

GENENTECH INC  
Form 10-Q  
November 04, 2005

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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(Mark One)

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

For the quarterly period ended September 30, 2005

or

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)

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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.

<u>Class</u>	<u>Number of Shares Outstanding</u>
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 puttable 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.

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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,

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	2005	2004	2005	2004
<b>Operating revenues</b>				
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
<b>Total operating revenues</b>	<b>1,751,822</b>	<b>1,202,644</b>	<b>4,740,279</b>	<b>3,305,857</b>
<b>Costs and expenses</b>				
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

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Special items: litigation-related	13,507	13,419	44,291	40,276
<b>Total costs and expenses</b>	<b>1,168,589</b>	<b>864,571</b>	<b>3,357,150</b>	<b>2,467,860</b>
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
<b>Earnings per share</b>				
Basic	\$ 0.34	\$ 0.22	\$ 0.89	\$ 0.55
Diluted	\$ 0.33	\$ 0.21	\$ 0.87	\$ 0.53
<b>Weighted-average shares used to compute earnings per share:</b>				
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

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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

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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
<b>Net cash provided by operating activities</b>	<b>1,647,267</b>	<b>852,057</b>
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
<b>Net cash used in investing activities</b>	<b>(1,302,194)</b>	<b>(501,180)</b>
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	-
<b>Net cash provided by (used in) financing activities</b>	<b>1,106,632</b>	<b>(400,261)</b>
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	<u>\$ 1,721,828</u>	<u>\$ 322,768</u>
Supplemental disclosure of cash flow information		
Non-cash investing and financing activities	\$ 93,831	\$ -

Capitalization of construction in progress related to financing lease transaction

Exchange of XOMA note receivable for a prepaid royalty and other long-term asset

29,205

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See Notes to Condensed Consolidated Financial Statements.

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GENENTECH, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2005	December 31, 2004
<b>Assets</b>		
<b>Current assets</b>		
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
<b>Total current assets</b>	<b>4,794,579</b>	<b>3,425,340</b>
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

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Total assets	\$ 12,099,306	\$ 9,403,395
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
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
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
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.

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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
<b>Earnings per share:</b>				
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

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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.

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### 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
<b>Numerator:</b>				
Net income	\$ 359,413	\$ 230,874	\$ 939,753	\$ 578,231
<b>Denominator:</b>				
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*):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	Number of shares	608	19,619	17,765
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

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	<u>\$ 621.4</u>	<u>\$ 590.4</u>

### 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	<u>\$ 2,519.9</u>	<u>\$ 1,932.0</u>	<u>\$ 587.9</u>	<u>\$ 2,488.4</u>	<u>\$ 1,820.0</u>	<u>\$ 668.4</u>

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

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#### 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

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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	\$	<u>2,000.0</u>

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

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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.

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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

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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;

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- 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

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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](mailto: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;

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- 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.

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- 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.

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## 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

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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	

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,			Nine Months Ended September 30,		
	2005	2004	% Change	2005	2004	% Change
<b>Net U.S. Product Sales</b>						
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	<u>\$ 1,451.0</u>	<u>\$ 1,005.5</u>	44	<u>\$ 3,911.1</u>	<u>\$ 2,682.6</u>	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.

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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

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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%.

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

Research and Development	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	2004	% Change	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

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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

Other Income, Net <i>(in millions)</i>	Three Months Ended September 30,			Nine Months Ended September 30,		
	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.

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#### 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)

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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		
<b>Total</b>	<b>13.8</b>	<b>78.95</b>	<b>39.5</b>	<b>40.5</b>

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

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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 I, 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

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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

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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)

	Shares Available for Grant	Options Outstanding	
		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 <sup>(1)</sup>	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)

As of September 30, 2005	Exercisable		Unexercisable		Total	
	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 <sup>(1)</sup>	3	85.83	17,041	86.00	17,044	86.00
<b>Total Options Outstanding</b>	<b>38,928</b>		<b>48,806</b>		<b>87,734</b>	

(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-

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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.

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- 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

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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;

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- 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

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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 affect 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.

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- 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.

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- 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.

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- 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.

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- 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.

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- 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 interest in 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.

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### 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	<u>10.5</u>		<u>39.5</u>	<u>40.5</u>

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.

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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