sBLA Filing") shall be [*]

4.3.8 FDA Approval. The Target Date to obtain FDA approval of the sBLA, thereby enabling sale of Product manufactured at the Facility ("FDA Approval") shall be [*]

4.3.9 Extension of Target Dates. In the event that Wyeth is unable to complete any of the foregoing activities required of Wyeth by the applicable Target Date and such failure is caused by Genentech's failure to timely perform any obligation required of it under any of the Transaction Agreements, which failure materially prevents or delays Wyeth from completing any of the foregoing activities required of Wyeth by the applicable Target Date(s), such Target Date(s) shall be extended for that number of days by which Genentech's failure to perform prevented or delayed Wyeth's performance of such activities.

4.4 Delivery of Genentech Proprietary Materials. By no later than the applicable delivery deadlines set forth in the Technology Transfer Project Plan, Genentech shall deliver to Wyeth, [*] recurring shipments of (i) [*] and (ii) [*]. Genentech shall provide such Genentech Proprietary Materials in such quantities as are set forth in the Technology Transfer Project Plan and, once Commercial Production has commenced, in such quantities as are set forth in the Manufacturing Documentation, all in accordance with the production plan set by the JPT. [*]

4.5 Changes to Technology Transfer Project Plan; Genentech Changes to the Manufacturing Process. Prior to the Sourcing Date, and subject to Section 3.1.6 hereof, the TOC shall have the authority to modify or supplement attachments and exhibits to the Technology Transfer Project Plan as necessary to ensure implementation of the Manufacturing Process in the Facility in a timely manner. In addition, prior to the Sourcing Date, subject to Section 8.5, Genentech may, in its sole discretion, modify the Manufacturing Process as it deems appropriate or useful to ensure implementation of the Manufacturing Process in the Facility in a timely manner, provided, however, that (i) Genentech shall not have the right to require Wyeth to modify the Manufacturing Process in a way that would, in Wyeth's reasonable judgment, violate any applicable laws or regulations or that would result in the infringement or practice of any Patent Right owned or Controlled by Wyeth, its Affiliates or any Third Party, provided that in the case where such a Patent Right would be infringed or practiced, Wyeth must notify Genentech of the existence of such Patent Right prior to the implementation of such modification by Wyeth, and (ii) [*] (i.e., above and beyond the costs of implementing the Manufacturing Process prior to such modifications) and such modifications shall not be implemented until the Parties mutually agree upon any revisions, if any, to the Target Dates specified in Section 4.3 that may be necessary as a result of such modifications. To the extent Genentech elects to make any modifications to the Manufacturing Process after the Sourcing Date, such modifications shall be subject to the provisions of Article 8.

4.6 Modifications and Improvements to Facility. Except with respect to changes to the Manufacturing Process that are made by Genentech in accordance with Section 4.5 or any changes made in accordance with Section 8.1 or required by the FDA in accordance with Section 8.4, which changes shall be subject to either Section 4.5 or Article 8 as the case requires, [*] Genentech shall provide Wyeth with the Genentech Equipment specified in the Technology Transfer Project Plan, and all documentation regarding the design, operation, calibration, and maintenance thereof. [*]

4.7 Development Runs.

4.7.1 Conduct of Development Runs. During the Technology Transfer, Wyeth shall use its Commercially Reasonable Diligent Efforts to conduct Development Runs at such size and in such quantity (subject

to the remaining provisions of this Section 4.7) sufficient to produce [*] Completed Development Runs as set forth in the Technology Transfer Project Plan and to achieve Development Run Completion as quickly as possible using as few Development Run Starts as possible. The Parties agree and acknowledge that the [*] Development Run Starts initiated by Wyeth may conclude with the fermentation phase of the Manufacturing Process ("Fermentation Run Starts"), [*] Wyeth shall manufacture such Development Runs [*]. With respect to each Development Run, Wyeth shall perform in-process, comparability and release testing and analysis, as required by and in accordance with the Quality Agreement. Upon completion of each Development Run, Wyeth shall deliver to Genentech the complete documentation for such Run as required by the Technology Transfer Project Plan. Wyeth and Genentech shall collaboratively analyze all appropriate data pertaining to each Development Run to identify any anomalies or errors in each Development Batch and identify possible causes and solutions in order to apply such solutions to the next subsequent Development Run Start.

4.7.2 Additional Runs; Termination Rights. If Wyeth is unable to achieve [*] Completed Development Runs [*] Development Run Starts, Genentech shall either (i) terminate the Transaction Agreements in accordance with Section 21.5.1 or (ii) authorize Wyeth to commence up to [*] additional Development Runs Starts [*] Completed Development Runs. Genentech shall notify Wyeth, in writing, of its election within ten (10) business days after Genentech's receipt from Wyeth of an investigation report regarding the root cause(s) of the Development Run failures. If Genentech fails to notify Wyeth in such ten (10) business day period, Wyeth shall provide written notice to Genentech of such failure and Wyeth shall then have the right (at its sole discretion) to commence [*] additional Development Run Starts; provided, that if Wyeth does not elect to commence such additional Development Runs and Genentech has not terminated the Agreement within fifteen (15) days of such notice from Wyeth, Wyeth shall have the right to terminate the Agreement in accordance with Section 21.5.2. [*] Development Run Starts [*]. If Wyeth elects to commence additional Development Run Starts as provided above and still fails to achieve [*] Completed Development Runs [*] Development Run Starts as applicable based on Wyeth's election, either Genentech or Wyeth shall have the right to terminate the Transaction Agreements in accordance with Section 21.5.

4.7.3 Shipping. In order to test shipping and transfer procedures, Wyeth, at Genentech's expense, shall ship [*] of frozen Product resulting from a Completed Development Run to Genentech using a Vessel and in accordance with the delivery terms set forth in Section 5.8 hereof to test shipping logistics and validation. At Genentech's election, Genentech, to the extent permitted by applicable laws and regulations, may make whatever further use (other than use in humans) of the material from such Completed Development Run (including, without limitation, any Product therefrom) by having Wyeth deliver such Batches to Genentech at Genentech's cost and in accordance with the delivery terms set forth in Section 5.8 hereof or Genentech can direct Wyeth, at Genentech's cost, to dispose of the material from such Completed Development Runs.

4.8 Qualification Runs.

4.8.1 Conduct of Qualification Runs. Genentech shall use its Commercially Reasonable Diligent Efforts to review and approve the deliverables specified in Section 4.6 above documenting the [*] Completed Development Runs and GMP Commissioning activities (including, without limitation, all required equipment and Facility qualifications and validations described in Section 12.3) in a manner that will enable Wyeth to adhere to the timeline of activities set forth in Section 4.3. Once Genentech has reviewed and approved such deliverables, Wyeth shall use its Commercially Reasonable Diligent Efforts to perform all required process validation obligations described in Section 12.3 and to commence the Qualification Runs. Subject to Section 4.8.2 below, Wyeth shall use its Commercially Reasonable Diligent Efforts to manufacture [*] enable licensure of the Facility for the Product [*]

4.8.2 Additional Runs; Termination Rights. If the ESC in good faith determines, based on the conduct of in-process testing of [*] Qualification Run Starts and the evaluation of the results of such in-process tests, that Wyeth is not likely to meet the [*] Qualification Run Starts, Wyeth shall be authorized to commence up to [*] additional Qualification Run Starts if and only if those additional Qualification Runs Starts would enable achievement of [*] Successful Qualification Batches [*]; such additional Qualification Runs Starts would not be authorized if [*] Successful Qualification Batches [*] would be mathematically impossible [*] Qualification Run Starts, and in such event, Genentech shall either (i) terminate the Transaction Agreements in accordance with Section 21.5.1 or (ii) authorize Wyeth to commence [*] additional Qualification Runs Starts to achieve [*]

Successful Qualification Batches [*] Genentech shall notify Wyeth, in writing, of its election within ten (10) business days after receipt of an investigation report from Wyeth regarding the root cause(s) of the Qualification Run failures. If Genentech fails to so notify Wyeth during such time period, Wyeth shall be deemed to have been authorized to commence [*] Qualification Run Starts. If Wyeth is authorized to conduct the [*] additional Qualification Runs and yet does not achieve [*] Successful Qualification Batches [*] Qualification Run Starts, Genentech shall either (i) terminate the Transaction Agreements in accordance with Section 21.5.1 or (ii) authorize Wyeth to commence [*] additional Qualification Runs Starts to achieve [*] Successful Qualification Batches [*]. Genentech shall notify Wyeth, in writing, of its election within ten (10) business days after receipt of an investigation report from Wyeth regarding the root cause(s) of the Qualification Run failures. If Genentech fails to so notify Wyeth during such time period, Wyeth shall be deemed to have been authorized to commence [*] additional Qualification Run Starts. If Genentech authorizes or Wyeth is deemed to be authorized to commence additional Run Starts in accordance with (ii) above, and Wyeth still fails to achieve [*] Successful Qualification Batches [*] from those additional Qualification Run Starts, either Genentech or Wyeth shall have the right to terminate the Transaction Agreements in accordance with Section 21.5. Notwithstanding the foregoing, if the ESC makes a good faith determination in accordance with Section 5.1.1 that the initial [*] Qualification Runs [*] but later determine [*] Qualification Runs, the Bonus Runs shall be deemed to be authorized, additional Qualification Runs for purposes of this Agreement.

4.8.3 Payment and Shipping of Qualification Batches. Wyeth shall provide all Qualification Batches and all documentation associated with each Batch to Genentech, at no other costs other than the cost specified in Sections 4.9, 5.8 and 6.6.2 and in accordance with Genentech's supply to Wyeth of the Genentech Proprietary Materials as provided in Section 4.4 and the delivery terms set forth in Section 5.8 hereof. Subject to FDA regulations, Genentech may make whatever further use of such Qualification Batches in the Territory, including, without limitation, any saleable Product therefrom, as it shall determine appropriate; provided, however, Genentech shall not sell or otherwise use in humans any Product from any Qualification Batch that is not a Successful Qualification Batch, was not manufactured in accordance with cGMP standards, or is otherwise not useable for such purposes.

4.9 Materials, Suppliers and Inventory.

4.9.1 Raw Materials. A list of Raw Materials is included in the Technology Transfer Project Plan, which list may be amended from time to time by Genentech at its reasonable discretion in accordance with the change control provisions set forth in Article 8. Genentech will provide detailed "Raw Material Specifications" for each Raw Material on the Raw Material list during the Technology Transfer, as such Raw Material Specifications may be amended from time to time by Genentech in its reasonable discretion in accordance with the change control provisions set forth in Article 8. The Raw Material Specifications will include specifications for [*] for each Raw Material. [*]. [*] If Genentech enters into new supply contracts for Raw Materials used in the manufacture of the Product, then, during the Term, Genentech shall provide [*] the products and services provided thereunder [*]. Genentech shall provide Wyeth with [*] or if Genentech is not permitted to provide such [*] to Wyeth, Genentech shall provide Wyeth with a [*]; provided, further that Genentech shall use its Commercially Reasonable Efforts to secure the right to provide such [*] to Wyeth. [*] as provided for in the Quality Agreement; [*] such Raw Materials in the quantities reasonably necessary to fulfill Wyeth's obligations hereunder (including the maintenance of safety stock of all Raw Materials). [*] shall only be used for manufacture of the Product and for no other purpose, unless otherwise agreed in [*].

4.9.2 Raw Materials Management and Safety Stock. Wyeth shall, [*] use its Commercially Reasonable Efforts to [*], maintain and store such amounts of Raw Materials as reasonably required for the Development Runs described in Section 4.7, the Qualification Runs described in Section 4.8 and the Commercial Runs described in Article 5, each in accordance with the applicable Bill of Materials for each such Run. Such Bill of Materials shall be provided to Wyeth by Genentech. In addition, beginning at a time prior to Commercial Production to be determined with precision by the TOC, Wyeth shall, [*], use its Commercially Reasonable Efforts to [*], maintain and store a safety stock of Raw Materials sufficient to [*] Commercial Production. Wyeth will secure such Raw Materials and provide such procurement and management services with no additional mark-up or administrative fees; provided, however, that to the extent Wyeth is unable to [*] for Development Runs, Qualification Runs or Commercial Runs (with respect to the Commercial Runs, only to the extent that Genentech

has excess inventory of such Raw Materials), Genentech shall provide such Raw Materials and components to Wyeth [*] and provided, further, that if Wyeth places orders for Raw Materials and components in accordance with the provisions of this Section 4.9.2 but [*] do not fill such orders, Wyeth shall have no liability in respect thereof (or for failing to make Run Starts as a result thereof) and shall be deemed to have satisfied its obligations under this Section 4.9.2. [*]. In addition, within fifteen (15) days after the end of each calendar quarter, Wyeth shall submit to Genentech a statement setting forth in reasonable detail the actual amounts of all Raw Materials actually used by Wyeth during such calendar quarter. During the thirty (30) day period after Wyeth submits such statement to Genentech, Wyeth and Genentech together shall review such statement and make adjustments to such schedule as are mutually agreed to by Wyeth and Genentech (such agreement not to be unreasonably withheld or delayed). [*]. For purposes of this Section 4.9, "Standard Bill of Materials Cost" means the Standard Cost multiplied by the Projected Usage (as those terms are defined in Section 4.9.5). Within thirty (30) days after the end of each Calendar Year (or more frequently as the Parties determine is necessary), Wyeth and Genentech shall mutually agree on a revised Standard Bill of Materials Cost (such agreement not to be unreasonably withheld or delayed) based on changes to either the Standard Cost, Bill of Materials or Projected Usage during such Calendar Year.

4.9.3 Raw Materials Testing. Wyeth shall use its Commercially Reasonable Efforts to perform testing and evaluation of the Raw Materials as required by the applicable Raw Material Specifications or Product Specifications and cGMP, and otherwise in accordance with the Technology Transfer Project Plan, the Quality Agreement and standard operating procedures to be agreed upon in writing by the Parties.

4.9.4 Inventory Management. Wyeth shall use its Commercially Reasonable Efforts to create and maintain a database for reporting of inventory information and demand forecasts for all Raw Materials (including Specialized Raw Materials) and Genentech Proprietary Materials. Wyeth shall provide Genentech's Materials Planning Department with detailed reports from this database [*] to enable Genentech to monitor Raw Materials and Genentech Proprietary Materials usage by Wyeth and plan for future requirements.

4.9.5 Standard Cost; Projected Usage. The standard cost for all Raw Materials [*] and Genentech's standard cost for all Genentech Proprietary Materials [*] (collectively, the "Standard Cost") shall be established [*]. The quantities of Raw Materials and Genentech Proprietary Materials required for each Run (including appropriate amounts of wastage) (the "Projected Usage") that will be used to establish the initial Budgeted Cost (as defined below) have been provided to Wyeth by Genentech prior to the Effective Date; provided, that the TOC shall have the right to evaluate and approve modifications to the amount(s) of wastage included in the Projected Usage based on Genentech's actual wastage of such materials in its conduct of the [*]

4.9.6 Excessive Use. [*]

(a) [*]

(b) [*]

4.9.7 Additional Materials. For the avoidance of doubt but subject to Article 8, during the Term, [*]

4.10 Regulatory Matters. Genentech shall use its Commercially Reasonable Diligent Efforts to prepare, file, prosecute and maintain the sBLA. Wyeth shall use its Commercially Reasonable Diligent Efforts to timely provide reasonable assistance to Genentech for Genentech to obtain and maintain all Regulatory Approvals that are required for Wyeth to manufacture Product at the Facility and that are required for Genentech to market and sell Finished Product containing such Product in the Territory, including, without limitation, (i) Genentech's preparation, filing and maintenance of the sBLA, (ii) reasonably assisting with the preparation and review of the draft chemistry, manufacturing and controls sections of the sBLA, (iii) reasonably assisting Genentech in responding to requests and inquiries from the FDA prior to, during and after regulatory review periods, (iv) providing all data, records and reports reasonably requested by Genentech relevant to such FDA review periods, and (v) attending meetings with the FDA to the extent Genentech reasonably requests for Wyeth to participate given its unique knowledge or its status as manufacturer of Product under this Agreement. Wyeth personnel shall also prepare necessary materials related to the Facility in support of, and represent the Facility at, Genentech's preliminary meetings with the FDA to

obtain information from the FDA as to the acceptability of the proposed approach for manufacturing Product at the Facility, Product validation (comparability) and licensure of the Facility. In addition, as of the date of PAI Readiness, Wyeth personnel shall have (i) prepared all materials related to the Facility necessary to support the PAI, (ii) trained all necessary personnel to perform their required responsibilities during the PAI and (iii) readied the Facility for the PAI. Wyeth shall lead the PAI of the Facility with Genentech's assistance and participation. [*] In addition, Genentech shall use its Commercially Reasonable Diligent Efforts to proactively respond to inquiries from all Regulatory Agencies other than the FDA to persuade such other Regulatory Agencies of the redundancy of additional inspections other than the PAI and cGMP inspections conducted by the FDA.

4.11 Manufacturing Documentation. Genentech shall, by the relevant date that is set forth in the Technology Transfer Project Plan, as such date may be modified by the TOC, provide to Wyeth the Manufacturing Documentation described in the Technology Transfer Project Plan. Thereafter, from time to time and in accordance with the schedule set forth in the Technology Transfer Project Plan, Genentech shall provide to Wyeth such additional Manufacturing Documentation as Wyeth shall reasonably require in order to implement the Technology Transfer Project Plan and the Manufacturing Process and otherwise perform its obligations under this Agreement. [*] In accordance with the terms of the Technology Transfer Project Plan, Genentech and Wyeth shall agree on a reasonable process, systems, and tools for managing hardcopy documents, data, and other information during Technology Transfer and Commercial Production. Genentech and Wyeth shall mutually agree on reasonable written security procedures for safeguarding all Confidential Information.

ARTICLE 5.
COMMERCIAL PRODUCTION AND SUPPLY; DELIVERIES

5.1 Commercial Production Ramp-Up. Except as set forth in this Section 5.1, Wyeth shall not conduct any Commercial Production prior to the Sourcing Date. [*]

5.1.1 Bonus Pre-Commercial Run Starts. If the ESC in good faith determines, based on the conduct of in-process testing of [*] and the evaluation of the results of such in-process tests, [*] Wyeth shall be authorized to start and to manufacture [*] Commercial Runs (the "Bonus Runs") [*]. Once such Bonus Runs are complete, Wyeth and the Facility shall be subject to the terms of Section 5.1.2 below.

5.1.2 [*]

5.1.3 Partial Commercial Production. Wyeth shall use its Commercially Reasonable Diligent Efforts to commence Run Starts [*]

5.1.4 Full Commercial Production. Wyeth shall use its Commercially Reasonable Diligent Efforts to ramp up the commercial run rate of the Facility from [*]. For the avoidance of doubt, Wyeth shall ramp up the run rate in its sole discretion and use Commercially Reasonable Diligent Efforts to have the Facility running at full Commercial Production by the Sourcing Date.

5.1.5 Production Issues. After Commercial Production has commenced, any change to the Manufacturing Process shall be made as set forth in Article 8 hereof and the Quality Agreement. Issues relating to the quality of Product shall be resolved in accordance with the Quality Agreement.

5.2 Commercial Production. Following the Sourcing Date, Wyeth shall dedicate the [*] of the Facility exclusively to Commercial Production in accordance with the terms and conditions of this Agreement. [*] Notwithstanding the foregoing, Wyeth shall have no obligation to make any Run Starts after the expiration or earlier termination of this Agreement.

5.3 Efforts, Targets and Requirements For Commercial Production.

5.3.1 Commercially Reasonable Efforts. Wyeth shall use its Commercially Reasonable Efforts to conduct Commercial Production as specified in this Agreement. Without limiting the foregoing, commencing on the Sourcing Date, Wyeth shall use its Commercially Reasonable Efforts to [*] and to make Successful Batches and

deliver such Batches. If Wyeth fails to achieve a Success Rate in any full Calendar Year after the Sourcing Date equal to or greater than [*], the Parties shall initiate a review led by the Project Team Leaders to identify and resolve the manufacturing issues, if any, that may be impacting the success of the Manufacturing Process. If the Project Team Leaders determine that any such manufacturing issues exist, the Parties, through the Operational Issue resolution process provided for in Section 3.2, will collaborate to address and resolve such issues under the direction of the ESC. During such resolution process, Genentech will have the right to deploy a reasonable number of additional Genentech personnel at the Facility as mutually agreed to by the Parties, such agreement not to be unreasonably withheld or delayed, to ensure an increased level of coordination and oversight of the resolution of such manufacturing issues. [*].

5.3.2 Commercial Production Requirements. Within a reasonable period of time prior to the start of Commercial Production, Genentech may propose a checklist of requirements to be fulfilled and maintained by Wyeth using its Commercially Reasonable Efforts during the remainder of the Term, subject to and in accordance with Wyeth's rights and obligations under this Agreement. Such checklist and the substance of such requirements and any modifications thereto shall be subject to review and approval by the JPT, and such checklist may include, without limitation, that Wyeth use its Commercially Reasonable Efforts to ensure: (i) that the Facility is compliant with all federal, state and local regulations in effect in the United States; (ii) that, subject to the provisions of this Agreement, the Facility is outfitted with all tools, equipment and utility services necessary to perform Commercial Production; (iii) that, subject to the provisions of this Agreement, the Facility has been properly maintained and that any maintenance that is required to be performed on equipment and tools within the Facility has been performed prior to Commercial Production; (iv) that the Facility is reasonably staffed with supervisors, engineers, technicians, inspectors, and other personnel reasonably necessary, and with reasonable and sufficient technical expertise, to perform Commercial Production in accordance with the terms of this Agreement, including any quality testing of Product produced; (v) that the Facility is protected from contamination; and (vi) that, subject to the provisions of this Agreement, Wyeth has adequate stock of Raw Materials on hand to perform Commercial Production in accordance with the terms of this Agreement. To the extent reasonably practical, such checklist shall be consistent with Wyeth's standard operating procedures.

5.4 Annual Maximum Purchase Commitment. [*].

5.5 Management of Production Plans.

5.5.1 Production Plans. The JPT shall participate in a weekly meeting (or at such frequency as otherwise mutually agreed), in person or via telephone, to review and discuss production, supply and logistics operations for the next three (3) month period, including: (i) the dates or approximate dates on which Runs will start and be performed; (ii) dates or approximate dates for Wyeth's and Genentech's release of Product; (iii) size or approximate size of Batches; (iv) dates or approximate dates for delivery of Batches; (v) destination for shipment of Batches; and (vi) status of Batches undergoing investigation. All of the foregoing estimates and information shall be compiled into a "Production Plan" that shall be distributed to the entire JPT promptly after each such meeting and updated accordingly in subsequent meetings.

5.5.2 Delivery. Genentech and Wyeth will work together in good faith to determine delivery dates and a shipping schedule for deliveries of Product under this Agreement, and shall establish a written "Delivery Schedule" as a part of the Production Plan.

5.6 Acceptance of Product. In accordance with the Quality Agreement and applicable standard operating procedures approved by both Parties, Wyeth shall deliver to Genentech samples of all Batches manufactured under this Agreement and the related Batch Records and other Manufacturing Data for each Batch. Upon receipt of such samples and documentation, Genentech shall use its Commercially Reasonable Efforts to perform testing and review of Manufacturing Data and samples (as appropriate) for each Batch [*]. Genentech shall use its Commercially Reasonable Efforts to initiate and conduct any Genentech quality investigation associated with such Batch in accordance with Genentech's applicable standard operating procedures as quickly as reasonably possible; provided that Genentech shall not be subject to any time limit for completing any such quality investigation. Subject to Genentech's right to reject a Batch as provided under Article 9 hereof, a Batch shall be deemed to have been accepted by Genentech (the "Acceptance") on the earlier of either (i) the date on which Wyeth receives written

notice from Genentech that such Batch has been released by Genentech pursuant to applicable release testing standard operating protocols established pursuant to the Quality Agreement ("Release") or (ii) [*] days after Genentech's receipt of samples of such Batch together with the related Batch Record and other Batch documentation (the date determined in accordance with clause (i) or (ii), as the case may be, is referred to herein as the "Acceptance Date"). If any quality investigation remains open [*] after Genentech's receipt of samples of such Batch together with the related Batch Record and other Batch documentation, the Batch will be deemed to have been accepted on the Acceptance Date as set forth above, but such Batch will not be considered to be released unless Genentech's quality organization has notified Wyeth that it has released such Batch.

5.7 Vessels. In accordance with the Production Plan developed pursuant to Section 5.5.1, Genentech, [*], shall procure and provide, in a timely manner, to Wyeth sufficient quantities of Vessels for shipment of Product by Genentech from Wyeth's Facility to Genentech's designated facility. Wyeth shall maintain such Vessels pursuant to the terms of the Quality Agreement. Title to such Vessels shall be retained by Genentech. Such Vessels shall be deemed to be "Portable Equipment" and shall be subject to Section 15.2 hereof. All Vessels supplied by Genentech shall be cleaned and shall have the proper fittings configured for use in the Facility prior to delivery thereof to Wyeth, and Wyeth shall be responsible for re-cleaning and sterilizing each Vessel prior to use in accordance with the Manufacturing Documentation and Wyeth's standard operating procedures. Genentech shall use its Commercially Reasonable Efforts to deliver Vessels to Wyeth on a delivery schedule established by the JPT and in accordance with the Production Plan (which plan shall require Genentech to deliver Vessels [*] prior to the date(s) set forth therein for commencing purification for any Batch); provided, however, that Wyeth shall notify Genentech [*] prior to commencing purification for any Batch if it has an insufficient number of Vessels for such Batch and, subject to Wyeth's providing such notice, Genentech shall be solely responsible for ensuring that a sufficient number of Vessels delivered as set forth above are delivered to Wyeth prior to the final purification step for any Batch to ensure their availability for the storage of Product upon completion of the final purification step for such Batch. Subject to Wyeth's providing notice as set forth in the proviso in the preceding sentence, in the event that Genentech fails to timely deliver a sufficient number of Vessels to Wyeth for the storage of Product upon completion of the final purification step for a Batch, such Batch shall be deemed to be a Successful Batch and to have been accepted by Genentech for purposes of Section 5.6 and Article 6 hereof as of the date Wyeth completes the final purification step despite the fact that such Batch is not filled into a Vessel. Additionally, Genentech shall reimburse Wyeth for all costs incurred by Wyeth in destroying any Product that cannot be stored due to Genentech's failure to deliver a sufficient number of Vessels to Wyeth in a timely manner; provided, however, that if Wyeth does not notify Genentech [*] to commencing purification of a Batch that it has an insufficient number of Vessels, such Batch shall not be deemed a Successful Batch if it is destroyed or is otherwise unsaleable as a result of improper storage, and Genentech shall have no obligation to reimburse Wyeth for any costs incurred in destroying any Product resulting from such Batch that Wyeth cannot store.

5.8 Delivery Terms. Genentech shall undertake and arrange for shipment of Product [*] after the date of Release or, for Product that has not been Released, [*] after the Acceptance Date for such Product. Wyeth shall provide storage for such Product [*] during the period prior to shipment as set forth above. In the event Genentech's carrier fails to accept delivery of Product [*], as applicable, Wyeth shall have the right, at its sole discretion, to either destroy the Product upon fourteen (14) days prior notice to Genentech or store such Product to the extent adequate storage space is available in the Warehouse; provided, however, that Genentech shall reimburse Wyeth for the fully-absorbed cost of storing or destroying such Product [*]. On the agreed-upon shipment date, Wyeth shall deliver Product in a Vessel, suitably packed in agreed-upon shipping containers, [*] at the Facility loading dock for pick-up by Genentech's designated carrier (the "Designated Carrier"), [*] Prior to the delivery of any Product to the Designated Carrier, Genentech shall obtain all appropriate approvals and consents of any governmental authority necessary for the transportation or shipment of such Product. Wyeth shall comply with all applicable laws and regulations regarding the packaging of Product for shipment [*] Product resulting from Development Runs and Qualification Runs (see Sections 4.6 and 4.8 hereof) shall also be subject to the delivery terms set forth in this Section 5.8. [*]

5.9 Storing and Packaging. Subject to Sections 5.7 and 5.8, Wyeth shall store and package the Product, [*], according to the Product Specifications and the Quality Agreement. With respect to each Batch, Wyeth shall not ship any Product to Genentech prior to the Acceptance Date for such Batch unless so directed in writing by Genentech.

ARTICLE 6.
FINANCIAL TERMS

6.1 Signing Bonus. As consideration for the execution of this Agreement, Genentech shall pay Wyeth a one-time signing bonus of [*]

6.2 Technology Transfer Assistance Fee. Genentech shall pay to Wyeth [*]

6.3 Equipment Transfer. Genentech shall purchase and deliver to the Facility the Centrifuge, along with all manuals and documentation pertaining thereto, [*] Wyeth shall install, [*] and use the Centrifuge in the manufacture of the Product during the Term. [*]

6.4 Milestones; Milestone Payments. For each milestone set forth in this Section 6.3 (each, a "Milestone") that Wyeth achieves by the respective Target Date described in Section 4.3, Genentech shall pay Wyeth the associated payment (each, a "Milestone Payment"). [*].

6.4.1 Completion of Milestone A: Mechanical Completion. Upon achievement of Mechanical Completion (see Section 4.3.1 for the applicable Target Date), Genentech shall be obligated to pay to Wyeth a Milestone Payment of [*]

6.4.2 Completion of Milestone B: Development Run Completion. Upon achievement of Development Run Completion (see Section 4.3.2 for the applicable Target Date), Genentech shall be obligated to pay to Wyeth a Milestone Payment of [*]

6.4.3 Completion of Milestone C: PAI Readiness. Upon achievement of PAI Readiness (see Section 4.3.6 for the applicable Target Date), Genentech shall be obligated to pay to Wyeth a Milestone Payment of [*]

6.5 Completion of Successful Pre-Approval Inspection. On the date that Wyeth receives notice from the FDA or Genentech that the Facility successfully passed the PAI with no further follow-up items that will impact FDA Approval or re-inspection(s) required, [*]

6.6 Conversion Fees; Invoicing.

6.6.1 Development Run Starts. For each Development Run Start (up to a maximum of [*] Development Run Starts), Genentech shall pay Wyeth a Conversion Fee equal to [*] Wyeth shall invoice Genentech for the Conversion Fee of each Development Run Start following the Run Start for that Development Run. [*]

6.6.2 Qualification Run Starts. For each of the first [*] Genentech shall be obligated to pay Wyeth a Conversion Fee equal to [*]

6.7 Commercial Batches.

6.7.1 Start Fees. For each Commercial Run Start commenced by Wyeth during the Term [*] Commercial Run Starts per Calendar Year), including Run Starts for Bonus Runs commenced pursuant to Section 5.1.1, Genentech shall pay Wyeth [*]

Calendar Year	**Applicable Start Fee per Commercial Run Start**
2005 + 2006	[*]
2007	[*]
2008	[*]
2009	[*]

[*]

6.7.2 Success Fees. Except as otherwise expressly set forth in this Agreement, for each Successful Commercial Batch [*]

6.8 Invoicing Genentech for Batches and Start Fees.

6.8.1 Batches.

(a) Wyeth may invoice Genentech for the Conversion Fee for each Development Run (as per Sections 4.7 and 6.6.1) on or after the Run Start for each Development Run.

(b) Wyeth may invoice Genentech for the Conversion Fee for each Qualification Run (as per Sections 4.8 and 6.6.2) on or after the Run Start for each Qualification Run.

(c) Wyeth may invoice Genentech for the balance of the Conversion Fee due for each Commercial Batch (up to the Annual Maximum Purchase Commitment in each Calendar Year and subject to Sections 5.1, 5.3 and 5.4) on or after the Acceptance Date of such Commercial Batch. Each such invoice shall reference the Batch Number, Batch Record, the Acceptance Date, the Start Fee, the Success Fee and the total Conversion Fee for such Batch. With respect to those Batches for which Wyeth has previously invoiced a Start Fee, Wyeth shall only invoice Genentech for the Success Fee (the Conversion Fee less the Start Fee) and indicate previous invoicing and the status of payment of the Start Fee on the invoice.

6.8.2 Start Fees. For amounts owed under Sections 6.7, Wyeth may submit invoices to Genentech on or after the date of each Run Start. Such invoices shall reference the Batch Number, the total Conversion Fee for the Batch and the Start Fee for the Run Start.

6.9 Payment Method. All amounts owed under invoices (except as set forth below) shall be due and payable in United States currency within [*] days after the invoice date for all invoices for Success Fee payments or (ii) [*] days after the invoice date for all other payments, [*] In the event that a Party believes, in good faith, that any portion of an invoice issued hereunder by the other Party is incorrect or otherwise inaccurate, the Party questioning such invoice shall, no later than the applicable due date for payment of that invoice (i) issue a written notice to the other Party describing in reasonable detail the nature of the dispute and (ii) pay any undisputed portion of such invoice. Upon receipt of such notice, the Parties shall use their respective Commercially Reasonable Efforts to resolve such dispute within fifteen (15) days after such notice; provided, that if the Parties are unable to resolve such dispute, it shall be handled in accordance with Article 23. All payments due hereunder shall be made by wire transfer from a bank in the United States in immediately available funds to a bank in the United States designated in writing by the Party to receive payment. All payment amounts set forth herein are in United States dollars and all payments hereunder shall be made in United States dollars. [*]

6.10 Audit.

(a) For at least three (3) years after final payment under this Agreement, Wyeth shall maintain complete and accurate books, records, documents, and other evidence of Raw Materials usage, the Run Starts and Commercial Production of Product made pursuant to this Agreement (for purposes of this Section 6.10, hereinafter collectively called "Wyeth Production Records"). Prior to the end of such three (3) year period, Genentech, acting through its independent public accountants of recognized national standing selected by Genentech and reasonably acceptable to Wyeth, shall have a right at its own expense to examine and audit such Wyeth Production Records at those Wyeth facilities where such Wyeth Production Records are kept once per Calendar Year, upon at least thirty (30) days' prior written notice. Wyeth may require any such accountant to sign a non-disclosure agreement prior to the audit.

(b) For at least three (3) years after final payment under this Agreement, Wyeth shall maintain complete and accurate books, records, documents, and other evidence of costs, expenses and allowances for which Wyeth may be entitled to payment or reimbursement under Section 4.5, Section 4.9 or Article 8 (for purposes of this Section 6.10, hereinafter collectively called "Wyeth Financial Records"). Prior to the end of such three (3) year period, Genentech, acting through its independent public accountants of recognized national standing selected by Genentech and reasonably acceptable to Wyeth, shall have a right at its own expense to examine and

audit such Wyeth Financial Records at those Wyeth facilities where such Wyeth Financial Records are kept once per Calendar Year, upon at least thirty (30) days' prior written notice. Wyeth may require any such accountant to sign a non-disclosure agreement prior to the audit.

(c) For at least three (3) years after final payment under this Agreement, Genentech shall maintain complete and accurate books, records, documents, and other evidence of costs, expenses and allowances for which Genentech may be entitled to payment or reimbursement under Section 4.9 or Article 9 or Article 11 (for purposes of this Section 6.10, hereinafter collectively called "Genentech Financial Records"). Prior to the end of such three (3) year period, Wyeth, acting through its independent public accountants of recognized national standing selected by Wyeth and reasonably acceptable to Genentech, shall have a right at its own expense to examine and audit such Genentech Financial Records at those Genentech facilities where such Genentech Financial Records are kept once per Calendar Year, upon at least thirty (30) days' prior written notice. Genentech may require any such accountant to sign a non-disclosure agreement prior to the audit

ARTICLE 7.
MANUFACTURER WARRANTIES

7.1 Product Warranties by Wyeth. With respect to each Batch from a Qualification Run or Commercial Run that is shipped to Genentech, Wyeth hereby warrants to Genentech that, as of the earlier of (a) the time of delivery of such Batch to Genentech's Designated Carrier or (b) sixty (60) days after the Acceptance Date related thereto (in either case, the "Warranty Date"), such Batch:

7.1.1 conforms to the Product Specifications existing as of the time of the inoculation of the [*] bioreactor for such Batch (or such earlier time as may be appropriate in the event that there are any modifications to those portions of the Manufacturing Process occurring prior to the inoculation of the [*] bioreactor or which require changes to the materials used (or specifications therefor) prior to the inoculation [*] bioreactor);

7.1.2 was manufactured in compliance with the requirements of cGMP;

7.1.3 was manufactured in compliance with the requirements of all applicable material federal, state and local laws, ordinances and governmental rules and regulations of the United States;

7.1.4 was manufactured in compliance with Wyeth's applicable standard operating procedures;

7.1.5 was manufactured in compliance with the Quality Agreement; and

7.1.6 is being transferred free and clear of any liens or encumbrances of any kind to the extent arising through or as a result of the acts or omissions of Wyeth, its Affiliates or their respective agents.

ARTICLE 8.
SPECIFICATION AND MANUFACTURING PROCESS CHANGES

8.1 Genentech Requested Changes to Product Specification and Manufacturing Process. Except as otherwise expressly set forth to the contrary in the Quality Agreement or Section 4.5 of this Agreement, in the event that Genentech is required, or desires, to change the Product Specifications, testing methods or the Manufacturing Process after the Sourcing Date, Wyeth shall use its Commercially Reasonable Efforts to accommodate such request to the extent doing so would not have a direct and material adverse impact on any other product manufactured or to be manufactured by Wyeth at its Andover, Massachusetts facility, provided that the foregoing is subject to the provisions of Section 8.5. Genentech shall be responsible for all costs incurred by either Party or its Affiliates in connection with making any such changes and shall reimburse Wyeth for all such costs (on a fully-absorbed basis) [*] after Wyeth submits an invoice to Genentech for such costs.

8.2 Wyeth Requested Changes to Product Specification and Manufacturing Process Changes. Notwithstanding anything to the contrary in this Agreement and/or the Quality Agreement, Wyeth shall not change the Product Specifications, testing methods or the Manufacturing Process except with Genentech's prior written consent, which consent shall not be unreasonably withheld or delayed, provided that the foregoing is subject to the

provisions of Section 8.5. Any Wyeth-requested changes that are approved by Genentech shall be in accordance with the Quality Agreement and standard operating procedures (i.e., change control procedures) agreed upon in writing by Genentech and Wyeth from time to time. Genentech shall retain the right and responsibility for final approval of any changes to the Manufacturing Process, testing methods, facilities, and equipment used to manufacture the Product or the specifications for the Product. Wyeth shall be responsible for all costs incurred by Wyeth in implementing a change requested by Wyeth in accordance with this Section 8.2.

8.3 Wyeth Requested Changes to Shared Facilities. For facilities, warehouses, utilities, and equipment that Wyeth utilizes for both the Product and other products, Wyeth shall inform Genentech of any revisions or changes to these facilities, warehouses, utilities, or equipment that may impact the Product, and, in such event, Wyeth shall not make any revisions or changes to these facilities, warehouses, utilities, or equipment without prior written approval of Genentech, such approval not to be unreasonably withheld or delayed, provided that the foregoing is subject to the provisions of Section 8.5. Any such revisions or changes, once approved, shall be implemented by Wyeth in accordance with the Quality Agreement and standard operating procedures (i.e., change control procedures) agreed upon in writing by Genentech and Wyeth from time to time. Wyeth shall be responsible for all costs incurred by Wyeth in implementing a revision or change to these facilities, warehouses, utilities, or equipment requested by Wyeth. In the event that Wyeth desires to revise or change any facilities, warehouses, utilities, or equipment at Wyeth's Andover, Massachusetts facility and such revision or change could reasonably be expected to impact the manufacture, storage, testing or shipment of Product by Wyeth at the Facility, Wyeth shall provide advance written notice to Genentech of any such revisions or changes sufficiently in advance of the implementation of such revisions or changes so as to enable (i) Genentech to review and provide comments on such revisions or changes and (ii) the Parties to make any necessary adjustments to the manufacture, storage, testing or shipment of Product by Wyeth at the Facility.

8.4 FDA Requested Changes.

8.4.1 Facility Related. If the FDA requests or requires that a change be made in the Facility or the utilities or equipment used to manufacture the Product or if changes to the Facility or the utilities or equipment used to manufacture the Product are required in order to comply with applicable laws or regulations (including, without limitation, cGMP), in each of the foregoing cases, which changes are not Product specific (i.e., the changes must be made regardless of the product being manufactured in the Facility), Wyeth, subject to Section 8.5, shall use its Commercially Reasonable Efforts to make such changes in accordance with the Quality Agreement and standard operating procedures (i.e., change control procedures) agreed upon in writing by Genentech and Wyeth from time to time. Such changes shall be subject to Genentech's approval, which approval shall not be unreasonably withheld or delayed. Wyeth shall be responsible for all costs incurred by Wyeth in connection with making any such change(s).

8.4.2 Process or Product Related. If the FDA requests or requires that a change be made in the Manufacturing Process, the Product Specifications or the Facility, utilities or equipment used to manufacture the Product (solely to the extent such facility, utility or equipment change is Product specific), or if changes to the Manufacturing Process, Product Specifications or the Facility, utilities or equipment used to manufacture the Product (solely to the extent such facility, utility or equipment change is Product specific) are required in order to comply with applicable laws or regulations, Wyeth, subject to Section 8.5, shall use its Commercially Reasonable Efforts to make such changes in accordance with the Quality Agreement and standard operating procedures (i.e., change control procedures) agreed upon in writing by Genentech and Wyeth from time to time. Such changes shall be subject to Genentech's approval, which approval shall not be unreasonably withheld or delayed. Genentech shall be responsible for all costs incurred by either Party or its Affiliates in connection with making any such changes and shall reimburse Wyeth for all such costs (on a fully-absorbed basis) [*] after Wyeth submits an invoice to Genentech for such costs.

8.5 Process for Making Requested Changes.

8.5.1 Notice and Review. With respect to any change requested in accordance with Sections 8.1, 8.2, 8.3 or 8.4, the Party requesting the change (or the Party that receives a request from the FDA to make a change) shall promptly advise the other Party, in writing, of any such requested change(s), and provide all information reasonably necessary to the other Party to evaluate the effect of and possible means for implementing such requested

change(s). The TOC (drawing on any necessary assistance it requires from the JPT or any JPSTs) shall promptly advise the ESC as to (i) the most efficient and least impactful manner to accomplish such requested change (making full use of any scheduled shutdowns of the Facility to the extent possible) and (ii) any revisions to the Technology Transfer and/or Commercial Production schedules that may result from such change(s). The notification and approval procedure shall be in accordance with the change control procedures established pursuant to the Quality Agreement and standard operating procedures agreed upon by the Parties from time to time. Following completion of the evaluation procedure established pursuant to the Quality Agreement, the Parties shall hold a JPT meeting in a timely manner with appropriate advisors invited to discuss implementing such changes as appropriate.

8.5.2 Excessive Downtime. If the TOC, in evaluating a requested change, determines that (i) the time to implement such change would require [*] of Facility downtime (if the requested change would be made prior to Commercial Production) or (ii) the time to implement such change would require [*] of Facility downtime (if the requested change would be made during Commercial Production), the Party requesting such change shall have the right to either (a) withdraw the request, (b) resubmit a modified version of the requested change to the TOC for reevaluation or (c) confirm that such requested change is necessary and submit such requested change to the non-requesting Party for consideration. Notwithstanding any provision to the contrary, if the non-requesting Party is presented with a requested change in accordance with (c) above, the non-requesting Party shall, within ten (10) business days after receipt of the request, either agree to such requested change or provide notice of termination of this Agreement in accordance with Section 21.7. In the event that the requested change originated with the FDA, the terms of this Section 8.5.2 shall still apply, but in such event, either Party shall have the right to terminate this Agreement in accordance with Section 21.7.

8.5.3 Adjustments to Agreements. Prior to implementation of any Genentech or FDA requested change(s) to the Product Specifications, Manufacturing Process, the Facility, or equipment or utilities used to manufacture the Product, the Parties agree to negotiate in good faith in an attempt to reach agreement on (i) any increases in the Conversion Fee for any Product manufactured under this Agreement by Wyeth that directly result from such material change, giving due consideration to the effect of such material change on Wyeth's direct manufacturing costs for Product, and (ii) any other amendments to this Agreement or any of the other Transaction Agreements which may be necessitated by such material changes.

8.5.4 Costs. Prior to implementation of any Genentech or FDA requested change(s), Wyeth will provide Genentech with an estimate of the reasonable and necessary expenses that would be incurred by Wyeth as a result of the implementation of any such change(s) to the Product Specifications, Manufacturing Process, the Facility, or equipment or utilities used to manufacture the Product, including, without limitation, its validation and analytical development costs, and capital expenditure costs. If such change(s) are implemented, Genentech will reimburse Wyeth for the reasonable and necessary expenses as agreed upon in advance and incurred by Wyeth as a result of any such change(s) to the Product Specifications, Manufacturing Process, the Facility, or equipment or utilities used to manufacture the Product, including, without limitation, reimbursing Wyeth for its additional validation and analytical development costs and capital expenditure costs with no additional mark-up or administrative fees.

8.5.5 Implementation. Wyeth shall promptly make those changes described in this Section 8.5; provided, that Wyeth shall have no obligation to make any such change where doing so would, in Wyeth's reasonable judgment, violate any applicable laws or regulations or that would result in the infringement or practice of any Patent Right owned or Controlled by Wyeth, its Affiliates or any Third Party, provided that in the case where such a Patent Right would be infringed or practiced Wyeth must notify Genentech of the existence of such Patent Right prior to the implementation of such modification by Wyeth. Wyeth shall cooperate with Genentech in good faith to implement all agreed upon changes to the Product Specifications or Manufacturing Process in accordance with the agreed upon schedule. During the pendency of Wyeth implementing any such changes to the Manufacturing Process, Product Specifications, the Facility, or equipment or utilities used to manufacture the Product, Wyeth, to the extent possible in light of the changes being made, shall, at Genentech's written request, produce and Genentech shall purchase Product in accordance with the terms of this Agreement and the Manufacturing Process, Product Specifications, the Facility, or equipment or utilities used to manufacture the Product in effect immediately prior to the implementation of such change, and Genentech shall pay such invoice in accordance with Section 6.9.

8.5.6 Raw Materials. If any such changes to the Product Specifications, Manufacturing Process, the Facility, or equipment or utilities used to manufacture the Product, renders obsolete or unusable any Raw Materials, components or supplies used to manufacture the Product, and to the extent such materials may not be returned to the appropriate vendor for a credit, Wyeth shall either destroy or deliver to Genentech, at Genentech's sole option and expense, that amount of inventory of such Raw Materials (for which Genentech has reimbursed Wyeth or remains obligated to reimburse Wyeth), components or supplies, as the case may be, so rendered obsolete or unusable, not to exceed the amount of such Raw Materials, components or supplies which would have been reasonably required for Wyeth to maintain in inventory (including, without limitation, any safety stock) in order to meet its obligations to manufacture and supply Product under this Agreement. Wyeth shall invoice Genentech for Wyeth's cost of all such Raw Materials rendered obsolete or unusable upon destruction or delivery of such Raw Materials and Genentech shall pay such invoice in accordance with Section 6.9.

8.6 Vendor or Supplier Changes. Notwithstanding anything to the contrary in this Agreement and/or the Quality Agreement, Wyeth shall not change any vendor or supplier of Raw Materials or analytical reagents used in the manufacture or testing of Product except with Genentech's prior written consent, which consent shall not be unreasonably withheld or delayed.

ARTICLE 9.
NON-CONFORMING PRODUCT

9.1 Notice of Non-Conformance.

9.1.1 In the event that Genentech, in good faith, reasonably determines through review of Batch Records and other Manufacturing Data provided by Wyeth and/or testing of the Product by Genentech that a Batch from a Qualification Run or Commercial Run is Non-Conforming Product, Genentech may reject such Batch on the grounds that such Product is Non-Conforming Product by giving written notice thereof to Wyeth [*] after samples of such Product are delivered to Genentech for testing in accordance with Section 5.6.

9.1.2 In the event that, after the Acceptance Date, Genentech determines, in good faith, that any Batch from a Qualification Run or Commercial Run is determined to have been Non-Conforming Product as of the Warranty Date, and the cause of such non-conformance as of the Warranty Date is not a Pre-existing Defect, Genentech may reject such Batch by giving prompt notice thereof to Wyeth, [*] after the Warranty Date for such Batch.

9.1.3 In the case of any rejection under Section 9.1.1 or 9.1.2 above, the notice of rejection shall state with particularity all of the reasons for such rejection and specify the manner in which such Product is alleged to be Non-Conforming Product and shall be accompanied by any test results or reports evidencing such non-conformity. Alternatively, rather than initially issuing a notice of rejection under Section 9.1.1 above, Genentech may give written notice to Wyeth within the time period set forth in Section 9.1.1 above of a Genentech decision to investigate whether a Batch is potentially non-conforming, which notice shall include, for Wyeth's review and comment, a written plan for investigating and resolving such potential non-conformance, which investigation shall be completed in accordance with the procedures established pursuant to the Quality Agreement. For the sake of clarity, Genentech shall not have the right to reject any Batch and require Wyeth to refund any Success Fee if such Non-Conforming Product is non-conforming due to any action or omission of Genentech or its employees or agents or Genentech's Designated Carrier after delivery of such Product to Genentech's Designated Carrier.

9.2 No Wyeth Liability. After rejection of a Batch or Batches in accordance with Section 9.1.1 or 9.1.2, if it is determined by agreement of the members of the JQT (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that either (i) an alleged Batch (or Batches) of Non-Conforming Product was not in fact Non-Conforming Product as of the Warranty Date, or (ii) an alleged Batch (or Batches) of Non-Conforming Product was in fact Non-Conforming Product as of the Warranty Date and such non-conformity was not caused by Wyeth (or its agents) but by a Pre-existing Defect, then Wyeth shall have no liability to Genentech with respect thereto, and Genentech shall pay to Wyeth [*] after such determination the Conversion Fee and/or Success Fee (as applicable) for such Product, if not already paid.

9.3 Wyeth Liability; Replacement of Product. Subject to Section 9.2, if Genentech has provided the notice as and when required under Section 9.1.1 or 9.1.2, as the case may be, and it is determined that Wyeth is responsible for such non-conformance, at Genentech's written request, Wyeth shall use its Commercially Reasonable Efforts to replace such Non-Conforming Product as soon as practicable with conforming Product, and Wyeth shall promptly and in any event [*] credit to Genentech the amount of the Success Fee, if any, previously paid by Genentech to Wyeth for such Non-Conforming Product, such credit to be applied on the next invoice submitted by Wyeth to Genentech, and Genentech shall pay the Conversion Fee (including the Start Fee and Success Fee) for the replacement Product.

9.4 Cooperation in Investigations, Disposition of Non-Conforming Product. If Genentech desires to make a claim against Wyeth with respect to and reject a Batch of Non-Conforming Product pursuant to Section 9.3, Genentech agrees that it shall not dispose of or allow such Product to be disposed of without written prior notification to Wyeth. Disposition of Non-Conforming Product shall be determined in accordance with the provisions of the Quality Agreement. If any rejected Product is disposed of by or on behalf of Genentech prior to completion of all investigations and final determination as to whether or not such Product is Non-Conforming Product in accordance with this Article 9, Genentech shall be deemed to have waived all rights under this Article 9 with respect to such Product and shall be deemed to have accepted such Product for purposes of Section 5.6 and the payment provisions of this Agreement.

ARTICLE 10.
MANUFACTURING AUDITS; CERTIFICATE OF COMPLIANCE; AND REGULATORY MATTERS

10.1 Audits of Facility.

10.1.1 During Technology Transfer. During Technology Transfer and in support of Technology Transfer activities, including the PAI, Genentech shall have the right, at its own cost, to conduct [*] cGMP compliance audits of the Facility and the pertinent records maintained by Wyeth in connection with the conduct of the Manufacturing Process and the manufacture of Product, all in accordance with the Technology Transfer Project Plan and pursuant to the Quality Agreement. Such cGMP audits shall be conducted upon Genentech's request and with reasonable prior written notice to Wyeth to permit Wyeth to support said cGMP audits. In addition, Genentech shall have the right, at its own cost, to perform, directly or through its representatives, For Cause Audits and additional follow-up audits that are reasonably necessary as a result of the findings of any of the foregoing audits, all in accordance with the Technology Transfer Project Plan and pursuant to the Quality Agreement. During such audits, personnel of Genentech or its representatives shall have access only to all public areas (including the cafeteria) and those areas that are directly related to the performance of Wyeth's obligations under this Agreement, including the manufacture, testing, storage and shipping of Product. Any such audits shall be during Wyeth's normal business hours on dates mutually agreed to by the Parties.

10.1.2 During Commercial Production. During Commercial Production, Genentech shall have the right, at its own cost, to perform, directly or through its representatives, a cGMP compliance audit [*] as well as For Cause Audits and additional follow-up audits that are reasonably necessary as a result of the findings of any of the foregoing audits, all in accordance with the Quality Agreement. During such audits, personnel of Genentech or its representatives shall have access only to all public areas (including the cafeteria) and those areas that are directly related to the performance of Wyeth's obligations under this Agreement, including the manufacture, testing, storage and shipping of Product. Any such audits shall be during Wyeth's normal business hours on dates mutually agreed to by the Parties.

10.1.3 Security Audit. Upon Genentech's request and with reasonable prior written notice to Wyeth to permit Wyeth to support such audit, Genentech shall have the right, at its own cost, to conduct a security audit of the Facility and the pertinent records maintained by Wyeth in connection with the security procedures of the Facility, prior to the start of the first Qualification Run. Such audit shall be during Wyeth's normal business hours on dates mutually agreed to by the Parties.

10.1.4 Audit Reports. The conduct of any audit under this Section 10.1 and any findings of such audit (excluding information not generated in the conduct of such audit) shall constitute Genentech's Confidential Information, and accordingly the Parties agree that both the conduct of any audit and any findings of such audit are subject to Article 19. Genentech shall provide copies of such findings to Wyeth promptly following completion of the audit.

10.1.5 Personnel. Genentech shall be responsible for the actions of its employees, agents or representatives involved in conducting any audit of Wyeth's facilities while they are in such facilities or are otherwise on Wyeth's property. Genentech shall not assign any employee, agent or representative to conduct an audit unless such employee, representative or agent is legally obligated to maintain the confidentiality of and limit their use of Wyeth's Confidential Information under terms and conditions no less restrictive than those set forth in this Agreement.

10.2 Certificates; Manufacturing Issues; Records.

10.2.1 Certificates; Manufacturing Issues. Within [*] after completion of manufacture, testing and Wyeth's disposition of a Batch (including review of records by Wyeth), unless otherwise agreed by Genentech, Wyeth shall furnish to Genentech the Batch Records and Wyeth's release documentation described in the Quality Agreement, including, without limitation, a Certificate of Analysis, a Certificate of Compliance and a summary (in a format to be agreed upon by Genentech and Wyeth) of any deviations or investigations that occurred during the manufacturing or testing of the Product that is part of such shipment. Subject to Section 5.6 hereof, the provisions set forth in the Quality Agreement regarding deviations shall control whether a deviation results in Non-Conforming Product.

10.2.2 Records. Wyeth shall maintain all of its manufacturing and analytical records, all records of shipments of Product and all validation data relating to Product for the time periods required by applicable United States laws and regulations. Wyeth agrees that, in response to any complaint, or in the defense by Genentech of any litigation (other than litigation between Genentech and Wyeth), hearing, regulatory proceeding or investigation relating to Product, Wyeth, at Genentech's expense, shall use its Commercially Reasonable Efforts to make available to Genentech such Wyeth employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections.

10.3 Complaints. Wyeth shall provide Genentech with a copy of any complaints received by Wyeth with respect to the Product in accordance with the Quality Agreement and standard operating procedures to be agreed upon by Genentech and Wyeth from time to time. Genentech shall have responsibility for responding to all such complaints, and for promptly providing Wyeth with a copy of any responses to complaints relating to the manufacture of the Product. Wyeth shall use its Commercially Reasonable Efforts to respond to requests from Genentech for information in Wyeth's possession that is necessary for Genentech to respond to complaints arising out of the manufacture of the Product. Genentech shall have sole responsibility for reporting any complaints relating to the Product to the FDA and any other Regulatory Agency, including, but not limited to, complaints relating to the manufacture of the Product and adverse drug experience reports. Genentech shall provide Wyeth with a copy of all reports submitted to the FDA or any other Regulatory Agency regarding the Product that relate or are attributable to any manufacturing, testing, storage, or shipping activities by or on behalf of Wyeth. Genentech shall maintain complaint files in accordance with cGMP and all other applicable laws and regulations.

10.4 Regulatory Correspondence.

10.4.1 Notification to Other Parties of Regulatory Correspondence. Each Party shall immediately and within one (1) business day notify the other Party in writing of, and shall provide the other Party with copies of, any correspondence and other documentation received or prepared by such Party in connection with any of the following events: (i) receipt of a regulatory letter, warning letter, or similar item, from the FDA or any other Regulatory Agency directed to the manufacture, testing, storage or packaging of Product by Wyeth or in connection with any general cGMP inspections applicable to the Facility; (ii) any recall, market withdrawal or correction of any Batch manufactured, tested, stored, or packaged hereunder or resulting Finished Product, in the case of such Product or Finished Product where the recall, market withdrawal or correction is attributable to any manufacturing, testing,

storage, or packaging activities by or on behalf of Wyeth; and (iii) receipt of a regulatory letter, warning letter or similar item from the FDA or any other Regulatory Agency directed to or any regulatory comments related to Product manufactured, tested, stored, or packaged hereunder or resulting Finished Product, in the case of such Product or Finished Product where the comments relate or are attributable to any manufacturing, testing, storage, or packaging activities by or on behalf of Wyeth.

10.4.2 Regulatory Correspondence Requiring a Wyeth Response. In the event Wyeth receives any regulatory letter or comments from any Regulatory Agency in the Territory directed to its manufacture, testing, storage, or packaging of Product requiring a response or action by Wyeth, including, but not limited to, receipt of a Form 483 (Inspectional Observations) or a warning letter, Genentech will, to the extent within its control or possession, promptly provide Wyeth with all data or information required by Wyeth in preparing any response related to Wyeth's manufacture, testing, storage, or packaging of Product and will cooperate fully with Wyeth in preparing such response. Wyeth shall provide Genentech with a copy of each such response (redacted to remove information not related to the manufacture, testing, storage, or packaging of Product, the Facility or Wyeth's other obligations under this Agreement) for Genentech's review and comment prior to Wyeth's submission of its detailed written response. Wyeth shall give all due consideration to any Genentech comments to each such proposed Wyeth response provided that Genentech conveys its comments to Wyeth in a timely manner. Likewise, in the event Genentech receives any regulatory letter or comments from any Regulatory Agency in the Territory related to any Product manufactured, tested, stored, or packaged at the Facility, including, but not limited to, receipt of a Form 483 (Inspectional Observations) or a warning letter, Wyeth will, to the extent within its control or possession, promptly provide Genentech with relevant data or information related to the Product manufactured, tested, stored, or packaged at the Facility sufficient for Genentech to prepare any response related to the manufacture, testing, storage, or packaging of Product and will cooperate fully with Genentech in preparing such response. Genentech shall provide Wyeth with a copy of each such response (redacted to remove information not related to the manufacture, testing, storage, or packaging of Product at Wyeth's Facility or Genentech's obligations under this Agreement) for Wyeth's review and comment prior to Genentech's submission of its detailed written response. Genentech shall give all due consideration to any Wyeth comments to each such proposed Genentech response provided that Wyeth conveys its comments to Genentech in a timely manner.

10.5 Inspections; Non-Compliance; Failure to Manufacture.

10.5.1 Inspections. In the event the Facility is inspected, or Wyeth is notified that the Facility will be inspected, by representatives of any Regulatory Agency in the Territory directed to Wyeth's manufacture, testing, storage, or packaging of Product, Wyeth shall notify Genentech within one (1) business day after receipt of notice of such inspection, and shall supply Genentech with copies of any correspondence or portions of correspondence which relate to the Product. Genentech may send, and upon the request of Wyeth shall send, representatives to the Facility to participate in any portion of such inspection that is directed to the Product.

10.5.2 Non-Compliance; Failure to Manufacture. In the event that any Regulatory Agency in the Territory shall determine, as a result of an inspection described in Section 10.5.1 above, that Wyeth is not in compliance with applicable United States laws or regulations or otherwise not in compliance with cGMP with respect to the manufacture, testing, storage, or packaging of Product, Wyeth shall use its Commercially Reasonable Efforts to remedy any such non-compliance as soon as practicable subject to the provisions of Article 8.

ARTICLE 11.
RECALLS

11.1 Recalls. Genentech shall notify Wyeth promptly (and in any event within one (1) business day of receipt of written notice) if any Batch manufactured by Wyeth or resulting Finished Product is the subject of a threatened or actual recall, market withdrawal or correction attributable to any manufacturing, testing, storage, or shipping activities conducted by or on behalf of Wyeth [*]. Notwithstanding the foregoing, to the extent such recall, market withdrawal or correction was caused directly by Wyeth's breach of any of its warranties set forth in Article 7 hereof as of the Warranty Date with respect to the subject Batch and not caused by a Pre-existing Defect or an action of omission of Genentech, its Affiliates, Genentech's Designated Carrier or any of their respective employees or agents, Wyeth shall credit Genentech for the Success Fee (prorated based on the amount of Product recovered or

destroyed in the recall) for the Product recalled or used to make such recalled Finished Product and shall reimburse Genentech for all of Genentech's reasonable out-of-pocket expenses directly related to the implementation and conduct of the recall, market withdrawal or correction, if any. As between the Parties, Genentech or its agent shall make all decisions regarding, and in all events shall have sole authority for, conducting any recalls, market withdrawals or corrections with respect to the Product in the Territory; provided, however, that if Wyeth reasonably and in good faith notifies Genentech that a recall is necessary with respect to a given Batch and Genentech elects not to make such recall, Genentech, [*]

ARTICLE 12.
QUALITY ASSURANCE; QUALITY CONTROL; VALIDATION; STABILITY

12.1 Responsibility for Quality Assurance and Quality Control. Responsibility for quality assurance and quality control of Product shall be allocated between Genentech and Wyeth as set forth in the Quality Agreement. To the extent reasonably practicable and consistent with industry practice and cGMP, Wyeth shall incorporate its obligations under the Quality Agreement into standard operating procedures that comply with the Quality Agreement. In general, (a) Wyeth shall be responsible for performing certain in-process testing and acceptance testing on the Product as set forth in the Technology Transfer Project Plan and the Quality Agreement, and (b) Genentech shall be responsible for acceptance of all test results and authorizing final Release of all Product to the market as set forth in the Quality Agreement.

12.2 Validation of Facility. Wyeth shall use its Commercially Reasonable Efforts to qualify and validate the Facility, including all utilities, manufacturing equipment and systems, cleaning procedures, computer systems, testing equipment and non-Product specific processes such as sterilization used in the manufacture of Product at the Facility, as further defined in the Technology Transfer Project Plan and Quality Agreement. Wyeth shall use its Commercially Reasonable Efforts to complete all validation reports by sBLA Filing or earlier as defined in the Technology Transfer Project Plan and shall make all relevant validation reports applicable thereto prepared by or for Wyeth available to Genentech for review at Genentech's reasonable request.

12.3 Validation of Manufacturing Process. In accordance with the requirements of Article 4, the Technology Transfer Project Plan and the Quality Agreement, Genentech shall use its Commercially Reasonable Efforts to provide Wyeth with all Manufacturing Documentation related to the validated Manufacturing Process, as further described therein. Genentech is responsible for defining the process validation in a process validation project plan. The process validation project plan will (i) describe all process validation studies to be completed by the Parties including those previously performed for the Product that need not be repeated and those needed to validate and demonstrate comparability of the Manufacturing Process as implemented at the Facility to the Manufacturing Process as conducted by Genentech as required by the FDA and (ii) identify those studies for which Wyeth has specific responsibilities (typically additional sampling and associated sample handling) per Genentech's process validation protocols.

12.4 Stability. Genentech shall conduct all necessary stability testing to comply with cGMP and other applicable regulatory guidelines. Wyeth shall prepare all stability samples, and shall sublot stability samples and package and ship stability samples to Genentech, all in accordance with schedules, protocols and procedures agreed upon by Wyeth and Genentech and established pursuant to the Quality Agreement.

ARTICLE 13.
WYETH'S OBLIGATIONS AS MANUFACTURER

13.1 Control of Working Cell Bank. Wyeth shall maintain all portions of the Working Cell Bank that it receives in safe and secure storage under its control in the Facility, and shall not permit the transfer of the Working Cell Bank to any Wyeth facility other than the Facility or to any Third Party, in each case that is not specifically authorized in advance and in writing by Genentech.

13.2 Manufacturing Capabilities. Wyeth or one or more of its Affiliates (or its or their successors upon sale of the Facility) shall, at all relevant times throughout the Term, own or lawfully control the Facility. Wyeth or one or more of its Affiliates shall use its Commercially Reasonable Efforts to staff the Facility with sufficient

numbers of appropriately qualified managers, supervisors, engineers, technicians, inspectors, and other personnel, all of whom have reasonable and sufficient technical expertise, in each case to enable Wyeth to manufacture Product in accordance with the Product Specifications and to fulfill its obligations under this Agreement.

13.3 Compliance with Law. Wyeth shall use its Commercially Reasonable Efforts to perform all work and services under this Agreement in conformance with cGMP and in conformance with the substantive requirements of all applicable material federal, state and local laws, ordinances and governmental rules or regulations in the United States, and shall have all applicable licenses and permits required of it to perform the work and services hereunder, the absence of which would materially adversely affect the marketability of the Product. In addition, Wyeth shall use its Commercially Reasonable Efforts to comply with all applicable material United States laws and regulatory requirements relating to general safety and compliance in handling and storage of the Working Cell Bank and any Raw Materials, other Genentech Proprietary Materials and additional components used in manufacturing Product.

13.4 Facility. Wyeth shall use its Commercially Reasonable Efforts to ensure that the Facility is maintained in accordance with cGMP and Wyeth's standard operating procedures for the Facility are in such condition as will allow Wyeth to manufacture the Product in accordance with the terms and conditions of this Agreement. Wyeth shall use its Commercially Reasonable Efforts to maintain security practices at the Facility consistent with industry standards for comparable manufacturing facilities.

13.5 Subcontracting. Wyeth shall not subcontract any of its obligations hereunder relating to the manufacture of Product or the testing thereof without the prior written approval of Genentech, such approval not to be unreasonably withheld or delayed. The JPT shall review the list of Wyeth subcontractors that will participate in the Technology Transfer. As part of the process for obtaining Genentech's approval for the use of subcontractors for the testing of Product, such subcontractors will be subject to Genentech's certification process and in accordance with the Quality Agreement. As between the Parties, Wyeth shall be liable for the actions of any subcontractor(s) approved and certified in accordance with this Section 13.5 to the same extent as if Wyeth has performed the subcontracted work itself.

13.6 Regulatory Documentation.

13.6.1 Manufacturing and Control Records. Wyeth shall use its Commercially Reasonable Efforts to provide Genentech in a timely manner with a copy of any Wyeth manufacturing and control records for Product that are required for any Genentech regulatory filings with respect to the Product, which records shall be in Wyeth's standard formats unless otherwise agreed upon, in writing, by the Parties.

13.6.2 Other Information. Wyeth shall use its Commercially Reasonable Efforts to provide Genentech promptly after the end of each annual reporting period for the Product (as calculated consistent with applicable United States regulations and guidelines) with such Product related information as is reasonably requested in writing by Genentech for the preparation of the annual report with respect to the manufacturing and control of the Product for such annual reporting period. Thereafter, Genentech shall provide to Wyeth [*] prior to Genentech's filing with the respective regulatory authorities a copy of such Genentech annual report, and Genentech shall take into consideration any Wyeth comments to such annual report with respect to the manufacture of Product.

13.7 Manufacturing Data. Wyeth shall use its Commercially Reasonable Efforts to collect Manufacturing Data from each Batch and make reports summarizing the same available to the JPT in the form of a monthly manufacturing status report in Wyeth's standard format or in such other format as may be agreed by the Parties. Wyeth shall use its Commercially Reasonable Efforts to retain such Manufacturing Data in accordance with the requirements of applicable United States laws, rules and regulations.

13.8 Retention and Reserve Samples. Wyeth shall use its Commercially Reasonable Efforts to isolate, identify and, subject to Section 21.9.4 hereof, retain retention and reserve samples of all Raw Materials and in-process production steps used in the production of Product as may be required by standard operating procedures to be agreed upon in writing by Wyeth and Genentech from time to time.

13.9 Analytical Testing. Wyeth shall perform the analytical testing on Product as contemplated by the Quality Agreement.

13.10 Accurate Documentation. Each Party shall use its Commercially Reasonable Efforts to ensure all records and documentation provided to the other Party in connection with the manufacture of Product shall be accurate in all material respects.

ARTICLE 14.
LICENSES

14.1 License Grants by Genentech.

14.1.1 Genentech, on behalf of itself and its Affiliates, hereby grants to Wyeth and Wyeth's Affiliates a non-exclusive, royalty-free, non-sublicensable (except as necessary for approved subcontractors to perform their obligations in connection with the manufacture or testing of Product under this Agreement) license under Genentech Confidential Information, and under Patent Rights and all other intellectual property rights, if any, owned or Controlled by Genentech or its Affiliates as of the Effective Date or during the Term excluding the Excluded Patents, to the extent necessary to make (solely at the Facility) and sell (solely to Genentech or Genentech's Affiliates in the Territory) Product in accordance with the terms and conditions of the Transaction Agreements.

14.1.2 Genentech, on behalf of itself and its Affiliates, hereby grants to Wyeth and Wyeth's Affiliates a non-exclusive, royalty-free, non-sublicensable, transferable (solely with the sale or transfer of the Facility), perpetual, irrevocable license under the Facility Data solely for the purpose of operating the Facility with respect to any other pharmaceutical product (and any equipment installed therein) following the expiration or termination of this Agreement. For purposes of this Section 14.1.2, "Facility Data" means those elements of the Genentech Confidential Information (including, without limitation, the Genentech Data) that directly pertain to the Facility, the operation of the Facility and/or the equipment installed at the Facility.

14.2 Covenant Not To Sue. Wyeth, on behalf of itself and its Affiliates, hereby covenants that it shall not file suit or assert any claim against Genentech, Roche, their respective Affiliates, their distributors, authorized sales agents and downstream purchasers and users of Product (collectively, the "Licensed Parties") based on infringement by the Licensed Parties of any Manufacturing Process Patent (as defined below), or use of Wyeth know-how or Wyeth Confidential Information that is necessary to perform the Manufacturing Process, in each case arising from the Licensed Parties' use, further manufacture, sale, offer to sell or importation of Product manufactured by Wyeth and delivered to Genentech hereunder (the "Nonsuit"); provided that, Genentech shall be required to reimburse Wyeth for any payments Wyeth is required to make to any Third Party in consideration of licenses or other rights under Manufacturing Process Patents (as defined below) granted to Wyeth by such Third Party and conveyed to the Licensed Parties pursuant to the Nonsuit as a result of (i) Wyeth's practice of any of the Manufacturing Process Patents in the manufacture of Product in accordance with the Manufacturing Process hereunder or (ii) the Licensed Parties' use, further manufacture, sale, offer to sell or importation of Product manufactured by Wyeth and delivered to Genentech hereunder. The Nonsuit granted pursuant to this Section 14.2 shall not apply to any Herceptin that is not manufactured by Wyeth hereunder or any other antibody or any other product.

For purposes of this Article 14, a "Manufacturing Process Patent" means and includes those claims of any Patent Rights owned or Controlled by Wyeth or its Affiliates as of the Effective Date or during the Term of this Agreement, which claims are directed to any part of the Manufacturing Process as it exists on the Effective Date or as it is modified during the Term in accordance with Article 8, subject to the restrictions of Section 14.3. For the sake of clarity, excluded from Manufacturing Process Patents are those claims of Patent Rights owned or Controlled by Wyeth that (a) are not directed to the Manufacturing Process or the manufacture of Herceptin and (b) are specifically directed to (i) all or part of the composition of matter of Herceptin (solely to the extent that such claims were conceived and reduced to practice by Wyeth without use of or reference to Genentech Confidential Information and not from Wyeth's performance of its obligations under any of the Transaction Agreements) or an antibody other than Herceptin, or a product other than Herceptin, (ii) any formulation of Herceptin, any other antibody or any other product, or (iii) any method of using Herceptin, or (iv) any method of using any other

antibody or any other product.

14.3 Modifications to the Manufacturing Process. In the event that Genentech requests a modification to the Manufacturing Process pursuant to Section 8.1 or a request to modify the Manufacturing Process is made pursuant to Sections 8.2, 8.3 or 8.4, and any such change would result in the infringement or practice of any Patent Rights owned or Controlled by Wyeth, or would result in the use of a Wyeth Trade Secret (as defined below) Wyeth shall identify such Patent Right or Wyeth Trade Secret to Genentech, and Genentech shall have the option to obtain a limited license or covenant not to sue under such Patent Rights or Wyeth Trade Secret on commercially reasonable terms, which license or covenant not to sue shall be limited to Product manufactured by Wyeth for Genentech under this Agreement and to Genentech's practice (or a Third Party's practice on behalf of Genentech) of such licensed modifications to the Manufacturing Process for so long as Genentech continues to manufacture Herceptin using such licensed modification (i.e., such license shall be transferable after the expiration or termination of this Agreement and shall apply to Herceptin manufactured by or for Genentech after the Term). In the event that the Parties are unable to reach agreement on commercially reasonable terms despite good faith efforts to do so, the matter shall be submitted to a Third Party expert in the field who is mutually acceptable to the Parties, which Third Party shall review the positions of both Parties and shall conclusively establish the final, binding commercially reasonable terms and conditions for such license by (i) applying standards consistent with comparable industry licenses that have been negotiated between independent parties conducting arms-length negotiations (i.e., without giving regard to Wyeth and Genentech's relationship under the Transaction Agreements) and (ii) not granting terms that would materially alter the terms of any Wyeth license of the Patent Rights or Wyeth Trade Secret that has been granted to a Third Party prior to the commencement of negotiations between the Parties and that contains a "most favored nation" or comparable provision requiring adjustment of the terms of such Third Party license to match any more favorable terms later granted by Wyeth under a separate license of the Patent Rights or Wyeth Trade Secrets. The costs of such Third Party expert shall be paid for by Genentech. For purposes of this Section 14.3, "Wyeth Trade Secret" means a trade secret owned or controlled by Wyeth that is Wyeth Confidential Information, that is not utilized as part of the Manufacturing Process prior to the request to modify the Manufacturing Process pursuant to Section 8.4, and which would be utilized as a result of such modification of the Manufacturing Process.

14.4 No Implied Licenses. Each Party acknowledges and agrees that, except as expressly set forth in this Agreement, no rights or licenses, express, implied or otherwise, covering or relating to the manufacture, use or sale of Product, Herceptin, Finished Product or any other product or process, are granted to either Party by the other Party. Except as expressly set forth in this Agreement, the Transaction Agreements do not grant any right or license, express, implied or otherwise, to either Party under any intellectual property rights of the other Party, by virtue of disclosure of Confidential Information or otherwise and no other right or license is to be implied or inferred from any provision of the Transaction Agreements or by the conduct of the Parties.

ARTICLE 15.
OWNERSHIP OF INTELLECTUAL PROPERTY, MATERIALS AND EQUIPMENT

15.1 Inventorship, Existing Confidential Information, and Inventions.

15.1.1 Inventorship. Inventorship shall be determined in accordance with the rules of inventorship of United States patent laws. As between the Parties, (i) each Party shall solely own any and all inventions or discoveries that are conceived or reduced to practice solely by such Party or its employees or agents in the course of or resulting from the Transaction Agreements, and (ii) the Parties shall jointly own inventions or discoveries that are conceived or reduced to practice jointly by or on behalf of the Parties in the course of or resulting from the Transaction Agreements, without duty of accounting or reporting. The Parties hereby agree that neither Party shall be considered an "employee or agent" of the other Party.

15.1.2 Ownership of Confidential Information. As between the Parties, Genentech shall own all Genentech Confidential Information, and Wyeth shall own all Wyeth Confidential Information; provided, however, that the foregoing shall not limit Genentech's ownership of its rights in and to the Cell Line, the Master Cell Bank, the Working Cell Bank and/or the Manufacturing Process.

15.1.3 Inventions. Notwithstanding Section 15.1.1, as between the Parties:

(a) Subject to Section 14.1, Genentech shall own all rights, including without limitation, all intellectual property rights, in and title to the biological materials described as the Cell Line, the Master Cell Bank, and/or the Working Cell Bank that were made by either Party in performing its obligations under the Transaction Agreements, and all progeny of any of the foregoing that were made by either Party in performing its obligations under the Transaction Agreements.

(b) Subject to Section 14.1, Genentech shall own all of its rights, including without limitation, all intellectual property rights, in and title to the Manufacturing Process and/or the Product, as each of the foregoing existed prior to the Effective Date or as may have been improved, invented or created solely by Genentech, its Affiliates or any of their respective employees, consultants or agents during the Term of this Agreement.

(c) Genentech shall own all rights, including without limitation, all intellectual property rights, in and title to the Herceptin Improvements, as defined below. "Herceptin Improvements" means, and includes, any and all improvements or enhancements to the Cell Line, the Master Cell Bank, the Working Cell Bank, the Manufacturing Process and/or the Product (or any derivatives or variant of the foregoing, or any use of or method of manufacture of the foregoing) that (i) are created by either Party and arise from the performance of their respective obligations under any of the Transaction Agreements and (ii) are solely related to the Cell Line, the Master Cell Bank, the Working Cell Bank, the Manufacturing Process and/or the Product. For the avoidance of doubt, Herceptin Improvements exclude Dual Use Improvements (as defined below).

(d) Wyeth shall assign to Genentech its entire right, title and interest in any and all Herceptin Improvements (and all intellectual property rights therein, excluding pre-existing intellectual property that may be necessary to practice such Herceptin Improvement).

(e) For purposes of this Agreement, a "Dual Use Improvement" shall mean any and all improvements, enhancements or discoveries relating to the Cell Line, the Master Cell Bank, the Working Cell Bank, and/or the Manufacturing Process as to which Wyeth would be deemed an inventor pursuant to Section 15.1.1, which improvement, enhancement or discovery (x) arose from Wyeth's performance of its obligations under any of the Transaction Agreements or through the Permitted Use of Genentech Confidential Information (as defined below) and (y) includes: (i) an enhancement or an improvement to any cell line in addition to or other than the Cell Line, the Master Cell Bank, or the Working Cell Bank, or (ii) a method or process which may be used to manufacture, generate or propagate any cell line in addition to or other than the Cell Line, the Master Cell Bank, or the Working Cell Bank, or (iii) a method for the manufacture of any product in addition to or other than the Product. For purposes of this Section 15.1, a "Permitted Use of Genentech Confidential Information" means, and is limited to, Wyeth's use of Genentech Confidential Information that is expressly permitted under the terms of this Agreement, and excludes any use of Genentech Confidential Information that is proscribed under the terms of this Agreement.

(f) Ownership of Dual Use Improvements shall be determined according to inventorship, pursuant to Section 15.1.1 herein. Subject to Section 15.1.3(g) below, Wyeth shall retain ownership of Wyeth's interest in any Dual Use Improvements as to which Wyeth is a sole or joint inventor, and any intellectual property rights therein.

(g) Wyeth hereby grants to Genentech under its interest in any Dual Use Improvements and any intellectual property rights therein, the following license and option rights:

(i) an exclusive, perpetual, irrevocable, fully-paid (subject to Genentech's obligation to reimburse Wyeth for any payments Wyeth is required to make to any Third Party as a result of Wyeth granting such license to Genentech and Genentech's practice thereof) worldwide license to use such Dual Use Improvement solely for the manufacture of Herceptin or any anti HER-2 antibody that, under applicable United States laws and regulations, is substitutable for Herceptin as a generic product; and

(ii) an option to negotiate a nonexclusive, nontransferable license, on commercially reasonable terms and conditions, to use such Dual Use Improvement for the manufacture of proteins other than either Herceptin or any anti HER-2 antibody that under applicable United States laws and regulations is substitutable

for Herceptin as a generic product (the "Dual Use Improvement Option"). The Dual Use Improvement Option may be exercised by Genentech by providing written notice to Wyeth within sixty (60) days after Wyeth provides Genentech written notification of the existence of such Dual Use Improvement. In the event that Genentech notifies Wyeth of its desire to negotiate for such a license, the Parties shall negotiate in good faith to arrive at commercially reasonable terms and conditions for such license for a period of one-hundred eighty (180) days. In the event that the Parties are unable to reach agreement on commercially reasonable terms by the end of such one hundred eighty (180) day period despite good faith efforts to do so, the matter shall be submitted to a Third Party expert in the field who is mutually acceptable to the Parties, which Third Party shall review the positions of both Parties and shall conclusively establish the final, binding commercially reasonable terms and conditions for such license by (i) applying standards consistent with comparable industry licenses that have been negotiated between independent parties conducting arms-length negotiations (i.e., without giving regard to Wyeth and Genentech's relationship under the Transaction Agreements) and (ii) not granting terms that would materially alter the terms of any Wyeth license of the Dual Use Improvement that has been granted to a Third Party prior to the commencement of negotiations between the Parties and that contains a "most favored nation" or comparable provision requiring adjustment of the terms of such Third Party license to match any more favorable terms later granted by Wyeth under a separate license of the Dual Use Improvement; provided, however, that the Parties shall have no obligation to submit the unresolved terms of a license to a Dual Use Improvement to such expert in the event that the Dual Use Improvement to be licensed was conceived and reduced to practice without use of or reference to the Genentech Confidential Information. The costs of such Third Party expert shall be paid for by Genentech. Notwithstanding the foregoing, except as set forth in Section 15.1.3(g)(i) above, Wyeth shall have no obligation to grant to Genentech any license or other right, title or interest in or to any Dual Use Improvement to the extent doing so would be prohibited by any agreement in existence between Wyeth and any Third Party at the time such Dual Use Improvement is made. Notwithstanding the foregoing, after the Effective Date, Wyeth shall not knowingly enter into any agreement with a Third Party that would materially diminish Genentech's rights to take a license to a Dual Use Improvement under a Dual Use Improvement Option.

(h) Subject to Sections 14.2 and 14.3, Wyeth shall have no obligation to assign or otherwise grant to Genentech any right, title or interest in or to any Wyeth Other Invention (as defined below). For purposes of this Section 15.1, "Wyeth Other Invention" means any invention, development or discovery (including any intellectual property rights therein) that was made by or on behalf of Wyeth or any of its Affiliates, or which otherwise came into the control of Wyeth or any of its Affiliates prior to the Effective Date or during the term of any of the Transaction Agreements, provided any such invention, development or discovery (including any intellectual property rights therein) (i) is not a Herceptin Improvement or a Dual Use Improvement, (ii) did not arise from the use of Genentech Confidential Information and (iii) did not arise from the performance of Wyeth's obligations under the Transaction Agreements.

15.1.4 Survival. The terms of this Section 15.1 shall survive the expiration or termination of this Agreement, and shall be binding upon and inure to the benefit of the successors and assigns of the Parties. The Parties will continue to reasonably cooperate with each other to perfect the rights granted in this Section 15.1.

15.2 Ownership of Equipment.

15.2.1 Genentech Equipment. Genentech shall own all right, title and interest in and to any and all equipment [*] materials, and other assets purchased by Genentech and provided to Wyeth for use under this Agreement, including, without limitation, the equipment listed in Exhibit D of the Technology Transfer Project Plan, the Portable Equipment specified in Section 5.7 and Non-Portable Equipment (collectively, the "Genentech Equipment"), free and clear of any right or claim of Wyeth. All Genentech Equipment shall be maintained in good repair by Wyeth.

15.2.2 Facilities; Wyeth Equipment. Wyeth or one or more of its Affiliates shall own all right, title and interest in and to any and all facilities improvements, [*] and any and all equipment, materials, and other assets purchased by Wyeth or such Affiliates hereunder (including, without limitation, the Wyeth Equipment).

15.2.3 Purchase of Genentech Equipment by Wyeth. Notwithstanding the foregoing, however, at the expiration or termination of this Agreement, Wyeth may, upon mutual agreement of the Parties (including

mutual agreement as to the amount Wyeth shall reimburse Genentech thereof to retain such Genentech Equipment), retain some or all of the Genentech Equipment. In addition, all of the Genentech Equipment shall also be subject to the provisions of Section 21.9 below.

15.2.4 Removal of Genentech Equipment. Upon expiration or termination of this Agreement, if Wyeth fails to timely arrange for the removal, at Genentech's expense, of the Genentech Equipment (other than the Genentech Equipment that the Parties have mutually agreed that Wyeth shall retain and reimburse Genentech for) from the Facility, Genentech shall send written notice requesting such removal. If such removal has not occurred within thirty (30) days after such notice, then Genentech shall be entitled to hire a qualified Third Party at Genentech's expense to enter the Facility with written notice at least five (5) business days in advance and remove such Genentech Equipment, which shall be removed in a reasonable manner without damage to the Facility. For clarification purposes, removal of the Genentech Equipment shall not in and of itself be considered damage to the Facility.

ARTICLE 16.
REPRESENTATIONS AND WARRANTIES

16.1 Genentech. Genentech hereby represents and warrants to Wyeth that:

16.1.1 As of the Effective Date, and without expanding any representation and warranty set forth in this Section 16.1, Genentech owns or has sufficient right, title or interest in and to the Working Cell Bank, Genentech Confidential Information (including, without limitation, the Manufacturing Documentation), and all information to be supplied by Genentech to Wyeth under any of the Transaction Agreements to supply the same to Wyeth for Wyeth's use in accordance with the terms and conditions of the Transaction Agreements;

16.1.2 Except as otherwise disclosed to Wyeth by Genentech as of the Effective Date, to the actual knowledge of members of the Genentech legal department as of the Effective Date, without a duty of inquiry and without conducting any additional inquiry with respect to this Agreement, there is no lawsuit pending against Genentech in the Territory that alleges patent infringement by the manufacture or sale of the Product, the use of the Manufacturing Process or the use or propagation of any of the Genentech Proprietary Materials or Raw Materials (to the extent such use or propagation is undertaken as part of performing the Manufacturing Process);

16.1.3 Except as otherwise disclosed to Wyeth by Genentech as of the Effective Date, to the actual knowledge of members of the Genentech legal department as of the Effective Date, without a duty of inquiry and without conducting any additional inquiry with respect to this Agreement, Genentech has not received written notice alleging infringement of a Third Party patent by the manufacture or sale of the Product;

16.1.4 To the actual knowledge of members of the Genentech legal department as of the Effective Date, without a duty of inquiry and without conducting any additional inquiry with respect to this Agreement, the manufacture, use or sale of the Product, the use of the Manufacturing Process (including the use or propagation of any of the Genentech Proprietary Materials or the Raw Materials to the extent such use or propagation is undertaken as part of performing the Manufacturing Process) do not infringe any issued United States patent owned or controlled by any Third Party;

16.1.5 To the actual knowledge of members of the Genentech legal department as of the Effective Date, without a duty of inquiry and without conducting any additional inquiry with respect to this Agreement, based upon the scope of claims and content of such patent applications as of the Effective Date, no Third Party has any United States patent application pending which, if issued, would be infringed by the manufacture, use or sale of the Product, the use of the Manufacturing Process, including the use of any of the Genentech Proprietary Materials or the Raw Materials to the extent such use is undertaken as part of performing the Manufacturing Process;

16.1.6 Genentech's license agreements to the [*] and [*] (as those terms are defined in Exhibit A hereto) grant Genentech the right to retain Wyeth to manufacture Product as provided hereunder and as a result, Wyeth's manufacture of the Product hereunder and in accordance with the terms and conditions of this Agreement would not constitute an unlicensed infringement of the [*]; and

16.1.7 Genentech has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations under this Agreement.

16.2 Wyeth. Wyeth hereby represents and warrants to Genentech that:

16.2.1 To Wyeth's knowledge as of the Effective Date, Wyeth is free to supply the Wyeth Confidential Information to Genentech;

16.2.2 Wyeth has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations under this Agreement;

16.2.3 Wyeth owns, lawfully controls or has sufficient rights to use the Facility to perform its obligations hereunder; and

16.2.4 Wyeth has not entered into written agreements with any Third Party to conduct commercial production at the Facility or is otherwise subject to any covenant or obligation that would result in Wyeth not being able to fulfill the manufacturing obligations assumed by it hereunder.

ARTICLE 17.
INDEMNIFICATION AND INSURANCE

17.1 Indemnification.

17.1.1 Indemnification by Genentech. Subject to and except to the extent of any indemnification from Wyeth pursuant to Section 17.1.2 below, Genentech shall indemnify, defend and hold Wyeth, its Affiliates, and their respective directors, officers, employees and the estates and heirs thereof (the "Wyeth Indemnified Parties") harmless from and against any and all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses), (collectively, the "Liabilities") to the extent such Liabilities arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of [*] Notwithstanding the foregoing, Genentech's indemnity obligation hereunder shall not apply to those Liabilities for which Wyeth is obligated to indemnify Genentech pursuant to Section 17.1.2 [*]

17.1.2 Indemnification by Wyeth. Wyeth shall indemnify, defend and hold Genentech, and its Affiliates, directors, officers, employees and the estates and heirs thereof (the "Genentech Indemnified Parties") harmless from and against all Liabilities to the extent such Liabilities arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of [*] Notwithstanding the foregoing, Wyeth's indemnity obligation hereunder shall not apply to those Liabilities for which Genentech is obligated to indemnify Wyeth pursuant to Section 17.1.1 [*]

17.2 Indemnification Procedures.

17.2.1 Identification of Indemnitor and Indemnitee. An "Indemnitor" means Genentech with respect to Section 17.1.1 hereof, and Wyeth with respect to Section 17.1.2 hereof. An "Indemnitee" means any of Wyeth, its Affiliates, and their respective directors, officers, and employees with respect to Section 17.1.1 hereof, and any of Genentech, and its respective Affiliates, directors, officers and employees with respect to Section 17.1.2 hereof.

17.2.2 Indemnification Procedures. An Indemnitee that intends to claim indemnification under Section 17.1.1 or 17.1.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, and employees intend to claim such indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, and employees to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, such settlement does not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein in order for the Indemnitor to exercise such rights. No such

claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

17.3 Insurance.

17.3.1 Insurance. During the term of this Agreement, and thereafter for the period of time required below, each Party shall maintain:

(i) Workers Compensation Insurance as required by applicable law with Employers Liability limits at a limit of [*]

(ii) Commercial General Liability ("CGL") insurance, including contractual and professional liability coverage, in the [*] for bodily injury and property damage with an [*]

(iii) A Fidelity Bond or Crime Coverage policy; and

(iv) All Risks property insurance, including transit coverage (transit coverage may be included in separate policy), in an amount equal to the value of Genentech's property while it is at the Facility. Coverage afforded herein shall be primary coverage up to the required limit regardless of other insurance clauses.

17.3.2 Special Requirements.

(a) Genentech or Wyeth, as applicable, shall be named as additional insureds under the insurance policies set forth in Section 17.3.1, excluding the Workers Compensation policy.

(b) Genentech or Wyeth, as applicable, shall have the right to perform, directly or through its representatives, property inspections and loss control inspections with respect to the all-risk property policy.

(c) The CGL insurance policy shall be under either an occurrence or a claims made based policy form and the CGL insurance coverage shall be maintained by Genentech or Wyeth, as applicable, for at least three (3) years following expiration or termination of this Agreement.

(d) Each of the above insurance policies shall be primary insurance as respects Genentech's or Wyeth's participation under this Agreement.

(e) All of the above insurance coverage shall be maintained with an insurance company or companies having an A.M. Best's rating of "A-VII" or higher.

17.3.3 Notice of Insurance. Within thirty (30) days from the execution of this Agreement, each Party shall provide the other Party a certificate insurance reflecting the above requirements. Renewal certificates shall continue to be provided throughout the term of this Agreement, and in case of cancellation or material change, a thirty (30) day notice shall be provided to the other Party.

17.4 Survival of Indemnification Obligations. The provisions of Section 17.1 and 17.2 and the right of a Party to seek coverage from an insurance policy required by Section 17.3 for events or activities that occurred prior to termination or expiration of this Agreement shall survive the termination or expiration of this Agreement.

ARTICLE 18.
LIABILITY

18.1 Liability for Intentional Breach by Wyeth. [*]

18.2 Duty to Mitigate Damages. In the event of an uncured Intentional Breach by Wyeth as expressly set forth in Section 18.1, Genentech shall use its Commercially Reasonable Efforts to take all actions to mitigate any damages arising from such breach, including, without limitation, drawing from Genentech's existing inventory of Product that is above and beyond its risk mitigation inventory (as described below) or other reasonably available sources of Product to address any shortfall in inventory resulting from such breach; provided, however, that this Section 18.2 shall not obligate Genentech (i) to draw from its risk mitigation inventory, [*], intermediate formulations thereof and Finished Product) to mitigate such damages or (ii) to initiate Product manufacturing at an alternate production site if such manufacturing would have a material adverse impact on Genentech's production or supply of any other biopharmaceutical product.

18.3 Disclaimer of Consequential Damages. EXCEPT FOR CLAIMS ARISING FROM (A) THE INTENTIONAL MISUSE OR MISAPPROPRIATION OF THE OTHER PARTY'S CONFIDENTIAL INFORMATION OR INTELLECTUAL PROPERTY, (B) ANY INDEMNIFICATION OBLIGATIONS ARISING UNDER ARTICLE 17 OR (C) [*], IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING FROM OR RELATED TO BREACH OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, ANY CLAIMS FOR DAMAGES BASED UPON LOST PROFITS FOR SALES TO THIRD PARTIES.

18.4 Limitation of Liability.

18.4.1 Except as set forth in Section 18.1 above and for claims arising from Wyeth's indemnification obligations under Section 17.1.2, [*] however the same may be caused, including, without limitation, through the fault, breach of contract, tort (including the concurrent or sole and exclusive negligence), strict liability or otherwise of Wyeth, provided however, that to the extent such direct damages arose from the willful misconduct of Wyeth and its Affiliates, such liability cap(s) shall not apply. For purposes of the foregoing, any losses or damages arising out of a series of related events or the same set of operative facts or circumstances shall be treated as a single occurrence.

18.4.2 With respect to Genentech's direct damages for a breach of Wyeth's obligation to manufacture Product hereunder, [*] Genentech's damages shall be determined by calculating the incremental reasonable cost above the Conversion Fee (including only the per batch fees and excluding start up costs or fees, technology transfer costs or fees, capacity reservation or commitment costs or fees, lost opportunity costs or fees, development costs or fees whether billed separately or included as part of a per batch fee or cost) incurred by Genentech in obtaining that quantity of Product to meet any shortfall resulting from such Wyeth breach.

ARTICLE 19.
CONFIDENTIALITY

19.1 Confidentiality Obligations.

19.1.1 Wyeth Confidentiality Obligations. Wyeth shall not disclose Genentech Confidential Information to any Third Party other than:

(a) its employees who are bound by obligations of confidentiality and nonuse no less restrictive than those set forth in this Agreement, and who have a need to know such information in order to perform their duties in carrying out Wyeth's obligations under the Transaction Agreements,

(b) consultants, agents or subcontractors used by Wyeth in accordance with Section 13.5 hereof who are bound by obligations of confidentiality and nonuse no less restrictive than those set forth in this Agreement, and who have a need to know such information in order to provide direction to Wyeth or Genentech regarding their respective obligations under the Transaction Agreements or in order to (i) perform their duties in carrying out Wyeth's obligations under the Transaction Agreements, or (ii) provide direction to Wyeth regarding the subject matter of this Agreement, including, but not limited to, production, testing, storage or quality of the Product or regulatory or compliance issues related to the Product, or

(c) regulatory authorities, for example, the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

19.1.2 Genentech Confidentiality Obligations. Genentech shall not disclose any Wyeth Confidential Information to any Third Party other than:

(a) employees, consultants, agents or contractors of Genentech or Genentech's Affiliates who are bound by obligations of confidentiality and nonuse no less restrictive than those set forth in this Agreement and who have a need to know such information in order to perform their duties in carrying out Genentech's obligations under the Transaction Agreements, or in order to provide direction to Genentech regarding the subject matter of this Agreement, including, but not limited to, production, testing, storage or quality of the Product or regulatory or compliance issues related to the Product, or

(b) regulatory authorities, for example, the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

19.2 Terms of Agreement. Subject to Sections 19.3 and 20.1 hereof, neither Party shall, without the prior written consent of the other Party, disclose in any manner to any Third Party the terms and conditions of this Agreement. Notwithstanding the foregoing, either Party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable laws, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission (the "SEC"), provided, however, that before disclosing this Agreement or any of the terms hereof pursuant to this Section 19.2, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure. If a Party discloses this Agreement or any of the terms hereof in accordance with this Section 19.2, such Party agrees, at its own expense, to use diligent efforts to obtain confidential treatment of portions of this Agreement or such terms, as may be reasonably requested by the other Party.

19.3 Notification of Mandatory Disclosure.

19.3.1 Notification and Consultation. In the event that a Party (in such case, the "Notifying Party") believes it is required by applicable statute or regulation, or by judicial or administrative process to disclose any part of the other Party's (in such case, the "Notified Party") Confidential Information which is disclosed to it under this Agreement, the Notifying Party shall (i) promptly notify the Notified Party of each such requirement and identify the documents so required thereby, so that the Notified Party may seek an appropriate protective order or other remedy and/or waive compliance by the Notifying Party with the provisions of this Agreement, and (ii) consult with the Notified Party on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

19.3.2 Limited Disclosure. If, in the absence of such a protective order or such a waiver by the Notified Party of the provisions of this Agreement, the Notifying Party is nonetheless required by mandatory applicable law to disclose any part of the Notified Party's Confidential Information which is disclosed to it under this Agreement, the Notifying Party may disclose such Confidential Information without liability under this Agreement, except that the Notifying Party shall furnish only that portion of the Confidential Information which is legally required to be disclosed.

19.4 Maintenance of Confidentiality; Non-use Obligations.

19.4.1 [RESERVED].

19.4.2 Maintenance of Confidentiality. Each Party shall use reasonable and customary precautions to safeguard the other Party's Confidential Information, including ensuring that all employees, consultants, agents or contractors who are provided access to such Confidential Information are informed of the confidential and proprietary nature of such Confidential Information and have confidentiality and nonuse obligations that are at least as restrictive as those contained in this Agreement.

19.4.3 Non-use Obligations. Wyeth shall not use Genentech Confidential Information for any purpose other than performing its obligations under the Transaction Agreements, without first obtaining Genentech's prior written consent to such utilization. Wyeth Confidential Information shall not be utilized by Genentech for any purpose except as expressly set forth in the Transaction Agreements, without first obtaining Wyeth's prior written consent to each such utilization. Without limiting the foregoing, a Party (the "Asserting Party") and its Affiliates shall not assert against the other Party or that Party's Affiliates any intellectual property right owned or controlled by the Asserting Party or its Affiliates to the extent such assertion is based on knowledge or information obtained from access hereunder to the other Party's Confidential Information. Without limiting the foregoing, Wyeth and its Affiliates shall not use or refer to the Genentech Confidential Information either to make inventions or to file for Patent Rights except as expressly permitted under the terms and conditions of Section 15.1, and Genentech and its Affiliates shall not use or refer to the Wyeth Confidential Information either to make inventions or to file for Patent Rights except as expressly permitted under the terms and conditions of Section 15.1.

19.5 Survival of Confidentiality Obligations. The provisions of this Article 19 shall survive the termination or expiration of this Agreement for a period of five (5) years; provided, however, that with respect to the Facility Data, the provisions of this Article 19 shall survive the termination or expiration of this Agreement for so long as Wyeth uses such Facility Data and for a period of five (5) years thereafter.

19.6 Termination of Certain Prior Agreements. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated November 18, 2003. All Confidential Information exchanged between the Parties under such previous agreement shall be deemed Confidential Information under this Agreement (either Genentech Confidential Information or Wyeth Confidential Information, as the context requires) and shall be subject to the terms of this Agreement.

19.7 No Disclosure of Unrelated Information. Neither Party shall disclose Confidential Information to the other Party that is not reasonably necessary for performance of a Party's obligations under the Transaction Agreements, including but not limited to manufacturing processes for other products, marketing plans and clinical development plans. Notwithstanding the foregoing, nothing in this provision shall limit the confidentiality and non-use obligations and rights herein, including, without limitation, with respect to any such other Confidential Information inadvertently disclosed to or which is observed by the other Party or its representatives in the course of performing its obligations or exercising it rights under any of the Transaction Agreements.

ARTICLE 20.
PRESS RELEASES; USE OF NAMES

20.1 Press Releases. Following the Effective Date, the Parties shall agree upon a press release to announce the execution of this Agreement together with a corresponding question and answer outline for use in responding to inquiries about this Agreement. Such press release shall be made on or before September 31, 2004, the timing of which such announcement shall be mutually agreed by the Parties. Following the publication of such press release, each Party shall be entitled to make or publish any public statement consistent with the contents of such press release and question and answer outline without the need for further approval by the other. Except as set forth in the preceding sentences of this Section 20.1, no press release, publicity or other form of public written disclosure related to this Agreement shall be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing subject to Section 19.2 above. This Section 20.1 shall not apply to any disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with regional, national, federal or state or local laws or regulations in the Territory (including the rules and regulations of any national stock exchange on which such Party's securities are traded).

20.2 Use of Names. No Party shall make use of the name of any other Party in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party; provided, however, either Party may include the name of the other Party on a general list of business partners or collaborations.

ARTICLE 21.
TERM; TERMINATION

21.1 Term; Option to Extend. Unless sooner terminated pursuant to the terms of this Agreement, the term of this Agreement (the "Term") shall commence on the Effective Date and shall continue until [*]; provided, however, that the Parties may extend the Term for an additional one (1) year upon mutual written agreement of terms and conditions to be reached no later than [*]. During any such extension, all terms of this Agreement and the Quality Agreement shall apply. As used herein "Term" shall mean the initial Term, including any extension thereof.

21.2 Notice; Cure. In the even that a Party (the "Breaching Party") is in material breach of any provision of this Agreement, the other Party (the "Nonbreaching Party") may provide written notice thereof to the Breaching Party, specifying in reasonable detail the nature of such breach. The Breaching Party shall have (a) thirty (30) days after receipt of written notice to cure any breach of an obligation to make a payment under this Agreement (other than any portion thereof that is disputed in accordance with Section 6.9) and (b) ninety (90) days after receipt of such written notice to cure any other breach, or a longer period of time if the Breaching Party delivers written notice to the Nonbreaching Party of the Breaching Party's good faith determination that such material breach is not reasonably capable of being cured within such ninety (90) days and that the Breaching Party is working diligently to cure such breach, but in no event shall the time for curing such breach exceed an additional ninety (90) days or a total of one hundred eighty (180) days (any such period, a "Cure Period"). If the Breaching Party's breach is a material breach of a material provision of this Agreement, the Nonbreaching Party shall have no right to suspend its performance hereunder during the Cure Period unless and only to the extent that such breach by the Breaching Party adversely affects the ability of the Nonbreaching Party to perform.

21.3 Termination for Material Breach. In the event any material breach of a material provision of this Agreement is not cured within the applicable Cure Period, after receipt of written notice from the Nonbreaching Party to the Breaching Party in accordance with Section 21.2, this Agreement shall terminate as set forth in the Nonbreaching Party's notice of breach and in accordance with the terms of this Article 21; provided, however, that this Agreement shall not be terminated prior to the end of such Cure Period.

21.4 Termination for Failure to Timely Achieve Key Milestones.

21.4.1 Wyeth, in its sole discretion, may terminate this Agreement in its entirety upon thirty (30) days prior written notice to Genentech, if Genentech does not file the sBLA with the FDA within ninety (90) days after the completion of sBLA Data Delivery by Wyeth.

21.4.2 In addition, notwithstanding Section 24.1, either Party shall have the right to terminate this Agreement, in its sole discretion, upon thirty (30) days prior written notice to the other Party, in the event that either (i) the sBLA for the Product is withdrawn or rejected or (ii) FDA Approval is not received within one (1) Calendar Year of the date Genentech files the sBLA with the FDA.

21.5 Termination for Failure to Achieve Development Run Completion or [*]

21.5.1 Genentech may, in its sole discretion, terminate this Agreement in its entirety upon [*] prior written notice to Wyeth, if either (i) Wyeth cannot achieve Development Run Completion after [*] Following notice of termination under this Section 21.5.1, the Parties will use the remaining days of the Term to wind-down activities under this Agreement, consistent with Section 21.9.

21.5.2 Wyeth may, in its sole discretion, terminate this Agreement in its entirety [*] prior written notice to Genentech, if Genentech has not terminated the Agreement under Section 21.5.1 [*] after receiving notice from Wyeth of Genentech's failure to notify Wyeth of its election to either authorize additional Development Runs or terminate the Agreement (all in accordance with Section 4.7.2), [*] prior written notice to Genentech, if Wyeth cannot achieve Development Run Completion after either [*] prior written notice to Genentech, Wyeth cannot achieve [*] after completion of the total number of Qualification Run Starts authorized in accordance with Section 4.8.2. Following notice of termination under this Section 21.5.2, the Parties will use the remaining days of the Term to wind-down activities under this Agreement, consistent with Section 21.9.

21.6 Termination for Failure to Resolve Operational Issues. Genentech, in its sole discretion, shall have the right to terminate this Agreement in its entirety upon thirty (30) days prior written notice to Wyeth, if an Operational Issue is preventing substantial performance by either Party under this Agreement and remains unresolved for more than thirty (30) days after the mutually agreed Target Resolution Date for such issue despite good faith efforts by both Parties to resolve the issue in accordance with Section 3.2. Wyeth, in its sole discretion, shall have the right to terminate this Agreement in its entirety upon thirty (30) days prior written notice to Genentech, if an Operational Issue is preventing substantial performance by either Party under this Agreement and remains unresolved for more than sixty (60) days after the mutually agreed Target Resolution Date for such issue despite good faith efforts by both Parties to resolve the issue in accordance with Section 3.2.

21.7 Termination for Excessive Impact of Requested Changes. Either Party shall have the right to terminate this Agreement upon ninety (90) days prior written notice to the other Party in the event that any requested change made by the other Party or the FDA in accordance with Section 8.5 (and that is not withdrawn in accordance with Section 8.5.2) would result in either (i) [*] of Facility downtime (in the case of requested changes to be implemented prior to Commercial Production) or (ii) [*] of Facility downtime (in the case of requested changes to be implemented during Commercial Production).

21.8 Termination upon Certain Events; [*]

21.8.1 In the event (a) of any Change of Control of Wyeth or the business or operating unit(s) of Wyeth or its Affiliates that are performing all or substantially all of Wyeth's obligations hereunder (the "Wyeth Entities"), or (b) that Wyeth sells to a Third Party its Andover, Massachusetts facility or the portion thereof containing the Facility, Genentech shall have the right to terminate this Agreement, in its sole discretion, upon written notice to Wyeth and payment of the applicable Termination Fee, which notice must be delivered to Wyeth within thirty (30) days after consummation of such event or, if such event is not the subject of a public announcement made by Wyeth, within thirty (30) days after Wyeth delivers notice to Genentech that such event has been consummated. In addition, notwithstanding Section 24.1, either Party shall have the right to terminate this Agreement, in its sole discretion, upon thirty (30) days prior written notice to the other Party, in the event that the BLA for Herceptin is withdrawn by Genentech or Genentech otherwise withdraws Herceptin from the market in the United States. For purposes of this Section 21.8.1, "Change of Control" means the occurrence of any of the following events: (a) any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 and 13d-5 under the Exchange Act) of more than fifty percent (50%) of the total voting stock of a Wyeth Entity or (b) a Wyeth Entity consolidates with, or merges with or into, another person or sells, assigns, conveys, transfers, leases or otherwise disposes of all or substantially all of its assets to any person, or any person consolidates with, or merges with or into a Wyeth Entity, in any such event pursuant to a transaction in which the holders of the outstanding voting stock of that Wyeth Entity immediately prior to such transaction hold less than fifty percent (50%) of the outstanding voting stock of the surviving or transferee company or its parent company immediately after such transaction or immediately after such transaction any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act) is the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act), directly or indirectly, of more than fifty percent (50%) of the total voting stock of the surviving or transferee company or its parent company; provided, however, that a "Change of Control" shall not include a transfer of all or substantially all of the assets of a Wyeth Entity to one or more wholly owned subsidiaries or any merger or consolidation of Wyeth immediately after which holders of the outstanding voting stock of that Wyeth entity immediately prior to such transaction hold fifty percent (50%) or more of the outstanding voting stock of the surviving company or its parent company. For purposes of this definition, "Exchange Act" means the Securities Exchange Act of 1934 and the rules and regulations of the U.S. Securities and Exchange Commission thereunder, and any successor to such statute or such rules and regulations.

21.8.2 In the event of any termination of this Agreement by Genentech or Wyeth pursuant to this Section 21.8, Genentech, in addition to any amounts that may be payable in accordance with Section 21.9 below, shall pay to Wyeth [*]

21.9 Consequences of Termination.

21.9.1 Payment of Amounts Due; Cumulative Remedies. Expiration or termination of this Agreement for any reason shall not exempt any Party from paying to any other Party any amounts (other than amounts in dispute in accordance with procedures set forth in Section 6.9) owing to such Party at the time of such expiration or termination (and after resolution of such dispute, from paying such previously disputed amount, if applicable). Except as expressly stated otherwise herein, remedies under this Agreement are cumulative, and nothing in this Agreement shall prevent any Party, in the case of a material breach (after expiration of the applicable Cure Period and notice periods), from terminating this Agreement and seeking to enforce its rights under this Agreement.

21.9.2 Work in Progress. Upon any termination of this Agreement, Genentech shall pay Wyeth at the prevailing Conversion Fee for all Batches that have been manufactured but not yet delivered to Genentech as of the effective date of such termination and at a price to be agreed upon (but in no event to exceed the Conversion Fee) for all Batches that are otherwise in-process Runs as of the effective date of such termination. Upon termination of this Agreement, any Runs that were scheduled to be initiated on or after the effective date of such termination shall be canceled. Runs that are in-process at the [*] scale as of the effective date of any such termination shall not be cancelled without the mutual agreement of the Parties, and the Agreement shall continue to survive with respect to those in-process Runs.

21.9.3 Return of Raw Materials. Subject to Wyeth's obligation upon receipt of a notice of termination to place no further orders for Raw Materials, intermediates or packaging components except as may be necessary for completion of any portion of Wyeth's services hereunder that are not immediately terminated, upon expiration of this Agreement or termination of this Agreement pursuant to this Article 21, Wyeth shall either destroy or transfer to Genentech, at Genentech's option and expense, all remaining usable Raw Materials ordered from the [*] for the manufacture and packaging of Product under this Agreement. Wyeth shall invoice Genentech for Wyeth's cost of all such Raw Materials destroyed or delivered to Genentech under this Section 21.9.3 upon the date of destruction or delivery of such Raw Materials, and Genentech shall pay such invoice in accordance with the terms of Section 6.9.

21.9.4 Return of Genentech Proprietary Materials and of Genentech Confidential Information, Transfer of Genentech Equipment. Upon expiration or termination of this Agreement, unless otherwise directed by Genentech, Wyeth shall, within thirty (30) days after such expiration or termination: (i) either destroy or transfer to Genentech, at Genentech's option and expense, all quantities of Product and all quantities of the Cell Line, Master Cell Bank, and Working Cell Bank received by Wyeth under this Agreement or the Quality Agreement, with any such destruction to be certified in writing to Genentech by an authorized Wyeth officer, (ii) return all Genentech Confidential Information to Genentech, provided that Wyeth may keep one (1) copy of the Genentech Confidential Information for its legal records with such Confidential Information continuing to be subject to the confidentiality provisions of this Agreement, and (iii) return to Genentech all retention and reserve samples of Product being held by Wyeth pursuant to Section 13.8 hereof. In addition, if requested by Genentech, Wyeth, at Genentech's expense, shall transfer the Genentech Equipment to Genentech in accordance with Section 15.2 hereof.

21.9.5 Return of Wyeth Confidential Information. Upon expiration or termination of this Agreement, and at Wyeth's written request, Genentech shall promptly return all Wyeth Confidential Information to Wyeth; provided that Genentech may keep one (1) copy of such Wyeth Confidential Information for its legal records with such Confidential Information continuing to be subject to the confidentiality provisions of this Agreement.

21.9.6 Accrued Rights. Except as otherwise expressly set forth herein, any termination or expiration of this Agreement shall be without prejudice to any right which shall have accrued to the benefit of either Party and shall not relieve either Party of any warranties or obligations that have accrued prior to the effective date of such termination or expiration including, without limitation, any liability for breach of this Agreement, which obligations or warranties shall remain in full force and effect for the period provided therein or, if no period is provided therein, then such obligations shall remain in full force and effect indefinitely.

ARTICLE 22.
ASSIGNMENT

22.1 Assignment. This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party; provided, however, either Party may assign its interest under this Agreement, without the prior written consent of the other Party, (a) to an Affiliate, so long as such Party guarantees the obligations of such Affiliate, or (b) subject to Section 21.8, to a successor of such Party's business by reason of merger, sale of all or substantially all of the assets of the business to which this Agreement relates or other form of acquisition. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment. Notwithstanding anything in this Agreement to the contrary, Wyeth may use one or more of its Affiliates to perform all or a portion of its obligations hereunder, but Wyeth will not thereby be relieved of any obligation under this Agreement.

ARTICLE 23.
DISPUTE RESOLUTION

23.1 Intellectual Property Disputes. Any dispute relating to the determination of validity of a Party's patents or other issues relating to a Party's intellectual property and which dispute arises under this Agreement shall be submitted exclusively to any federal court having jurisdiction over the Parties and the matter, or to a state court in such jurisdiction if the applicable rules of civil procedure preclude federal court jurisdiction, and the Parties hereby consent to the jurisdiction and venue of such courts, and therefore Section 23.1 below shall not apply to any such disputes.

23.2 Dispute Resolution.

23.2.1 Disputes. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement that relates to a Party's rights and/or obligations under the Transaction Agreements. Unless otherwise specifically recited in this Agreement, disputes arising under the Transaction Agreements will be resolved as recited in this Section 23.1. In the event of the occurrence of such a dispute, either Party may, by written notice to the other Party, have such dispute referred to their respective executive officers designated below, or their respective successors or designees, for attempted resolution by good faith negotiations within thirty (30) business days after such notice is received. Such designated officers are as follows:

For Genentech -- Vice President, Global Supply Chain

For Wyeth -- Executive Vice President and General Manager, BioPharma Business Unit

In the event the executive officers, or their respective successors or designees, are not able to resolve such dispute within such thirty (30)-day period, or such other period of time as the Parties may mutually agree in writing, either Party may pursue any legal or equitable remedies available to it by filing a claim exclusively in the federal courts of the state of Delaware, provided, however, that if there is no federal court jurisdiction over such claim, either Party may pursue such claim exclusively in Delaware state court and, in the case of each of the foregoing, each Party hereby consents to the jurisdiction of such court and each Party hereby irrevocably waives its right to a jury trial before any such court. Notwithstanding the foregoing, nothing in this Section 23.1 (including the duty to engage in good faith negotiations between the Parties' executive officers) shall prohibit a Party from seeking provisional or equitable relief, including, without limitation, attachment, replevin, or preliminary or temporary injunctive relief from any state or federal court having jurisdiction over the matter to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the dispute pending the resolution of a dispute in accordance with the provisions of this Section 23.1.

ARTICLE 24.
FORCE MAJEURE

24.1 Effect of Force Majeure Event. Neither Party shall be in breach of this Agreement if there is any failure of its performance under this Agreement (except for payment of any amounts due under this Agreement) as a result of any reason beyond the control and without the fault or negligence of the Party affected thereby, including an act of God (including, without limitation, fire, earthquake, flood, storm or other natural disaster), act of government or state or an agency thereof (including without limitation, any changes to applicable laws or regulations, order or injunction, that has a material adverse affect on a Party's ability to perform its obligations hereunder), war, acts of terrorists, civil unrest, insurrection, embargo, lack of viability of any biological materials provided by Genentech and a failure of Genentech to replace such biological materials, an infectious virus or other contaminant which causes a shutdown for a substantial period of a large portion of Wyeth's Andover facility or all or part of the Facility itself due to contamination despite Wyeth's use of Commercially Reasonable Diligent Efforts to prevent such occurrence, prevention from or hindrance in obtaining energy or other utilities, a market shortage of or other failure of Third Party suppliers to supply Raw Materials or other necessary components of the Manufacturing Process (other than due to Wyeth's failure to satisfy its obligations under Section 4.9.2), or labor disputes (including work stoppages resulting therefrom) of whatever nature (each, a "Force Majeure Event"). Nothing in this Section 24.1 shall, however, release such Party from using its Commercially Reasonable Diligent Efforts to avoid or remove all such causes. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement.

24.2 Notice of Force Majeure. Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under this Agreement. Each Party further agrees to use Commercially Reasonable Diligent Efforts to correct the Force Majeure Event as quickly as practicable and to give the other Party prompt written notice when it is again fully able to perform such obligations.

24.3 Target Dates and Milestones. In the event of any Force Majeure Event, the Target Dates specified in Section 4.3 and/or the dates for completion of milestones set forth in Section 6.3 shall be extended by the period of time during which such Force Majeure Event exists.

24.4 Termination. Subject to Sections 21.8 and 21.9, either Party may terminate this Agreement if a Party is unable to substantially perform its obligations hereunder as a direct result of a Force Majeure Event that remains unresolved for a period of six (6) months despite efforts to correct the Force Majeure Event in accordance with Section 24.2.

ARTICLE 25.
MISCELLANEOUS

25.1 Notices. Other than notices within the jurisdiction of the respective Project Team Leaders, which shall be given to those individuals, any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with the original promptly sent by any of the foregoing manners), to the addresses or facsimile numbers of the other Parties set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to Genentech:
Corporate Secretary
Genentech, Inc.
One DNA Way
South San Francisco, CA 94080
Fax: (650) 952-9881
Phone: (650) 225-1672

with a copy to: Senior Vice President of Product Operations
Genentech, Inc.
One DNA Way, MS 53
South San Francisco, CA 94080
Fax: (650) 225-5007
Phone: (650) 225-3978

If to Wyeth: Executive Vice President and General Manager, BioPharma Business Unit
Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426
Fax: (484) 865-9091
Phone: (484) 865-7951

with a copy to: General Counsel
Wyeth
Five Giralda Farms
Madison, NJ 07940
Fax: (973) 660-7050
Phone: (973) 660-6138

and

Senior Vice President, Global Business Development
Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426
Fax: (484) 865-6476
Phone: (484) 865-5442

25.2 Applicable Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal substantive laws of the State of Delaware and with respect to patent disputes, United States federal law to the extent not covered by state law, without reference to the choice of law doctrine of such state.

25.3 Headings. The table of contents and all headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement.

25.4 Exhibits. All exhibits referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

25.5 Severability. Each Party hereby expressly agrees that it has no intention to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or any Party hereto, in a final unappealed or unappealable order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as enforcement of the remainder does not violate the Parties' overall intentions in this transaction.

25.6 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall hold itself out to Third Parties as purporting to act on behalf of, or serving as the agent of, the other Party.

25.7 Waiver. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

25.8 Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

25.9 Harmful or Additional Materials. During the Term, Wyeth shall not introduce any cell lines or biological products into the Facility other than as set forth herein without Genentech's prior written consent. In addition, Wyeth agrees not to use any form of penicillin or cephalosporin in the Manufacturing Process utilized at the Facility, without Genentech's prior written consent.

25.10 Non-Solicitation. The Parties recognize that each Party has a substantial interest in preserving and maintaining confidential its Confidential Information hereunder. Each Party recognizes that certain of the other Party's key or technical employees, including those engaged in manufacturing, validating and testing Product, may have access to such Confidential Information of the other Party. The Parties therefore agree not to knowingly solicit or otherwise induce or attempt to induce for purposes of employment, any key or technical employees from the other Party directly involved in the manufacturing, validating or testing of any Product during the Term and for a period of two (2) years thereafter, it being understood that the foregoing shall not include (i) employees who first approach a Party for employment, (ii) solicitations or hiring as part of a general employee solicitation not targeted specifically at employees of the other Party, and (iii) solicitations or hiring by members of a Party's organization without knowledge of this Agreement or who have not been exposed to the Confidential Information of the other Party.

25.11 Entirety; Amendments. This Agreement, including any exhibits attached hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof (i.e., purchase and supply of Product), and supersedes and terminates all other agreements, oral or otherwise, between the Parties, including, without limitation the LOI and the Confidential Disclosure Agreement between the Parties dated November 18, 2003. No terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless it is hereafter made in writing and signed by each of the Parties. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any purchase order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein. In the event of a conflict between this Agreement, the exhibits hereto, the Technology Transfer Project Plan or the Quality Agreement, the terms of this Agreement shall control. This Agreement may be amended and supplemented only by a written instrument signed by each of the Parties.

25.12 SAP Implementation. Wyeth shall use its Commercially Reasonable Diligent Efforts to avoid any material adverse impact on the conduct of either the Technology Transfer or the activities necessary to support FDA Approval as a result of the implementation of the enterprise resource planning system from SAP at Wyeth's Andover, Massachusetts facility during the Term.

25.13 Interpretation. For purposes of interpreting this Agreement, whenever the context requires, the singular number will include the plural, and vice versa; the masculine gender will include the feminine and neuter genders; the feminine gender will include the masculine and neuter genders; and the neuter gender will include the masculine and feminine genders. Any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not be applied in the construction or interpretation of this Agreement. As used in this Agreement, the words "include" and "including" and variations thereof, will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words "without limitation."

25.14 No Presumptions. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and each of the other Transaction Agreements and acknowledges that it has participated in the drafting hereof or thereof. In interpreting and applying the terms and provisions of any of the Transaction Agreements, the Parties agree that no presumption shall exist or be implied against the Party which

drafted such terms and provisions.

[the remainder of this page intentionally blank]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

GENENTECH, INC.

By: /s/LOUIS J. LAVIGNE, JR.
Name: Louis J. Lavigne, Jr.
Title: Executive Vice President & CFO

By: /s/DAVID A. EBERSMAN
Name: David A. Ebersman
Title: Sr. Vice President, Product Operations

Legal: JDJ Finance: RA

WYETH, acting through its
Wyeth Pharmaceuticals Division

By: /s/CAVAN M. REDMOND
Name: Cavan M. Redmond
Title: Executive Vice President and General Manager, BioPharma Business Unit

Exhibit A
Excluded Patents

[*]

Exhibit B
Countries in Territory

[*]

EXHIBIT 15.1

November 1, 2005

The Board of Directors and Stockholders of Genentech, Inc.

We are aware of the incorporation by reference in the Registration Statements pertaining to the Genentech, Inc. Tax Reduction Investment Plan, the 2004 Equity Incentive Plan, the 1999 Stock Plan, the 1996 Stock Option/Stock Incentive Plan, the 1994 Stock Option Plan, the 1990 Stock Option/Stock Incentive Plan, and the 1991 Employee Stock Plan, the Registration Statement (Form S-3 No. 333-37072) related to the resale of common shares deliverable upon the exchange of Liquid Yield Option Notes, the Registration Statement (Form S-4 No. 333-128400) related to the exchange offer for Senior Notes, and in the related Prospectuses, as applicable, contained in such Registration Statements of our report dated October 10, 2005, relating to the unaudited condensed consolidated interim financial statements of Genentech, Inc. that are included in its Form 10-Q for the quarter ended September 30, 2005.

Pursuant to Rule 436(c) of the Securities Act of 1933 our report is not a part of the registration statement prepared or certified by accountants within the meaning of section 7 or 11 of the Securities Act of 1933.

Very truly yours,

/s/ERNST & YOUNG LLP

EXHIBIT 31.1

CERTIFICATIONS

I, Arthur D. Levinson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genentech, 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 officer(s) 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 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: October 31, 2005

By: /s/ARTHUR D. LEVINSON
Arthur D. Levinson, Ph.D.
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, David A. Ebersman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genentech, 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 officer(s) 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 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: October 31, 2005

By: /s/ DAVID A. EBERSMAN
David A. Ebersman
Senior Vice President and
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Arthur D. Levinson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genentech, Inc. on Form 10-Q for the quarter ended September 30, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Genentech, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genentech, Inc.

By: /s/ ARTHUR D. LEVINSON
Name: Arthur D. Levinson, Ph.D.
Title: Chief Executive Officer
Date: October 31, 2005

I, David A. Ebersman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genentech, Inc. on Form 10-Q for the quarter ended September 30, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Genentech, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genentech, Inc.

By: /s/ DAVID A. EBERSMAN
Name: David A. Ebersman
Title: Senior Vice President and
Chief Financial Officer
Date: October 31, 2005