

GENENTECH INC  
Form 10-Q  
May 02, 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 March 31, 2005

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ .

Commission file number: 1-9813

GENENTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-2347624

(State or other jurisdiction  
of incorporation or organization)

(I.R.S. Employer  
Identification Number)

1 DNA Way, South San Francisco, California 94080-4990

(Address of principal executive offices and Zip Code)

(650) 225-1000

(Registrant's telephone number, including area code)

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

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

Indicate 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	1,056,450,956 Outstanding at April 26, 2005

GENENTECH, INC.  
TABLE OF CONTENTS

	<u>Page No.</u>
	<u>PART I - FINANCIAL INFORMATION</u>
Item 1.	3
	<u>Financial Statements</u>
	<u>Condensed Consolidated Statements of Income - for the three months ended March 31, 2005 and 2004</u>
	3
	<u>Condensed Consolidated Statements of Cash Flows - for the three months ended March 31, 2005 and 2004</u>
	4
	<u>Condensed Consolidated Balance Sheets - March 31, 2005 and December 31, 2004</u>
	5
	<u>Notes to Condensed Consolidated Financial Statements</u>
	6 - 13
	<u>Report of Independent Registered Public Accounting Firm</u>
	14
Item 2.	15 - 46
	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
Item 3.	47
	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
Item 4.	47
	<u>Controls and Procedures</u>

PART II - OTHER INFORMATION

Item 1.		48
	<u>Legal Proceedings</u>	
Item 2.		48
	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
Item 6.		49
	<u>Exhibits</u>	
		50
	<u>SIGNATURES</u>	

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 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.

- 2 -

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 March 31,

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	2005	2004
<b>Revenues</b>		
Product sales (including amounts from related parties: 2005-\$54,120; 2004-\$27,824)	\$ 1,186,002	\$ 763,700
Royalties (including amounts from related party: 2005-\$105,060; 2004-\$71,297)	231,915	154,097
Contract revenue (including amounts from related parties: 2005-\$26,460; 2004-\$36,621)	43,661	57,338
<b>Total operating revenues</b>	<b>1,461,578</b>	<b>975,135</b>
<b>Costs and expenses</b>		
Cost of sales (including amounts for related parties: 2005-\$50,030; 2004-\$22,645)	251,041	114,480
Research and development (including amounts for related parties: 2005-\$42,114; 2004-\$40,916) (including contract related: 2005-\$26,575; 2004-\$36,924)	243,240	190,345
Marketing, general and administrative	315,214	247,314
Collaboration profit sharing (including amounts for related party: 2005-\$23,648; 2004-\$11,822)	176,277	126,431
Recurring charges related to redemption	34,482	38,209
Special items: litigation-related	11,256	13,399
<b>Total costs and expenses</b>	<b>1,031,510</b>	<b>730,178</b>
Operating margin	430,068	244,957
Other income, net	16,396	22,321
Income before taxes	446,464	267,278
Income tax provision	162,290	90,691
Net income	<b>\$ 284,174</b>	<b>\$ 176,587</b>
<b>Earnings per share</b>		
Basic	<b>\$ 0.27</b>	<b>\$ 0.17</b>
Diluted	<b>\$ 0.27</b>	<b>\$ 0.16</b>
<b>Weighted-average shares used to compute earnings per share</b>		
Basic	1,046,832	1,055,198
Diluted	1,067,071	1,081,628

See Notes to Condensed Consolidated Financial Statements

- 3 -

GENENTECH, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

*(In thousands)**(Unaudited)*

	Three Months Ended March 31,	
	2005	2004
<b>Cash flows from operating activities</b>		
Net income	\$ 284,174	\$ 176,587
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	87,929	78,975
Deferred income taxes	(20,583)	(14,842)
Deferred revenue	(9,364)	(12,570)
Litigation-related liabilities	12,856	12,856
Tax benefit from employee stock options	50,624	149,699
Gain on sales of securities available-for-sale and other	(1,143)	(570)
Write-down of securities available-for-sale and other	3,514	-
Changes in assets and liabilities:		
Receivables and other current assets	(106,105)	(37,856)
Inventories	24,746	(55,089)
Investments in trading securities	(490)	(6,781)
Accounts payable and other current liabilities	54,679	(193,900)
<b>Net cash provided by operating activities</b>	<b>380,837</b>	<b>96,509</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(71,731)	(452,150)
Proceeds from sales and maturities of securities available-for-sale	162,168	172,845
Capital expenditures	(143,942)	(97,707)
Change in other assets	(5,140)	9,996
<b>Net cash used in investing activities</b>	<b>(58,645)</b>	<b>(367,016)</b>

<b>Cash flows from financing activities</b>		
Stock issuances	106,446	231,552
Stock repurchases	(155,538)	-
<b>Net cash (used in) provided by financing activities</b>	<b>(49,092)</b>	<b>231,552</b>
<b>Net increase (decrease) in cash and cash equivalents</b>		
Cash and cash equivalents at beginning of period	270,123	372,152
Cash and cash equivalents at end of period	\$ 543,223	\$ 333,197
<b>Supplemental disclosure of cash flow information</b>		
<b>Non-cash investing and financing activities</b>		
Capitalization related to financing lease transaction	\$ 44,000	\$ -
Exchange of XOMA note receivable for a prepaid royalty	29,205	-

See Notes to Condensed Consolidated Financial Statements.

- 4 -

GENENTECH, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)  
(Unaudited)

	March 31, 2005	December 31, 2004
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 543,223	\$ 270,123
Short-term investments	1,361,509	1,394,982
Accounts receivable -- product sales (net of allowances: 2005-\$59,943; 2004-\$59,366; including amounts from related parties: 2005-\$23,875; 2004-\$11,237)	688,480	599,052
Accounts receivable -- royalties (including amounts from related party: 2005-\$123,609; 2004-\$119,080)	229,203	217,482

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Accounts receivable -- other (net of allowances: 2005-\$2,050; 2004-\$2,191; including amounts from related parties: 2005-\$76,901; 2004-\$68,594)	152,826	140,838
Inventories	565,597	590,343
Prepaid expenses and other current assets	212,483	209,937
Total current assets	3,753,321	3,422,757
Long-term marketable debt and equity securities	800,395	1,115,327
Property, plant and equipment, net	2,230,957	2,091,404
Goodwill	1,315,019	1,315,019
Other intangible assets	635,216	668,391
Restricted cash and investments	682,000	682,000
Other long-term assets	282,561	108,497
Total assets	\$ 9,699,469	\$ 9,403,395
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 101,869	\$ 104,832
Taxes payable	234,583	134,937
Deferred revenue	45,995	45,989
Other accrued liabilities (including amounts to related parties: 2005-\$116,705; 2004-\$108,416)	910,056	957,508
Total current liabilities	1,292,503	1,243,266
Long-term debt	456,250	412,250
Deferred revenue	258,434	267,805
Litigation-related and other long-term liabilities	688,271	697,884
Total liabilities	2,695,458	2,621,205
Commitments and contingencies		
Stockholders' equity		
Preferred stock	-	-
Common stock	20,964	20,943
Additional paid-in capital	8,135,062	8,002,754
Accumulated other comprehensive income	227,062	290,948
Accumulated deficit, since June 30, 1999	(1,379,077)	(1,532,455)
Total stockholders' equity	7,004,011	6,782,190
Total liabilities and stockholders' equity	\$ 9,699,469	\$ 9,403,395

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of Presentation

We prepared the condensed consolidated financial statements following the requirements of the Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by accounting principles generally accepted in the United States of America (or "GAAP") can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2004. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of our financial position and operating results.

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

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Genentech and all subsidiaries. Genentech also consolidated a variable interest entity (or "VIE") in which Genentech is 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 the noncontrolling interest in the consolidated balance sheet. 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 from those estimates.

Certain reclassifications of prior period amounts have been made to our condensed consolidated financial statements to conform to the current year 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", effective for reporting periods beginning after June 15, 2005. On April 14, 2005, the Securities and Exchange Commission (or the "SEC") adopted a rule amendment that delayed the compliance dates for FAS 123R such that we



are now allowed to adopt the new standard no later than January 1, 2006. FAS 123R 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 purchase plans. We expect to adopt FAS 123R using the modified prospective basis measured and recognized on January 1, 2006. We expect that our adoption of FAS 123R will result in compensation expense comparable to those disclosed below, before the effect of capitalization of manufacturing related compensation expenses. 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 below in "Accounting for Stock-Based Compensation" section of this

- 6 -

note. 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, because the alternative fair value method of accounting prescribed by FAS No. 123 requires the use of option valuation models that were not developed for use in valuing 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 were determined as if we had accounted for our employee stock options and employee stock plan under the fair value method prescribed by FAS 123. The resulting effect on net income and earnings per share pursuant to FAS 123 is not likely to be representative of the effects in future periods, due to subsequent additional option grants and periods of vesting.

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. Because our employee stock options and stock plan shares have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing valuation models do not provide a reliable measure of the fair value of our employee stock options.

	Three Months Ended March 31,	
	2005	2004
	(In thousands, except per share amounts)	
Net income - as reported	\$ 284,174	\$ 176,587
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	40,389	45,883
	<u>                    </u>	<u>                    </u>

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Pro forma net income	\$ 243,785	\$ 130,704
Earnings per share:		
Basic-as reported	\$ 0.27	\$ 0.17
Basic-pro forma	\$ 0.23	\$ 0.12
Diluted-as reported		
Diluted-pro forma	\$ 0.22	\$ 0.12

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 March 31,	
	2005	2004
Risk-free interest rate	4.0%	3.0%
Dividend yield	0.0%	0.0%
Volatility factors of the expected market price of our Common Stock	32.0%	45.0%
Weighted-average expected life of option (years)	4.2	5.0

Due to the redemption of our special common stock in June 1999 (or "Redemption"), there is limited historical information available to determine the necessary inputs to value employee stock options and the stock issued under the employee stock plan. In 2004, having completed our first full four-year option vesting cycle on options issued after the Redemption, and having further analyzed economic data from marketable instruments and comparable

- 7 -

companies, the assumptions for volatility and expected lives were further refined to reflect what management believes to be a better measure of fair value. However, changes in these assumptions did not materially impact compensation expense presented above.

#### 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 March 31,	
	2005	2004
Numerator:		

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Net income	\$ 284,174	\$ 176,587
<b>Denominator:</b>		
Weighted-average shares outstanding used for basic earnings per share	1,046,832	1,055,198
Effect of dilutive stock options	20,239	26,430
Weighted-average shares and dilutive stock options used for diluted earnings per share	1,067,071	1,081,628

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

	Three Months Ended March 31,	
	2005	2004
Number of shares	19,907	199
Range of exercise prices	\$49.98-\$59.61	\$49.71-\$56.64

#### 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 activity in comprehensive income, net of income taxes, during the first quarters of 2005 and 2004 was as follows (*in millions*):

	Three Months Ended March 31,	
	2005	2004
Net income	\$ 284.2	\$ 176.6
Change in unrealized (losses) gains on securities available-for-sale	(76.8)	25.7
Change in unrealized gains on derivatives	13.0	3.4
Comprehensive income	\$ 220.4	\$ 205.7

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

	March 31, 2005	December 31, 2004
Unrealized gains on securities available-for-sale	\$ 228.3	\$ 305.1
Unrealized losses on derivatives	(1.2)	(14.2)

Accumulated other comprehensive income	\$ 227.1	\$ 290.9
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- 8 -

The activity in OCI, net of income taxes, related to our available-for-sale securities and cash flow hedges was as follows (*in millions*):

	Three Months Ended March 31,	
	2005	2004
Unrealized (losses) gains on securities available-for-sale (net of tax effect of (\$51.3) in 2005, \$17.1 in 2004)	\$ (76.9)	\$ 25.7
Reclassification adjustment for net gains on securities available-for-sale included in net income (tax effect in 2005 was not material)	0.1	-
Unrealized losses on derivatives (net of tax effect of \$8.3 in 2005, \$1.9 in 2004)	12.5	2.9
Reclassification adjustment for net gains on derivatives included in net income (net of tax effect of \$0.3 in 2005, \$0.4 in 2004)	0.5	0.5
Change in activity in OCI	\$ (63.8)	\$ 29.1

#### Derivative Financial Instruments

At March 31, 2005, net losses on derivative instruments expected to be reclassified from accumulated other comprehensive income to "other income, net" during the next twelve months are \$5.2 million. These net losses are primarily due to the recognition of premiums related to maturing foreign currency exchange options.

#### Note 2. Consolidated Financial Statement Detail

##### Inventories

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

	March 31, 2005	December 31, 2004
Raw materials and supplies	\$ 58.3	\$ 57.1
Work in process	391.0	451.8
Finished goods	116.3	81.5
Total	\$ 565.6	\$ 590.4

Other Intangible Assets

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

	March 31, 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	\$ 867.2	\$ 326.9	\$ 1,194.1	\$ 847.7	\$ 346.4
Core technology	443.5	356.3	87.2	443.5	351.0	92.5
Developed science technology	467.5	460.3	7.2	467.5	452.9	14.6
Tradenames	144.0	77.1	66.9	144.0	74.7	69.3
Patents	144.4	55.9	88.5	138.0	53.2	84.8
Other intangible assets	101.3	42.8	58.5	101.3	40.5	60.8
<b>Total</b>	<b>\$ 2,494.8</b>	<b>\$ 1,859.6</b>	<b>\$ 635.2</b>	<b>\$ 2,488.4</b>	<b>\$ 1,820.0</b>	<b>\$ 668.4</b>

Amortization expense of our other intangible assets was \$39.5 million and \$43.0 million for the first quarters of 2005 and 2004, respectively.

- 9 -

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 nine months)	\$ 103.8
2006	123.5
2007	122.0
2008	120.3
2009	71.2
Thereafter	94.4
<b>Total expected future annual amortization</b>	<b>\$ 635.2</b>

Note 3. Leases and Contingencies

Leases

During the quarter ended March 31, 2005, there were no significant changes to our synthetic lease arrangements, or our assessment of those arrangements under the provisions of FIN 46R, a revision of Interpretation 46, as discussed in Note 6, "Leases, Commitments and Contingencies" of our Annual Report on Form 10-K for the year ended December 31, 2004.

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to the Company's 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 quarter 2005, we have capitalized \$44.0 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 sheet. We expect at the time of completion of the project, if all the buildings and infrastructure were completed by the lessor, our construction asset and related obligation will be in excess of \$365.0 million. Our aggregate lease payments as contemplated by the Master Lease Agreement through 2020 (if there is no acceleration or delay in the rent commencement date for the second phase of the buildings) will be approximately \$540.1 million.

Contingencies

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

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

We and the City of Hope National Medical Center (or "COH") are parties to a 1976 agreement relating to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, Genentech has entered into license agreements with various companies to make, use and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe

royalties to the COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. On June 10, 2002, a jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, a jury voted to award the COH an additional \$200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and were included in the condensed consolidated balance sheets in "litigation-related and other long-term liabilities" at March 31, 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 will take longer than one year to further resolve the matter.

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 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. Because the appeal process and further interference proceedings are ongoing, the outcome of this matter cannot be determined at this time.

On March 13, 2001, Chiron filed a patent infringement lawsuit against us in the U.S. District Court in the Eastern District of California, alleging that the manufacture, use, sale and/or offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 4,753,894. Chiron is seeking compensatory damages for the alleged infringement, additional damages, and attorneys' fees and costs. Genentech filed a motion to dismiss this lawsuit, which was denied. On November 1, 2002, the parties filed a proposed stipulation to stay all proceedings in this lawsuit until (1) the interference involving U.S. Patent No. 4,753,894 is resolved or two years from entry of the proposed stipulation, whichever is sooner. On or about November 13, 2002, the Court entered the stipulation, staying the proceedings as requested by the parties. On November 10, 2004, the Court extended the stay until the resolution of all proceedings before the United States Supreme Court in a separate Chiron suit that has now been concluded. This lawsuit is separate from and in addition to the Chiron interference mentioned above. The final outcome of this matter 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 ("the '415 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.

- 11 -

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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. MedImmune filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. Oral argument of MedImmune's appeal was held on February 10, 2005. Because the appeal process is ongoing, the final outcome of this matter cannot be determined at this time.

We recorded \$13.5 million and \$13.4 million for the three months ended March 31, 2005 and 2004, respectively, for accrued interest and bond costs related to the COH trial judgment. In conjunction with the City of Hope judgment, we posted a surety bond and were required to pledge cash and investments of \$682.0 million at March 31, 2005 and December 31, 2004 to secure the bond. These amounts are reflected in the condensed consolidated balance sheets in "restricted cash and investments." 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.

#### Note 4. Relationship with Roche Holdings, Inc. (Roche) and Related Party Transactions

##### Relationship with Roche

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

We expect from time to time to 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. At March 31, 2005, Roche's ownership percentage was 56.0%. The Minimum Percentage at March 31, 2005 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be 55.7%. At April 26, 2005, Roche's ownership percentage was 0.1% below the lowest ownership percentage. Genentech and Roche are in discussion concerning this matter.

#### Related Party Transactions

We enter into transactions with our related parties, Roche Holdings, Inc. (including F. Hoffmann-La Roche (or "Hoffmann-La Roche") and other affiliates) 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

- 12 -

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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 \$16.5 million and \$25.8 million in the first quarters of 2005 and 2004, respectively. All other revenues from Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$155.9 million and \$98.9 million in the first quarters of 2005 and 2004, respectively. Cost of sales included amounts related to Hoffmann-La Roche of \$47.2 million and \$22.4 million in the first quarters of 2005 and 2004, respectively. R&D expenses included amounts related to Hoffmann-La Roche of \$32.4 million and \$31.2 million in the first quarters of 2005 and 2004, respectively.

#### Novartis

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

Under an arrangement with Novartis, a holding company of The Novartis Group, and Tanox, Inc., we currently supply Xolair and receive cost plus a mark-up similar to other supply arrangements. Novartis is expected to undertake primary bulk manufacturing responsibility in late 2005 or early 2006. Future production costs of Xolair may initially be higher than those currently reflected in our cost of sales as a result of any production shift from Genentech to Novartis, or to any other party, until production economies of scale can be achieved by that manufacturing party.

Collaboration profit sharing expenses were \$23.6 million in the first quarter of 2005 and \$11.8 million in the first quarter of 2004. R&D expenses include amounts related to Novartis of \$9.7 million in the first quarters of 2005 and 2004. Revenue from Novartis related to product sales and the associated cost of sales were \$3.3 million and \$2.8 million, respectively, in the first quarter of 2005. Revenue from Novartis related to product sales and the associated cost of sales was not material in the first quarter of 2004. Contract revenue from Novartis related to manufacturing,

commercial and ongoing development activities, was \$10.0 million in the first quarter of 2005 and \$10.8 million in the first quarter of 2004.

Note 5. Income Taxes

The effective income tax rate was 36% in the first quarter of 2005 compared to 34% in the first quarter of 2004. The increase in the income tax rate primarily reflects increased income before taxes and reduced benefits from R&D tax credits. The income tax provision for the first quarter of 2004 included a benefit of \$6.5 million related to a favorable change in estimates of research credits.

- 13 -

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Genentech, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of Genentech, Inc. as of March 31, 2005, and the related condensed consolidated statements of income and cash flows for the three-month periods ended March 31, 2005 and 2004. These financial statements are the responsibility of Genentech's management.

We conducted our reviews 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 to financial data, 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 reviews, we are not aware of any material modifications that should be made to the accompanying condensed consolidated 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  
April 11, 2005

- 14 -

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

**GENENTECH, INC.  
FINANCIAL REVIEW**

Overview

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

In the first quarter of 2005, our total operating revenues were \$1,461.6 million and our net income was \$284.2 million. For the remainder of 2005, we expect the growth of our business to continue to be driven by sales of our new products, Tarceva, Avastin, Xolair and Raptiva and continued sales of our established oncology products, Rituxan and Herceptin. We also expect sales of our other products, contract revenues and royalties to continue to contribute to the bottom-line.

We are in the final year of our 5x5 plan. We expect to exceed our most important goal of average annual non-GAAP EPS growth, while 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. 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, but we are uncertain if we will meet this goal due in part to the fact that we have changed our strategic focus to pursue earlier stage opportunities. Information on our 5x5 plan can be found on our website at <http://www.gene.com>.

Our long-term business objectives are reflected in our Horizon 2010 strategy and goals summarized below and on our website at <http://www.gene.com>.

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

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

Achieving these goals depends on our ability to make and capitalize on advances in basic research, to rapidly complete clinical development while designing high-quality trials, to shape the markets for our products, to increase our manufacturing capabilities and to maintain our unique corporate culture. These goals and objectives are further challenged by economic and industry-wide factors that affect our business. Some of the most important factors are discussed below:

- 15 -

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- 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 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 where protein biotherapeutics are involved. The manufacture of a biotherapeutic requires proper formulation of the product involved, executing on and scaling the manufacturing process used for that product, 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 to a manufacturing process used by our contract-manufacturers. In connection with our manufacturing efforts, we may need to record period charges associated with manufacturing failures or inefficiencies or other production-related costs that are not absorbed into inventory.

In addition, we may experience delays in the shipment of our products. We may also have inadequate manufacturing capacity to meet future demands. We anticipate that we may face a significant business challenge to increase bulk supply to keep pace with growing demand for our products. We are currently assessing our demand forecasts and our manufacturing plans in light of the recent successful clinical trial results for Avastin, Herceptin and Rituxan. If our forecasted demand significantly increases, or if actual demand exceeds our forecasts, or if our efforts to increase production (as described below) are unsuccessful and we are not able to find alternate sources of capacity, we may not have sufficient available bulk capacity to meet demand for some of our products. In order to maximize production output, we will need to successfully execute an aggressive production plan at all of our facilities and we will need to successfully implement all of our capacity enhancement projects, including start-up and licensure of our contract manufacturing facilities at Lonza Biologics and Wyeth Pharmaceuticals, licensure of our Porriño, Spain plant for commercial production, successful construction, qualification and licensure of our new plant in Vacaville, as well as qualification and licensure of yield improvements for the Avastin and Rituxan production processes. In addition, we are undertaking efforts to secure additional licensed filling capacity in order to mitigate the current risk associated with having a single licensed filling facility for many of our products. As part of this effort, we expect to begin constructing a new aseptic fill line in our South San Francisco plant in the third quarter of 2005. Further, we may incur period charges associated with securing alternate sources of capacity.

- 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 is our single largest payer, the new rules represent an important area of focus in 2005. We will be monitoring the situation closely and, in 2005, we continue to anticipate minimal impact to our revenues. To date, we have not seen any detectable effects of the new rules on our product sales.

- 16 -

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- 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 (or "NDA") and Biologics License Application (or "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 commercial data and information from use and disclosure 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.
- The success of our company is predicated on its ability to recruit and retain highly qualified and talented people in all areas of the company. In 2004 we experienced a 23% growth in the number of employees. This significant growth in employees is challenging to manage, especially given our work environment where our culture is important for our success. 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.

#### Marketed Products

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

## Oncology

### Rituxan

(rituximab) anti-CD20 antibody, which we commercialize with Biogen Idec Inc. (or "Biogen Idec"), is approved for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma.

### Avastin

(bevacizumab) is a humanized antibody that binds to vascular endothelial growth factor (or "VEGF") 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.

### Herceptin

(trastuzumab) anti-HER2 antibody is a humanized antibody 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 HER2 protein.

### Tarceva

(erlotinib), which we commercialize with OSI Pharmaceuticals, Inc. (or "OSI"), is a small molecule designed to block tumor cell growth by inhibiting the tyrosine kinase activity of HER1/epidermal growth factor receptor (or "EGFR") signaling pathway, 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.

## Specialty Biotherapeutics

### Nutropin

[somatropin (rDNA origin) for injection] is a growth hormone approved for the treatment of growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency prior to kidney transplantation and short stature associated with Turner syndrome.

### Nutropin AQ

[somatropin (rDNA origin) for injection] is a liquid formulation growth hormone approved for the same indications as Nutropin.

### Nutropin Depot

[somatropin (rDNA origin) for injectable suspension] is a long-acting growth hormone for the treatment of growth failure associated with pediatric growth hormone deficiency. On June 1, 2004, we and our collaborator Alkermes, Inc. made a decision to discontinue commercialization of Nutropin Depot. We expect sales of Nutropin Depot to cease in 2005.

## 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 recombinant human deoxyribonuclease (rhDNase) I approved for the treatment of cystic fibrosis.

### Xolair

(omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis Pharma AG (or "Novartis") in the United States, approved for the treatment of moderate-to-severe persistent 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.

### Licensed Product

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
- growth hormone products, Activase, Cathflo Activase and TNKase in Canada.

We also receive royalties on additional licensed products that are marketed by other companies. In January 2005, we entered into a patent license agreement with ImClone Systems Inc. (or "ImClone") under which we will receive certain royalties from ImClone on sales of ERBITUX® by ImClone and its commercialization partners.

### 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;
- 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.

- 18 -

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### 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 March 31, 2005, we have accrued \$638.5 million in "litigation-related and other long-term liabilities," 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 reliably measured and collectibility is reasonably assured. Royalty estimates are made in advance of amounts collected



using historical and forecasted trends.

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

- 19 -

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- 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.
- Upfront 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. Manufacturing profit is recognized when the product is shipped and title passes.
- Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
- Reimbursements of development, post-marketing and certain commercial costs are recognized as revenue as the related costs are incurred.

#### Income Taxes

Income tax expense is based on pretax financial accounting income under 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. We believe that our estimates are reasonable and that our reserves for income tax related uncertainties are adequate. 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 pretax earnings.

#### Inventories

Inventories consist of currently marketed products, products manufactured under contract and product candidates awaiting regulatory approval, which are capitalized based on management's judgment of probable near term commercialization. The valuation of inventory requires us to estimate obsolete or excess inventory. The determination

of obsolete or excess 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 costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies. In the event that a pre-approval product candidate receives regulatory approval, subsequent sales of previously reserved inventory will result in increased gross margins.

### Business Development Collaborations

Under Financial Accounting Standards Board 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.

- 20 -

### Results of Operations

(In millions)

	Three Months Ended March 31,		% Change
	2005	2004	
Product sales	\$ 1,186.0	\$ 763.7	55 %
Royalties	231.9	154.1	50
Contract revenue	43.7	57.3	(24)
Total operating revenues	1,461.6	975.1	50
Cost of sales	251.0	114.5	119
Research and development	243.2	190.3	28
Marketing, general and administrative	315.2	247.3	27
Collaboration profit sharing	176.3	126.4	39
Recurring charges related to redemption	34.5	38.2	(10)
Special items: litigation-related	11.3	13.4	(16)
Total costs and expenses	1,031.5	730.1	41
Operating margin	430.1	245.0	76
Other income, net	16.4	22.3	(26)

Income before taxes	446.5	267.3	67
Income tax provision	162.3	90.7	79
Net income	<u>\$ 284.2</u>	<u>\$ 176.6</u>	61
Operating margin as a % of operating revenues	29 %	25 %	
COS as a % of product sales	21	15	
R&D as a % of operating revenues	17	20	
MG&A as a % of operating revenues	22	25	
NI as a % of operating revenues	19	18	

\* 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 50% in the first quarter of 2005 from the comparable period in 2004. This increase was primarily due to higher product sales and royalty income. This increase is further discussed below.

- 21 -

### Total Product Sales

(In millions)

	Three Months Ended March 31,		
	2005	2004	% Change
Net U.S. Product Sales			
Rituxan	\$ 440.5	\$ 361.8	22 %
Avastin	202.9	38.1	433
Herceptin	129.6	108.7	19
Tarceva	47.6	-	-
Growth Hormone	89.9	84.0	7
Thrombolytics	50.6	44.3	14
Pulmozyme	44.0	38.0	16
Xolair	65.3	29.8	119
Raptiva	16.6	6.3	163
Total U.S. product sales	<u>\$ 1,087.0</u>	<u>\$ 711.0</u>	53

Net Product Sales to Collaborators			
Rituxan	\$ 33.0	\$ 38.8	(15)
Avastin	11.6	-	-
Herceptin	10.9	4.8	127
Growth Hormone	2.2	1.5	47
Thrombolytics	3.0	2.0	50
Pulmozyme	7.8	5.4	44
Xolair	3.3	0.2	1,550
Raptiva	7.5	-	-
Other	19.7	-	-
Total product sales to collaborators	\$ 99.0	\$ 52.7	88
Total product sales	\$ 1,186.0	\$ 763.7	55

Total product sales increased 55% to \$1,186.0 million in the first quarter of 2005 from the comparable period in 2004. Net U.S. sales increased 53% to \$1,087.0 million in the first quarter of 2005 from the comparable period in 2004. The increase in net U.S. sales was due to higher sales across all products, in particular sales of our new products, Avastin and Tarceva, and higher sales of Rituxan, Xolair and Herceptin. Avastin was launched in February 2004 and Tarceva was launched in November 2004. Net U.S. oncology sales accounted for 75% of net U.S. product sales compared to 72% in the first quarter of 2004. Increased U.S. sales volume, including new product shipments, accounted for 92%, or \$346.0 million, of the increase in U.S. net product sales in the first quarter of 2005. Changes in net U.S. sales prices across the portfolio accounted for an increase of 8%, or \$30.0 million, of the increase in U.S. net product sales in the first quarter of 2005.

#### Rituxan

In the first quarter of 2005, net U.S. sales of Rituxan increased 22% to \$440.5 million from the comparable period in 2004. Net U.S. sales in the first quarter of 2005 included \$9.6 million for a reorder to replace a shipment that was destroyed while in transit to a wholesaler. Total demand driven net U.S. sales in the first quarter of 2005 were \$430.9 million, a 19% growth over the first quarter of 2004. Net U.S. sales growth was primarily driven by increased sales volumes resulting from greater penetration in the non-Hodgkin's lymphoma (or "NHL") and chronic lymphocytic leukemia (or "CLL") markets, specifically front line indolent NHL, front line CLL, and indolent maintenance, which are all unapproved uses. Also impacting our year-over-year first quarter increase, to a lesser extent, was a price increase that was effective on September 9, 2004.

While penetration in the main hematological uses of Rituxan may be approaching peak levels, we believe there is still growth potential for use of Rituxan in the maintenance setting (an unapproved use) in treating NHL, Additional

opportunities for long-term Rituxan sales growth lie in other potential new indications, particularly in immunologic diseases such as rheumatoid arthritis.

In the recently published 2005 Centers for Medicare and Medicaid Services Final Rules for Medicare Reimbursement, there is minimal change in the overall reimbursement for Rituxan in 2005 when compared to that in 2004. To date, we have not seen any detectable effects of the new rules on our product sales, but we are closely monitoring the situation. Therefore, we anticipate that this change will have a limited impact on Rituxan sales in 2005.

#### Avastin

Net U.S. sales of Avastin increased to \$202.9 million in the first quarter of 2005 compared to \$38.1 million in the first quarter of 2004 driven by increased use in colorectal cancer, which continues to represent approximately 95% of current Avastin use. In both the first-line (our approved indication) and relapsed/refractory (an unapproved indication) settings, Avastin is being combined with a wide range of 5FU-based chemotherapies. Net U.S. sales of Avastin increased 7% from \$190.5 million in the fourth quarter of 2004. While we have had rapid uptake in the colorectal market, there remains potential growth in this indication driven mainly by increased time on therapy. We also anticipate longer-term growth to be driven by use in potential new indications, including non-small-cell lung and breast cancers.

On January 28, 2005, the Centers for Medicare and Medicaid Services published its final National Coverage Decision which had a positive outcome for Avastin. Specifically, the final decision provides Medicare coverage of drugs used in nine specified clinical trials, seven of which include Avastin. At present, all Medicare carriers and all of our targeted commercial payers are covering Avastin and reimbursement has proceeded as expected.

On March 14, 2005, we and our collaborator, Hoffmann-La Roche, announced that an interim analysis of a Phase III study of Avastin plus paclitaxel and carboplatin chemotherapies in first-line non-squamous, non-small cell lung cancer met its primary efficacy endpoint of improving overall survival, or a reduction in the risk of death, compared to chemotherapy alone. On April 14, 2005, we and our collaborator, Hoffmann-La Roche, announced that an interim analysis of a Phase III study of Avastin plus paclitaxel chemotherapy in first-line metastatic breast cancer met its primary efficacy endpoint of showing a statistically significant improvement in progression-free survival, compared to chemotherapy alone. Progression-free survival is an efficacy endpoint that measures the amount of time a therapy is able to delay the growth and spread of a patient's tumors. These trials were sponsored by the National Cancer Institute (or "NCI"), part of the National Institutes of Health, under a Cooperative Research and Development Agreement between NCI and us, and conducted by a network of researchers led by the Eastern Cooperative Oncology Group (or "ECOG"). According to ECOG, data from these studies will be submitted and presented at the annual meeting of the American Society of Clinical Oncology (ASCO), May 13 - 17, 2005.

#### Herceptin

Net U.S. sales of Herceptin increased 19% to \$129.6 million in the first quarter of 2005 from the first quarter of 2004. This growth was driven by multiple factors including physicians' extending the average treatment duration and increased first-line penetration. Also contributing to our first quarter increase and our future sales growth was a price increase that was effective on February 22, 2005. We currently believe there will be limited impact on Herceptin's usage under the new Medicare Act. We believe there is an opportunity for long-term Herceptin sales growth in the adjuvant setting, an unapproved use. In other unapproved uses, there continues to be growing adoption by physicians in the combination of Herceptin, carboplatin and taxane, a combination otherwise known as TCH. The TCH regimen has demonstrated an improved time to disease progression and may therefore lead to a longer treatment duration.

On April 25, 2005, we announced that two Phase III trials of Herceptin were stopped early after a preliminary joint interim analysis demonstrated an improvement in the primary endpoint of disease-free survival and in the secondary

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endpoint of overall survival. The trials compared Herceptin plus chemotherapy to chemotherapy alone as adjuvant therapy following initial treatment with surgery for women with early-stage (or cancer that has not spread beyond the breast and associated lymph nodes) human epidermal growth factor receptor 2 (HER2) positive breast cancer. The two studies were sponsored by the NCI and conducted by a network of researchers led by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the North Central Cancer Treatment Group (NCCTG), who conducted this prospectively-designed joint interim analysis. The joint interim analysis plan was developed following discussion with the FDA. According to the NCI, the cooperative groups will present results from these studies at the 2005 ASCO annual meeting.

#### Tarceva

Net U.S. sales of Tarceva were \$47.6 million in the first quarter of 2005, as compared to \$13.3 million in the fourth quarter of 2004. Tarceva was approved by the FDA on November 18, 2004. The increase in net U.S. product sales was driven primarily by rapid growth in patient market share in second- and third-line NSCLC.

#### Growth Hormone

Combined net U.S. sales of Nutropin products increased 7% in the first quarter of 2005 from the comparable period in 2004, primarily as a result of price increases.

#### Thrombolytics

Combined net U.S. sales of our three thrombolytics products, Activase, Cathflo Activase, and TNKase, increased 14% to \$50.6 million in the first quarter of 2005 from the comparable period in 2004. This increase was primarily driven by growth in our catheter clearance and stroke markets, as well as price increases on certain of our thrombolytic products. Sales of our thrombolytic products used to treat acute myocardial infarction continue to be impacted by the adoption by physicians of mechanical reperfusion strategies; however, the decline in the use of thrombolytics in the acute myocardial infarction market has been offset by growth in our other markets.

Our sales in the first quarters of 2005 and 2004 were impacted by continued competition from Retavase® (reteplase), a competing product, and its aggressive price discounting. In March 2005, Protein Design Labs purchased Retavase® from Centocor through their acquisition of ESP Pharma.

On January 4, 2005, Cathflo Activase received approval from the FDA for catheter clearance in pediatric patients. With this new indication, Cathflo Activase is the only thrombolytic approved for use in pediatric patients with dysfunctional central venous access devices.

#### Pulmozyme

Net U.S. sales of Pulmozyme increased 16% to \$44.0 million in the first quarter of 2005 from the comparable period in 2004. This increase primarily reflects an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and, to a lesser extent, a price increase in July 2004.

#### Xolair

Net U.S. sales of Xolair increased to \$65.3 million in the first quarter of 2005 compared to \$29.8 million in the first quarter of 2004. This overall growth was driven by growth in our prescriber base combined with strong payer coverage and a high perceived clinical response.

#### Raptiva

Net U.S. sales of Raptiva were \$16.6 million in the first quarter of 2005, compared to \$6.3 million in the first quarter of 2004 and \$16.4 million in the fourth quarter of 2004. This growth rate was due to continued acceptance of the

- 24 -

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product and effective reimbursement processing. Raptiva also had a price increase effective on September 3, 2004. However, the rate of growth in prescriptions and resulting revenue for Raptiva has been negatively impacted by the approval of ENBREL® for psoriasis. In addition, we recently analyzed data results of the exploratory study in patients with alopecia areata, an autoimmune disorder, and we did not observe evidence of benefit in this population of patients.

#### Sales to Collaborators

During the first quarter of 2005, product sales to collaborators, the majority of which were in non-U.S. markets, were \$99.0 million compared with \$52.7 million for the first quarter in 2004. This increase was primarily due to sales of product manufactured under a contract with a third party and sales of Avastin to Hoffman-La Roche.

Novartis Pharma AG, our collaborator on Xolair, launched Xolair in Canada on March 21, 2005.

Serono S.A. (or "Serono"), which has rights to market Raptiva in certain areas of the world outside the U.S., announced that Raptiva is available commercially in 18 countries as of March 31, 2005.

For the year 2005, we expect sales to collaborators to increase by approximately 50% relative to sales of \$197.7 million in 2004.

#### Royalties

Royalty revenues increased 50% to \$231.9 million in the first quarter of 2005 from the comparable period in 2004. The increase was due to higher international 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. The ERBITUX® arrangement included a one-time payment to us, which was recognized in the first quarter of 2005, relating to 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 continue to expect the royalty line to increase by approximately 30% over \$641.1 million for 2004. See "Related Party Transactions" below for more information on royalties from Hoffmann-La Roche.

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 royalty 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" section in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

Contract Revenues

Contract revenues decreased 24% to \$43.7 million in the first quarter of 2005 from \$57.3 million in the comparable period in 2004. The decrease was primarily due to lower revenues from our collaborators, including Hoffmann-La Roche. 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 myriad of factors, including the timing and level of reimbursements from ongoing development efforts, milestones and opt-in payments received, and new contract arrangements. In 2005, we currently expect contract revenues to decrease by approximately 10% as compared to \$231.2 million in 2004.

Cost of Sales

Cost of sales (or "COS") as a percentage of product sales were 21% in the first quarter of 2005 compared to 15% in the first quarter 2004. This increase from the prior year was primarily due to changes in product sales mix, including significantly higher sales to collaborators which have a higher cost as a percentage of sales, and also due to slightly

- 25 -

higher production costs and inventory reserves for several products. COS in the first quarter of 2004 were unusually low due to the low COS associated with the Avastin and Raptiva launch inventories and other favorable sales mix conditions.

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

Research and Development

R&D expenses increased 28% to \$243.2 million in the first quarter of 2005 from the comparable period in 2004. This increase reflects the ongoing clinical development of our pipeline products, higher expenses for early-stage projects, and increased post-marketing studies and in-licensing expense. R&D as a percentage of revenues was 17% in the first quarter of 2005 compared to 20% in the first quarter of 2004, primarily due to higher revenues. We anticipate a significant increase in R&D expenses in the upcoming quarters of 2005; in particular, expenses related to: (i) in-licensing, (ii) development research on advance oncology, immunology and angiogenic disorders, and (iii) our clinical development pipeline and clinical production costs for products including Avastin, Rituxan Immunology, Lucentis, BR3-Fc, anti-NGF, topical Hedgehog Antagonist and topical VEGF for diabetic foot ulcers. In 2005, we expect R&D expenses as a percentage of revenue to be comparable to 21% in 2004.

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

Research and Development	Three Months Ended March 31,		% Change
	2005	2004	



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Product development	\$ 146.0	\$ 112.3	30 %
Post-marketing studies	34.3	28.3	21
Total development	180.3	140.6	28
Research	50.7	43.4	17
In-licensing	12.2	6.3	94
Total	\$ 243.2	\$ 190.3	28

#### Marketing, General and Administrative

Overall marketing, general and administrative (or "MG&A") expenses increased 27% to \$315.2 million in the first quarter of 2005 from the comparable period in 2004. The increase in 2005 was due to: (i) an increase of \$31.6 million in commercial activities in support of the launch of Tarceva and ongoing launch support of Avastin; (ii) an increase of \$28.4 million primarily due to increased headcount and promotional costs related to pre-launch and launch activities of our specialty biotherapeutic products, and other product related expenses; and (iii) an increase of \$7.9 million in general and administrative costs primarily related to higher royalty expense associated with higher ex-U.S. sales by collaborators.

For the remainder of the year, we expect quarterly MG&A expenses to be higher than the first quarter of 2005 on an absolute basis and as a percentage of total operating revenues as promotional expenses increase for Tarceva, coupled with higher marketing and sales expenses for Avastin and Xolair products and pre-launch preparations for our pipeline products. In 2005, we expect MG&A as a percentage of total operating revenues to be similar to 24% in 2004.

#### Collaboration Profit Sharing

Collaboration profit sharing expenses increased 39% to \$176.3 million in the first quarter of 2005 from the comparable period in 2004 due to higher sales of Rituxan, Xolair and Tarceva and the related profit sharing expenses. In 2005, this line is expected to grow as our Rituxan, Xolair and Tarceva sales grow.

- 26 -

#### Recurring Charges Related to Redemption

We began recording recurring charges in the third quarter of 1999 related to the redemption of our special common stock in July 1999 and push-down accounting (see discussion below in "Relationship with Roche -- Redemption of Our Special Common Stock"). The charges in the first quarter of 2005 were \$34.5 million compared to \$38.2 million for the first quarter of 2004, and were comprised of the Redemption-related amortization of other intangible assets in both periods presented.

#### Special Items: Litigation-Related

We recorded \$13.5 million and \$13.4 million for the three months ended March 31, 2005 and 2004, respectively, for accrued interest and bond costs related to the City of Hope National Medical Center (or "COH") trial judgment. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results. The amount of cash paid, if any, or the timing of such payment

in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter; however, we expect that it will 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 in the first quarter of 2005 were amounts received on a litigation settlement.

## Other Income, Net

Other Income, Net	Three Months Ended March 31,		% Change
	2005	2004	
	(In millions)		
Gains on sales of biotechnology equity securities and other	\$ 0.9	\$ 0.7	29 %
Write-downs of biotechnology debt, equity securities and other	(3.5)	-	-
Interest income	21.8	23.0	(5)
Interest expense	(2.8)	(1.4)	100
<b>Total other income, net</b>	<b>\$ 16.4</b>	<b>\$ 22.3</b>	<b>(26)</b>

Other income, net decreased 26% to \$16.4 million in the first quarter of 2005 from the comparable period in 2004 primarily due to an other-than-temporary write-down of certain biotechnology debt and equity holdings.

For 2005, the interest income component of this line will vary with changes in interest rates. Currently, we do not anticipate taking any biotech stock gains this year to offset the costs of in-licensing arrangements, but we expect to have gains related to the expiration of certain of our biotechnology portfolio hedges.

## Income Tax Provision

The effective income tax rate increased to 36% in the first quarter of 2005 from 34% for the comparable period in 2004. The increase in the income tax rate primarily reflects increased income before taxes and reduced benefits from R&D tax credits. The income tax provision for the first quarter of 2004 included a benefit of \$6.5 million related to a favorable change in estimates of research credits.

We anticipate that our annual 2005 effective income tax rate will be comparable to the rate in 2004 of 36%. 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, future levels of R&D spending, and changes in overall levels of pretax earnings.

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Net Income and Earnings Per Share	Three Months Ended March 31,		% Change
	2005	2004	
	(In millions)		
Net income	\$ 284.2	\$ 176.6	61 %
Earnings per share:			
Basic	\$ 0.27	\$ 0.17	59
Diluted	\$ 0.27	\$ 0.16	69

Net income and diluted earnings per share (or "EPS") in the first quarter of 2005 increased from the comparable period in 2004. This increase was driven by higher revenues and a higher operating margin, partially offset by higher income taxes.

Liquidity and Capital Resources

Liquidity and Capital Resources	March 31, 2005	December 31, 2004
	(In millions)	
Cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	\$ 2,705.1	\$ 2,780.4
Net receivable - equity hedge instruments	111.1	21.3
Total cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	2,816.2	2,801.7
Working capital	2,460.8	2,179.5
Current ratio	2.9:1	2.8:1

Cash, cash equivalents, short-term investments and long-term marketable securities, excluding restricted cash, were approximately \$2.7 billion at March 31, 2005, a decrease of \$75.3 million, or 3%, from December 31, 2004. This decrease primarily reflects a decrease in unrealized gains on the biotechnology marketable investment portfolio, partially offset by an increase in cash generated from operations. 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 marked-to-market. Cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, net of the equity hedge instruments were approximately \$2.8 billion at March 31, 2005, an increase of \$14.5 million from December 31, 2004. See Note 1, "Summary of Significant Accounting Policies -- Comprehensive Income," in the Notes to the Condensed 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.

At the end of 2005, we expect our total unrestricted cash and investments to be relatively flat as compared to year-end 2004 levels of approximately \$2.8 billion.

Absent any additional financing, our total cash, unrestricted cash equivalents, short-term investments and marketable securities are expected to decline modestly over the next several years due to cash requirements for capital

expenditures, share repurchases under our stock repurchase program, synthetic lease repayments and cash requirements under our Master Lease Agreement with Slough, SSF, LLC, and other uses of working capital. See below for a discussion of our leasing arrangements. See "Our Affiliation Agreement With Roche Could Adversely Affect Our Cash Position" 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.

- 28 -

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#### 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 \$688.5 million at March 31, 2005, an increase of \$89.4 million from December 31, 2004. This increase reflects higher sales, in particular sales to collaborators, product sales of Tarceva and higher sales of Rituxan. The average collection period of our "accounts receivable -- product sales" as measured in days sales outstanding (or "DSO") increased to 52 days at the end of the first quarter of 2005 from 44 days at the end of the first quarter of 2004. The increase in DSO was primarily due to the granting of extended payment terms on sales of new products, in particular Avastin. For 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. During the first quarter ended March 31, 2005, we ceased to offer extended payment terms on sales of the newly launched products. As a result, we expect our DSO to decrease in the next few quarters.

On January 12, 2005, we and 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. We agreed to (i) exchange XOMA's obligation to repay the development loan plus accrued interest for a renegotiated royalty obligation by us, and (ii) allow repayment of XOMA's fourth quarter share of Raptiva operating losses by offsetting them against future royalties payable by us. XOMA is no longer responsible for funding any development or sales and marketing activities, nor does it have the rights or obligations to co-promote or co-develop Raptiva.

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 other current assets and \$24.7 million was included in other long-term assets on our condensed consolidated balance sheet. The prepaid royalty is being amortized to cost of sales 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 \$143.9 million during the first quarter of 2005 compared to \$97.7 million during the first quarter of 2004. Capital expenditures in the first quarter of 2005 were made for the ongoing construction of our manufacturing facility in Vacaville, California, to purchase land, equipment and information systems and for ongoing construction costs in support of our manufacturing and corporate infrastructure needs.

In 2005, we expect to spend approximately \$1.2 billion in capital expenditures. This increase in spending over 2004 will primarily support our manufacturing expansion, projects related to existing facilities, equipment and information systems purchases, and increases in office space and land purchases.

#### 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 plan. We received \$106.4 million during the first quarter of 2005 and \$231.6 million during the first quarter of 2004, related to stock option exercises and stock issuances under our employee stock purchase plan. We also used cash for stock repurchases of \$155.5 million during the first quarter of 2005 pursuant to our stock repurchase program approved by our Board of Directors. We had no stock repurchases in the first quarter of 2004. See below for further information on our stock repurchase program.

Under a stock repurchase program approved by our Board of Directors, Genentech is authorized to repurchase up to 50,000,000 shares of our common stock for an aggregate price of up to \$2.0 billion through December 31, 2005. In

- 29 -

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

Our shares repurchased during 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		
Total	3.2	48.23	28.9	21.1

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 sheet. 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

Our existing synthetic leases are discussed in Note 6, "Leases, Commitments and Contingencies" and "Off-Balance Sheet Arrangements" in Management's Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2004. During the quarter ended March 31, 2005, there were no significant changes to our synthetic lease arrangements, or our assessment of those arrangements under the provisions of FIN 46R, a revision of Interpretation 46, as discussed in the Annual Report.

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to the Company's 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 quarter 2005, we have capitalized \$44.0 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

- 30 -

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consolidated balance sheet. 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 three months of 2005, there were no significant changes in our payments due under contractual obligations as disclosed in our Annual Report on Form 10-K at December 31, 2004.

#### Contingencies

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

#### Relationship with Roche

#### Redemption of Our Special Common Stock

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

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

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

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prices to maintain its percentage ownership interest. At March 31, 2005, Roche's ownership percentage was 56.0%. The Minimum Percentage at March 31, 2005 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be 55.7%. At April 26, 2005, Roche's ownership percentage was 0.1% below the

lowest ownership percentage. Genentech and Roche are in discussion concerning this matter.

#### Related Party Transactions

We enter into transactions with our related parties, Roche Holdings, Inc. (including Hoffmann-La Roche and other affiliates) 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 \$16.5 million and \$25.8 million in the first quarters of 2005 and 2004, respectively. All other revenues from Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$155.9 million and \$98.9 million in the first quarters of 2005 and 2004, respectively. Cost of sales included amounts related to Hoffmann-La Roche of \$47.2 million and \$22.4 million in the first quarters of 2005 and 2004, respectively. R&D expenses included amounts related to Hoffmann-La Roche of \$32.4 million and \$31.2 million in the first quarters of 2005 and 2004, respectively.

#### Novartis

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

Under an arrangement with Novartis, a holding company of The Novartis Group, and Tanox, Inc., we currently supply Xolair and receive cost plus a mark-up similar to other supply arrangements. Novartis is expected to undertake primary bulk manufacturing responsibility in late 2005 or early 2006. Future production costs of Xolair may initially be higher than those currently reflected in our cost of sales as a result of any production shift from Genentech to Novartis, or to any other party, until production economies of scale can be achieved by that manufacturing party.

Collaboration profit sharing expenses were \$23.6 million in the first quarter of 2005 and \$11.8 million in the first quarter of 2004. R&D expenses include amounts related to Novartis of \$9.7 million in the first quarters of 2005 and 2004. Revenue from Novartis related to product sales and the associated cost of sales were \$3.3 million and \$2.8 million, respectively, in the first quarter of 2005. Revenue from Novartis related to product sales and the associated cost of sales was not material in the first quarter of 2004. Contract revenue from Novartis earned related to manufacturing, commercial and ongoing development activities, was \$10.0 million in the first quarter of 2005 and \$10.8 million in the first quarter 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	(798)	798	50.30
Exercises	-	(3,816)	23.70
Cancellations	404	(404)	38.86
March 31, 2005 (Year to date)	101,214	90,344	32.82

(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)

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As of March 31, 2005	Exercisable		Unexercisable		Total	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
In-the-Money	46,385	\$ 25.15	43,551	\$ 40.74	89,936	\$ 32.70
Out-of-the-Money <sup>(1)</sup>	21	56.64	387	59.08	408	58.95
<b>Total Options Outstanding</b>	<b>46,406</b>		<b>43,938</b>		<b>90,344</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, \$56.61, at the close of business on March 31, 2005.

- 33 -

Distribution and Dilutive Effect of Options

Employee and Executive Officer Option Grants

	2005	2004	2003
Net grants during the year as % of outstanding shares	0.03 %	1.82 %	1.69 %
Grants to Named Executive Officers* during the year as % of outstanding shares	0.00 %	0.19 %	0.18 %
Grants to Named Executive Officers during the year as % of total options granted	0.00 %	9.63 %	8.54 %

\* "Named Executive Officers" refers to our Chief Executive Officer and our four other most highly compensated executive officers as defined under Item 402(a) (3) of Regulation S-K of the federal securities laws.

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 Avastin, Rituxan, Herceptin, Tarceva, Xolair and Raptiva sales growth and our ability to deliver sustainable growth; achievement of our 5x5 goals including growth in non-GAAP EPS, and the of number 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; our ability to meet forecasted demand for our products; the impact of Medicare legislation on sales of our products; and our expected revenues from sales to collaborators, royalties, contract revenues, cost of sales, R&D and MG&A 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, and R&D and MG&A expenses, 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 Could Harm Our Business," "Protecting Our Proprietary Rights Is Difficult and Costly," "The Outcome of, and Costs Relating to, Pending Litigation or Other Legal Actions are Uncertain," 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, Rituxan, Herceptin, Tarceva, Xolair and Raptiva sales growth and our ability to deliver sustainable growth, our ability to meet forecasted demand for our products 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 Royalty and Contract Revenues Could Decline;" for the impact of Medicare legislation on our product sales, see "Decreases in Third Party Reimbursement Rates May Affect Our Product Sales;" for non-GAAP EPS growth, see all of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below. We disclaim any obligation and do not undertake to update or revise any forward-looking statements in this Form 10-Q.

- 34 -

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#### 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 and is dependent on numerous factors, a number of which are beyond our control. 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 primary or secondary 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 BLA preparation, discussions with the 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.

Factors affecting our R&D productivity and 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.
- Hoffmann-La Roche's decisions 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.

- 35 -

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- 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.
- As part of our strategy, we invest in R&D. R&D as a percentage of revenues can fluctuate with the changes in future levels of revenue. Lower revenues can lead to more limited spending on R&D efforts.

- We participate in a number of collaborative research arrangements. On many of these collaborations, our share of expenses recorded in our financial statements are 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 Could Harm Our Business" below.
- Future levels of revenue.

#### We May Be Unable to Obtain or Maintain Regulatory Approvals for Our Products

The biotechnology and pharmaceutical industries 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 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, after any of 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 cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or that we can 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.
- 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.

Moreover, it is possible that 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.

#### Difficulties or Delays in Product Manufacturing Could Harm Our Business

We currently produce all of our products and we produce some products for others 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. 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 manufacturing of biologics is a complex process and as a consequence we may have inadequate bulk capacity to meet our own demands and/or the demands of those for whom we produce product.

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. Our vial inventories have steadily increased toward target levels over the past six months, and we expect to begin construction of a new aseptic fill line in our South San Francisco site in the third quarter of 2005. However, 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.

In addition, 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 and Vacaville facilities are located in an area where earthquakes could occur, changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products we make for others due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. 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 business. 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 alliance companies' 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 currently are in the process of expanding our Vacaville facility, and are planning to build new facilities or enter into contracts for additional manufacturing capacity in the future, and pursue process improvements to increase yields for our commercial products and for those products we produce for others such as Roche. Any delay in the construction of the facilities, the ability to contract for additional manufacturing capacity, the receipt of FDA licensure for new facilities or process improvements or a significant increase in demand for a product beyond available capacity may cause us to have insufficient available capacity for the manufacture of our products and/or the products we produce for others. Insufficient available capacity to manufacture or have manufactured for us existing or new products that are ours or that we produce for others could cause shortfalls of available product inventory and an inability to supply market demand of one or more of our products and/or the products we produce for others for either a short period of time or an extended period of time. All of our efforts planning for additional manufacturing capacity are critical to providing for sufficient capacity to meet expected demand for our products, and for products we produce for others and we recognize that there are some inherent uncertainties associated with forecasting future demand, especially for newly introduced products, and that the manufacturing of biologics is a complex process.

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

- 37 -

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increasingly subject to greater public and regulatory scrutiny because of the perceived risk of contamination with bovine spongiform encephalopathy (or "BSE"). We have taken, and are continuing to take, precautions to minimize the risk of BSE contamination in our bovine source raw materials. We closely document the use of bovine source raw materials in our processes, take stringent measures to use the purest ingredients available and are working towards transitioning our processes to remove bovine source raw materials from final formulations. We are also in compliance with applicable U.S. and European guidelines on the handling and use of bovine source raw materials. Because of these efforts as well as those of the FDA, we believe that the risk of BSE contamination in our source materials is very low. However, 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), 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

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, possibly offset to some extent by increased physician payment rates for drug administration services related to certain of our oncology products. The Congressional rationale for this legislation was that (1) the payment for drugs by the Medicare program should more closely reflect the acquisition costs for those drugs, and (2) the reimbursement for the service codes associated with the administration of drugs should be increased to better reflect practice expense costs associated with those services. 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 matters discussed in Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities to third-parties. An adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third-parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

The presence of patents or other proprietary rights belonging to other parties may lead to our termination of the R&D of a particular product.

We believe that we have strong patent protection or the potential for strong patent protection for a number of our products that generate sales and royalty revenue or that we are developing. However, it is for the courts in the U.S. and in other jurisdictions ultimately to determine the strength of that patent protection.

The Outcome of, and Costs Relating to, Pending Litigation or Other Legal Actions are Uncertain

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

- 38 -

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the manufacture or sale of a product or potential product or a significant jury verdict or punitive damages award, 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.

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. We have policies and procedures governing our sales and marketing activities and we believe our sales and marketing activities are in compliance with these laws. 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). If the government were to bring charges against or convict us of violating these laws, there could be a material adverse effect on our business, including our financial condition and results of operations. We have been in the past, are currently, and may in the future be investigated for the promotional practices related to our products.

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 attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, on our ability to successfully integrate large number of new employees into our corporate culture, and on our ability to develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense.

Roche has the right to maintain its percentage ownership interest in our common stock. 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. This, and changes in stock option accounting rules could have an adverse effect on the number of shares we are able 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.

We Face Competition



We face competition from pharmaceutical companies, pharmaceutical divisions of chemical companies, and biotechnology companies of various sizes. Some competitors have greater clinical, regulatory and marketing resources and experience than we do. Many of these companies have commercial arrangements with other companies in the biotechnology industry to supplement their own research capabilities.

The introduction of new products or follow-on biologics or the development of new processes by competitors or new information about existing products may result in price reductions or product replacements, even for products protected by patents. However, we believe our competitive position is enhanced by our commitment to research leading to the discovery and development of new products and manufacturing methods. Other factors that should help us meet competition include ancillary services provided to support our products, customer service, and dissemination of technical information to prescribers of our products and to the health care community, including payors.

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.

We face competition in certain of our therapeutic markets. In the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to competing thrombolytic therapies and to the use of mechanical reperfusion therapies to treat acute myocardial infarction. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow.

- 39 -

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In the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. Competitors have also received approval to market their existing growth hormone products for additional indications beyond those that our products are currently approved. As a result of that competition, we have experienced and may continue to experience a loss in market share.

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, respectively.

Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil (or "5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with intravenous 5-FU/Leucovorin and CPT-11 (or "the Saltz Regimen"). In a Phase II trial, Avastin was found to provide benefit for first-line patients when used in combination with intravenous 5-FU/Leucovorin alone. In November 2004, we and Hoffmann-La Roche announced the preliminary results of a Phase III trial of Avastin in patients with advanced colorectal cancer who had previously received treatments. The trial achieved its primary endpoint of improving overall survival. With this positive data (assuming a sBLA is approved), Avastin may compete with ImClone/Bristol-Myers Squibb's ERBITUX®, an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer patients. In addition, Novartis recently announced that its oral VEGF-inhibitor, PTK-787, in combination with 5-FU/Leucovorin/Oxaliplatin (or "FOLFOX") in the first-line setting missed its progression free survival endpoint in a Phase III trial. The trial is continuing in an effort to assess overall survival; results are expected in the second half of 2006. PTK-787 is also being investigated with FOLFOX in the relapsed setting. If these results are successful, there is the potential for that product, if approved by the FDA, to

compete with Avastin.

Tarceva faces competition from Iressa™, the only other EGFR tyrosine kinase inhibitor indicated for NSCLC, although recent negative survival data about Iressa's™ efficacy in relapsed NSCLC (i.e. the ISEL trial) may substantially lessen that competition. Tarceva also 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 NSCLC.

#### Other Factors Could Affect Our Product Sales

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

- The timing of FDA approval, if any, of competitive products.
- Our pricing decisions, including a decision to increase or decrease the price of a product, and the pricing decisions of our competitors.
- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Negative safety or efficacy data from new clinical studies could cause the utilization and sales of our products to decrease.
- Negative safety or efficacy data from post-approval marketing experience could cause sales of our products to decrease or for a product to be recalled.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.

- 40 -

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- 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. For example, as described in Note 3, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q, at various times other companies have filed patent infringement lawsuits against us alleging that the manufacture, use and sale of certain of our products infringe their patents.
- 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.

#### Our Royalty and Contract Revenues Could Decline

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 benchmarks are achieved.
- The failure of or refusal of a licensee to pay royalties.
- The expiration or invalidation of our patents or licensed intellectual property. For example, patent litigations, interferences, oppositions, and other proceedings involving our patents often include claims by third-parties that such patents are invalid or unenforceable. If a court, patent office, or other authority were to determine that a patent under which we receive royalties and/or other revenues is invalid or unenforceable, that determination could cause us to suffer a loss of such royalties and/or revenues, and could cause us to incur other monetary damages.
- Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

- 41 -

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#### 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 to Obtain or Maintain

While we currently have 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. 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 action. 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. We have taken steps, when possible, to minimize potential environmental liability associated with the ownership and/or use of such properties by entering into agreements with responsible parties and relevant government agencies. However, certain events could occur which may require us to pay significant clean-up or other costs in order to maintain our operations on those properties. Such events include, but are not limited to, changes in environmental laws, discovery of new contamination, or unintended exacerbation of existing contamination. The occurrence of any such event could materially affect our ability to continue our business operations on those properties.

#### Fluctuations in Our Operating Results Could Affect the Price of Our Common Stock

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

- The overall competitive environment for our products as described in "We Face Competition" above.
- The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.
- The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the U.S. and the amount and timing of sales to their respective customers, which directly impacts both our product sales and royalty revenues.
- The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of therapy.
- The extent of product discounts extended to customers.

- 42 -

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- 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 in the process of implementing a new general ledger, financial reporting, order management, procurement and data warehouse systems to replace our current systems. We have functioning legacy systems in place, but we may not be successful in implementing 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 Highly 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 highly volatile.

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

- Announcements of technological innovations or new commercial products by us or our competitors.
- Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors.
- Developments or outcome of litigation, including litigation regarding proprietary and patent rights.
- Regulatory developments or delays concerning our products in the U.S. and foreign countries.
- Issues concerning the safety of our products or of biotechnology products generally.
- Economic and other external factors or a disaster or crisis.
- Period-to-period fluctuations in our financial results.

#### Our Affiliation Agreement With Roche 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 4, "Relationship with Roche Holdings, Inc. (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 estimated, 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 March 31, 2005, Roche owned 587,189,380 shares of our common stock or 56.0% 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. Roche currently intends to continue to allow our current management to conduct our business and operations as we have done in the past. However, we cannot assure stockholders that Roche will not institute a new business plan in the future. Roche's interests may conflict with minority shareholder interests.

#### Our Affiliation Agreement with Roche Could Limit Our Ability to Make Acquisitions and Could Have a Material Negative Impact on Our Liquidity

The affiliation agreement between us and Roche contains provisions that:

- Require the approval of the directors designated by Roche to make any acquisition or any sale or disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues.
- Enable Roche to maintain its percentage ownership interest in our common stock.
- Require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock based on an established Minimum Percentage. For information regarding Minimum Percentage, see Note 4, "Relationship with Roche Holdings, Inc. (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 a stock repurchase program 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:

- Competition by Roche 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 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.

The Company's 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 pretax earnings.

Recent Accounting Pronouncements May Impact Our Future Financial Position and Results of Operations

Under Financial Accounting Standards Board 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", effective for reporting periods beginning after June 15, 2005. On April 14, 2005, the Securities and Exchange Commission (or the "SEC") adopted a rule amendment that delayed

- 45 -

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the compliance dates for FAS 123R such that we are now allowed to adopt the new standard no later than January 1, 2006. FAS 123R 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 purchase plans. We expect to adopt FAS 123R using the modified prospective basis measured and recognized on January 1, 2006. We expect that our adoption of FAS 123R will result in compensation expense and EPS amounts comparable, before the effect of capitalization of manufacturing related compensation expenses, 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 this Form 10-Q. We are currently evaluating option valuation methodologies and assumptions in light of FAS 123R and the SEC guidance; 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 this Form 10-Q. We expect that the adoption of FAS 123R will have a material impact on our consolidated results of operations.

- 46 -

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### Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

### 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.* There was no change in the Company's internal control over financial reporting that occurred during the period covered by this Form 10-Q that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

- 47 -

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

See also Item 3 of our report on Form 10-K for the year ended December 31, 2004.

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.

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

Under a stock repurchase program approved by our Board of Directors, Genentech is authorized to repurchase up to 50,000,000 shares of our common stock for an aggregate price of up to \$2.0 billion through December 31, 2005. In this program, as in previous stock repurchase programs, 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 during 2005 were as follows (*shares in millions*):

Total Number of Shares Purchased in 2005	Average Price Paid	Total Number of Shares Purchased as Part of Publicly Announced Plans	Maximum Number of Shares that May Yet Be Purchased
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		per Share	or Programs	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		
Total	<u>3.2</u>	48.23	<u>28.9</u>	<u>21.1</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.

- 48 -

#### Item 6. Exhibits

- (i) 10.28 Form of Indemnification Agreement for Directors and Officers
- (ii) 10.29 Genentech, Inc. Supplemental Plan\*
- (iii) 15.1 Letter regarding Unaudited Interim Financial Information.
- (iv) 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.
- (v) 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.
- (vi) 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.

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\* Filed as an exhibit to our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 24, 2005 and incorporated herein by reference.

- 49 -

SIGNATURES

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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: April 29, 2005

/s/ARTHUR D. LEVINSON

Arthur D. Levinson, Ph.D.  
Chairman and Chief Executive Officer

Date: April 29, 2005

/s/DAVID A. EBERSMAN

David A. Ebersman  
Senior Vice President and  
Chief Financial Officer

Date: April 29, 2005

/s/JOHN M. WHITING

John M. Whiting  
Vice President, Controller and  
Chief Accounting Officer