

GENENTECH INC  
Form 10-Q  
November 01, 2004

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

FORM 10-Q

---

(Mark One)

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

For the quarterly period ended September 30, 2004

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)

Edgar Filing: GENENTECH INC - Form 10-Q

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	1,049,621,719 Outstanding at October 22, 2004

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 and nine months ended September 30, 2004 and 2003</u> 3
	<u>Condensed Consolidated Statements of Cash Flows - for the nine months ended September 30, 2004 and 2003</u> 4
	<u>Condensed Consolidated Balance Sheets - September 30, 2004 and December 31, 2003</u> 5
	<u>Notes to Condensed Consolidated Financial Statements</u> 6-18
	<u>Report of Independent Registered Public Accounting Firm</u> 19
Item 2.	20-55
	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
Item 3.	56
	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
Item 4.	56
	<u>Controls and Procedures</u>

PART II - OTHER INFORMATION

Item 1.		57
	<u>Legal Proceedings</u>	
Item 2.		57
	<u>Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	
Item 6.		58
	<u>Exhibits</u>	
		59
	<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 putable common stock, par value \$0.02 per share, all of which was redeemed by Roche Holdings, Inc. on June 30, 1999. All information relating to the number of shares, price per share and per share amounts of common stock give effect to the May 2004 two-for-one split of our common stock.

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.

PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

GENENTECH, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF INCOME

*(In thousands, except per share amounts)*

*(Unaudited)*

Edgar Filing: GENENTECH INC - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
<b>Revenues</b>				
Product sales (including amounts from related parties: three months - 2004-\$23,855; 2003-\$18,040; nine months - 2004-\$79,347; 2003-\$83,224)	\$ 1,005,511	\$ 654,948	\$ 2,682,577	\$ 1,897,754
Royalties (including amounts from related party: three months - 2004-\$83,099; 2003-\$59,912; nine months - 2004-\$238,468; 2003-\$164,376)	153,942	116,535	459,899	352,597
Contract revenue (including amounts from related parties: three months - 2004-\$15,271; 2003-\$31,332; nine months - 2004-\$85,783; 2003-\$52,035)	43,191	45,561	163,381	116,078
<b>Total operating revenues</b>	<b>1,202,644</b>	<b>817,044</b>	<b>3,305,857</b>	<b>2,366,429</b>
<b>Costs and expenses</b>				
Cost of sales (including amounts for related parties: three months - 2004-\$22,529; 2003-\$20,517; nine months - 2004-\$71,194; 2003-\$75,360)	165,990	115,673	467,153	353,921
Research and development (including amounts for related parties: three months - 2004-\$36,870; 2003-\$36,377; nine months - 2004-\$124,072; 2003-\$59,860) (including contract related: three months - 2004-\$18,673; 2003-\$29,660; nine months - 2004-\$90,168; 2003-\$56,112)	234,086	168,707	637,317	506,343
Marketing, general and administrative	264,648	209,860	788,616	531,340
Collaboration profit sharing (including amounts for related party: three months - 2004-\$21,560;	151,894	119,676	423,546	323,530

Edgar Filing: GENENTECH INC - Form 10-Q

2003-\$0;  
 nine months - 2004-\$48,209;  
 2003-\$0)

Recurring charges related to redemption	34,534	38,586	110,952	115,758
Special items: litigation-related	13,419	(131,617)	40,276	(105,008)
<b>Total costs and expenses</b>	<b>864,571</b>	<b>520,885</b>	<b>2,467,860</b>	<b>1,725,884</b>
Operating margin	338,073	296,159	837,997	640,545
Other income, net	23,510	15,884	61,274	72,456
Income before taxes and cumulative effect of accounting change	361,583	312,043	899,271	713,001
Income tax provision	130,709	112,407	321,040	229,549
Income before cumulative effect of accounting change	230,874	199,636	578,231	483,452
Cumulative effect of accounting change, net of tax	-	(47,655)	-	(47,655)
Net income	<u>\$ 230,874</u>	<u>\$ 151,981</u>	<u>\$ 578,231</u>	<u>\$ 435,797</u>

Earnings per share

Basic

Earnings before cumulative effect of accounting change	\$ 0.22	\$ 0.19	\$ 0.55	\$ 0.47
Cumulative effect of accounting change, net of tax	-	(0.04)	-	(0.05)
Net earnings per share	<u>\$ 0.22</u>	<u>\$ 0.15</u>	<u>\$ 0.55</u>	<u>\$ 0.42</u>

Diluted

Earnings before cumulative effect of accounting change	\$ 0.21	\$ 0.18	\$ 0.53	\$ 0.46
Cumulative effect of accounting change, net of tax	-	(0.04)	-	(0.05)
Net earnings per share	<u>\$ 0.21</u>	<u>\$ 0.14</u>	<u>\$ 0.53</u>	<u>\$ 0.41</u>

Weighted-average shares used to compute earnings per share

Basic	<u>1,055,140</u>	<u>1,040,762</u>	<u>1,057,006</u>	<u>1,030,140</u>
Diluted	<u>1,077,093</u>	<u>1,065,572</u>	<u>1,082,081</u>	<u>1,051,649</u>

GENENTECH, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)  
(Unaudited)

	Nine Months Ended September 30,	
	2004	2003
<b>Cash flows from operating activities</b>		
Net income	\$ 578,231	\$ 435,797
Adjustments to reconcile net income to net cash provided by operating activities:		
Cumulative effect of accounting change, net of tax	-	47,655
Depreciation and amortization	259,583	220,926
Deferred income taxes	(60,325)	(156,918)
Deferred revenue	(6,250)	251,851
Litigation-related liabilities	38,568	42,964
Tax benefit from employee stock options	274,918	202,528
Net gain on sales of securities available-for-sale and other	(11,736)	(17,797)
Write-down of securities available-for-sale	12,033	3,764
Loss on fixed asset dispositions	-	8,914
Changes in assets and liabilities:		
Receivables and other current assets	(274,416)	(73,878)
Inventories	(90,280)	(47,063)
Investments in trading securities	(38,021)	(26,701)
Accounts and taxes payables and other current liabilities	170,375	100,695
<b>Net cash provided by operating activities</b>	<b>852,680</b>	<b>992,737</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(825,950)	(1,168,001)
Proceeds from sales and maturities of securities available-for-sale	772,058	398,045
Capital expenditures	(418,214)	(211,245)

Change in other assets	(34,297)	(41,308)
Transfer from restricted cash, net	4,600	-
<b>Net cash used in investing activities</b>	<b>(501,803)</b>	<b>(1,022,509)</b>
Cash flows from financing activities		
Stock issuances	421,093	431,606
Stock repurchases	(821,354)	(195,274)
<b>Net cash (used in) provided by financing activities</b>	<b>(400,261)</b>	<b>236,332</b>
Net (decrease) increase in cash and cash equivalents	(49,384)	206,560
Cash and cash equivalents at beginning of period	372,152	208,130
Cash and cash equivalents at end of period	\$ 322,768	\$ 414,690

See Notes to Condensed Consolidated Financial Statements.

Page 4

GENENTECH, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2004	December 31, 2003
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 322,768	\$ 372,152
Short-term investments	1,437,396	1,139,620
Accounts receivable - product sales, net (including amounts from related parties: 2004-\$7,293; 2003-\$16,018)	570,353	315,097
Accounts receivable - royalties, net (including amounts from related party: 2004-\$117,799; 2003-\$113,739)	193,650	184,163
Accounts receivable - other, net (including amounts from related parties: 2004-\$66,442; 2003-\$71,863)	88,899	74,831
Inventories	559,920	469,640
Prepaid expenses and other current assets	203,481	201,327

Edgar Filing: GENENTECH INC - Form 10-Q

Total current assets	3,376,467	2,756,830
Long-term marketable debt and equity securities	1,310,422	1,422,886
Property, plant and equipment	1,922,313	1,617,912
Goodwill	1,315,019	1,315,019
Other intangible assets	677,049	810,810
Restricted cash and other long-term assets	776,576	812,714
Total assets	<u>\$ 9,377,846</u>	<u>\$ 8,736,171</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 60,081	\$ 59,700
Taxes payable	172,136	88,988
Other current liabilities (including amounts owed to related parties: 2004-\$94,950; 2003-\$58,138)	848,825	724,343
Total current liabilities	1,081,042	873,031
Long-term debt	412,250	412,250
Other long-term liabilities	916,988	930,592
Total liabilities	2,410,280	2,215,873
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock	21,088	20,990
Additional paid-in capital	7,945,843	7,359,416
Accumulated deficit, since June 30, 1999	(1,290,777)	(1,157,141)
Accumulated other comprehensive income	291,412	297,033
Total stockholders' equity	6,967,566	6,520,298
Total liabilities and stockholders' equity	<u>\$ 9,377,846</u>	<u>\$ 8,736,171</u>

See Notes to Condensed Consolidated Financial Statements.



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. 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. Certain reclassifications have been made to prior year amounts to conform with current period presentation.

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 for the full year. 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, 2003.

All information in this report relating to the number of shares, price per share and per share amounts of common stock give effect to the May 2004 two-for-one stock split of our common stock.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Genentech and all subsidiaries. Genentech also consolidates a variable interest entity for which Genentech is the primary beneficiary pursuant to Financial Accounting Standards Board (or FASB) Interpretation No. 46R (or FIN 46R), a revision to Interpretation 46, "Consolidation of Variable Interest Entities," an interpretation of Accounting Research Bulletin No. 51, and records the noncontrolling interest in the condensed consolidated balance sheet. Material intercompany accounts and transactions have been eliminated.

Use of Estimates

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

Accounting for Stock-Based Compensation

We have elected to continue to follow the intrinsic value method of accounting for stock-based compensation as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees." We apply the disclosure provisions of Statement of Financial Accounting Standards No. 123 (or FAS 123), "Accounting for Stock-based Compensation," as amended by FAS 148, "Accounting for Stock-based Compensation - Transition and Disclosure" (or FAS 148), as if the fair value-based method had been applied in measuring compensation expense. In management's opinion, the existing models do not provide a reliable single measure of the fair value of our employee stock options, thus these calculations may not accurately value such options. Under APB 25, we do not recognize compensation expense unless the exercise price of our employee stock options is less than the market price of the underlying stock on the date of grant. We grant all of our options at the fair market value of the underlying stock on the date of grant. Consequently, we have not recorded such expense in the periods presented.

We currently grant options under a stock option plan that allows for the granting of non-qualified stock options, incentive stock options and stock purchase rights to employees, directors and consultants of Genentech. Incentive stock options may only be granted to employees under this plan. Generally, non-qualified options and incentive options have a maximum term of 10 years. In general, options vest in increments over four years from the date of grant. We have an employee stock plan that allows eligible employees to purchase common stock at 85% of the lower of the fair market value on the grant date or the fair market value on the purchase date. Purchases are limited to 15% of each employee's eligible compensation and subject to certain Internal Revenue Service restrictions. All full-time employees of Genentech are eligible to participate in this employee stock plan.

We had stock option exercises of 1.8 million shares in the third quarter and 18.3 million shares in the first nine months of 2004.

The following information regarding net income and earnings per share has been determined as if we had accounted for our employee stock options and employee stock plan under the fair value method prescribed by FAS 123, as amended by FAS 148. 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 fair value of options was estimated at the date of grant using a Black-Scholes option valuation model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Risk-free interest rate	3.4%	2.8%	3.4%	2.8%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility factors of the expected market price of our Common Stock	43.0%	45.0%	43.0%	44.7%
Weighted-average expected life of option (years)	5	5	5	5

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Our employee stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate.

For purposes of disclosures pursuant to FAS 123, as amended by FAS 148, the estimated fair value of options is amortized to expense ratably over the options' vesting period.

The following table illustrates the effect on reported net income and earnings per share as if we had applied the fair value recognition provisions of FAS 123 to stock-based employee compensation (*in thousands, except per share amounts*):

Three Months Ended September 30,		Nine Months Ended September 30,	
2004	2003	2004	2003

Edgar Filing: GENENTECH INC - Form 10-Q

Net income - as reported	\$ 230,874	\$ 151,981	\$ 578,231	\$ 435,797
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	46,282	44,096	136,148	123,781
Pro forma net income	\$ 184,592	\$ 107,885	\$ 442,083	\$ 312,016
Earnings per share:				
Basic-as reported	\$ 0.22	\$ 0.15	\$ 0.55	\$ 0.42
Basic-pro forma	\$ 0.17	\$ 0.10	\$ 0.42	\$ 0.30
Diluted-as reported	\$ 0.21	\$ 0.14	\$ 0.53	\$ 0.41
Diluted-pro forma	\$ 0.17	\$ 0.10	\$ 0.41	\$ 0.30

Page 7

On March 31, 2004, the FASB issued an Exposure Draft, "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95" (proposed FAS 123R), which currently is expected to be effective for public companies in periods beginning after June 15, 2005. We would be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. The proposed FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. The proposed FAS 123R would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. The FASB expects to issue a final standard by December 31, 2004. We are currently evaluating option valuation methodologies and assumptions in light of the proposed FAS 123R related to employee stock options. Current estimates of option values using the Black-Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

Note 2. LEASES AND CONTINGENCIES

Leases

We lease various real properties under operating leases. Two of our operating leases are commonly referred to as "synthetic leases." Under FIN 46R, each lease is evaluated to determine if it qualifies as a variable interest entity (or VIE) and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

One of our synthetic leases relates to our manufacturing facility located in Vacaville, California. Under FIN 46R, we determined that the entity from which we lease the Vacaville facility qualifies as a VIE and that we are the primary beneficiary of this VIE, as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46R on July 1, 2003, we consolidated the entity.

Our other lease was entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us a building that we occupy in South San Francisco, California. We have evaluated our accounting for this lease under the provisions of FIN 46R, and have determined the following:

- as of July 1, 2003 and for each quarterly reporting period through September 30, 2004, our remaining synthetic lease entered into with BNP represents a variable interest in BNP;
- we are not the primary beneficiary of BNP as we do not absorb the majority of the entity's expected losses or expected residual returns. As part of this determination, we have received quarterly confirmations from BNP representing to us and we have reviewed their portfolio statements to confirm that the leased property does not represent greater than 50% of the fair value of BNP's assets; and
- we believe that the leased property is not a "specified asset" that represent essentially the only source of payment for our variable interest. As part of this determination, we have received quarterly confirmations from BNP representing to us and we have reviewed their portfolio statements to confirm that the leased property is not a "specified assets" held within a silo. That is, BNP has not financed an amount equal to or greater than 95% of the fair value of the leased assets with non-recourse debt, lessor participation, targeted equity or any other type of funding (silo funding) that would result in the leased property being the only source of payment. In addition, as part of BNP's representations and warranties, BNP has agreed not to incur additional indebtedness in the future or to change the character of other non-targeted equity or similar funding sources that in any way would result in the leased property being essentially the only source of repayment or to make any distributions from BNP that would result in silo funding equal to or exceeding 95% of the fair value of the leased property.

Accordingly, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP lease.

Future minimum lease payments were computed based on December 31, 2003 market-based interest rates, which are subject to fluctuations. The minimum payments under all leases, exclusive of the residual value guarantees, executory costs and sublease income, at December 31, 2003, are as follows (*in millions*):

	2004	2005	2006	2007	2008	Thereafter	Total
Vacaville synthetic lease <sup>(1)</sup>	\$ 6.2	\$ 6.2	\$ 5.6	\$ -	\$ -	\$ -	\$ 18.0
South San Francisco synthetic leases	2.7	2.6	1.1	-	-	-	6.4
Other operating	6.5	6.9	5.8	5.8	5.8	24.1	54.9

leases							
Total	\$ 15.4	\$ 15.7	\$ 12.5	\$ 5.8	\$ 5.8	\$ 24.1	\$ 79.3

(1) Represents a VIE, which we consolidated effective July 1, 2003, as we are the primary beneficiary of this VIE.

The following summarizes the approximate initial fair values of the facilities at the inception of the related leases, lease terms and residual value guarantee amounts for our two remaining synthetic leases (*in millions*):

	Approximate Initial Fair Value of Leased Property	Lease Expiration	Maximum Residual Value Guarantee
Vacaville lease	\$ 425.0	11/2006	\$ 371.8
South San Francisco lease 2	160.0	06/2007	136.0
Total	\$ 585.0		\$ 507.8

Two of our synthetic leases expired in the first nine months of 2004. Upon the expiration of these leases, we purchased the related properties from our lessor, BNP, and paid \$25.0 million in the first quarter and \$56.6 million in the third quarter of 2004 for the related properties.

We believe that there have been no impairments in the fair value or use of the properties that we lease under synthetic leases wherein we would be required to pay amounts under any of the residual value guarantees. We will continue to assess the fair values of the underlying properties and the use of the properties for impairment at least annually.

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnification in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses and expenses to be material.

#### 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 potential 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. The first trial of this suit began on August 28, 2001. On October 24, 2001, the jury hearing the lawsuit announced that it was unable to reach a verdict and on that basis the Court declared a mistrial. COH requested a retrial, and the retrial began on March 20, 2002. On June 10, 2002, the jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, the 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 other long-term liabilities in the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. On October 21, 2004 the Court of Appeal affirmed the verdict and damages awards in all respects. Also, on October 21, Genentech announced that it will seek review by the California Supreme Court, which has discretion over which cases it will review. We currently believe that if our petition for review of the COH verdict is granted, the process will likely take longer than one year. In the event that our petition for review is not granted or that the appeal process is resolved earlier, the pledged assets and associated liability may be reclassified as a current asset and liability, respectively. 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 our planned petition for a rehearing by the Court of Appeal and/or a review by the California Supreme Court.

On June 7, 2000, Chiron Corporation filed a patent infringement suit against us in the U.S. District Court in the Eastern District of California (Sacramento), alleging that the manufacture, use, sale and offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 6,054,561. This patent was granted on April 25, 2000, and will expire on June 28, 2005, and it relates to certain antibodies that bind to breast cancer cells and/or other cells. Chiron is seeking compensatory damages for the alleged infringement, additional damages (e.g., for willful infringement), and attorneys' fees and costs. On April 22, 2002, the Court issued its decision ("Markman Order") construing certain aspects of the patent claims that are in dispute. On June 25, 2002, the Court issued several decisions regarding summary judgment motions that previously had been filed by Chiron and us. In those decisions, the Court ruled as a matter of law that Herceptin infringes claims 1 to 25 of Chiron's patent, and also ruled as a matter of law in favor of Chiron on some but not all of Genentech's defenses and counterclaims regarding the alleged invalidity and/or unenforceability of the patent. The trial of this suit began on August 6, 2002. Following the first phase of the trial, which related to Genentech's remaining defenses and counterclaims regarding the alleged invalidity of the patent, the jury unanimously found that claims 1 to 25 of Chiron's patent were invalid, and on that basis the Court entered judgment in favor of Genentech. Chiron filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit ("Court of Appeals"), and Genentech filed a notice of cross-appeal. On April 6, 2004, we announced that a three-judge panel of the Court of Appeals unanimously affirmed the 2002 judgment of the U.S. District Court that found in favor of Genentech that all claims of Chiron's patent asserted against Genentech are invalid. On or about April 15, 2004, Chiron filed a Petition for Rehearing with the Court of Appeals seeking further review and reconsideration of that Court's decision. The Court of Appeals denied the Petition in its entirety on June 8, 2004. On October 4, 2004, Chiron filed a petition with the United States Supreme Court seeking review of the judgment in favor of Genentech. The briefing process related to this petition is ongoing.

On August 12, 2002, the U.S. Patent and Trademark Office (or Patent Office) declared an interference between the Chiron patent involved in the above-mentioned lawsuit (U.S. Patent No. 6,054,561) and a patent application exclusively licensed by Genentech from a university relating to anti-HER2 antibodies. An interference proceeding is declared to decide who first made a particular invention where two or more parties claim the same invention, whether the parties' claims are patentable, and consequently who is or is not entitled to a patent on the invention. In declaring this interference, the Patent Office has determined that there is a substantial question as to whether the inventors of the Chiron patent were first to invent and are entitled to this patent. If the Patent Office were to decide that the inventors of the university's patent application were first to invent and that their claims are patentable, a new patent would be issued to the university and the Chiron patent would be revoked. On October 24, 2002, the Patent

Page 10

---

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. The interference proceeding is ongoing and therefore the outcome of this matter cannot be determined at this time.

On March 13, 2001, Chiron filed another 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 second 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 (2) 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. This lawsuit is separate from and in addition to the Chiron suit mentioned above.

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. Genentech intends to vigorously defend itself against all of the allegations and claims in this lawsuit. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in Genentech's favor on all of MedImmune's antitrust and unfair competition claims. MedImmune sought to amend its complaint to reallege certain claims for antitrust and unfair competition. On February 19, 2004, the Court denied this motion in its entirety and final judgment was entered in favor of Genentech and Celltech and against MedImmune on March 15, 2004 on all antitrust and unfair competition claims. MedImmune filed a notice of appeal of this judgment with the U.S. Court of Appeals for the Federal Circuit. Concurrently, in the District Court litigation, Genentech filed a motion to dismiss all remaining claims in the case. On April 23, 2004, the District Court granted Genentech's motion and dismissed all remaining claims. Final judgment was entered in Genentech's favor on May 3, 2004, thus concluding proceedings in the District Court. MedImmune filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. Because the appeal process is ongoing, the final outcome of this matter cannot be determined at this time.

We recorded accrued interest and bond costs related to the COH trial judgment of \$13.4 million in the third quarters of 2004 and 2003, and \$40.3 million and \$40.0 million in the first nine months of 2004 and 2003, respectively. In 2002, we recognized \$543.9 million of litigation-related special charges, which included the COH trial judgment, including accrued interest and bond costs, and certain other litigation-related matters. In conjunction with the City of Hope judgment, we arranged to post a surety bond of \$600.0 million. As part of this arrangement, we were required to pledge \$630.0 million in cash and investments to secure the bond. In the second quarter of 2004, we were required to increase the surety bond to \$650.0 million and pledged an additional \$52.0 million, or a total of \$682.0 million, in cash and investments to secure the bond. These amounts are reflected in "restricted cash and other long-term assets" on the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. In addition, we accrued royalty expenses related to the City of Hope judgment of \$4.7 million in the first nine months of 2003 and none in the first nine months of 2004. This royalty expense is reflected in marketing, general and administrative expenses. 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 City of Hope trial results. These special charges represent our estimate of the costs for the current resolution of these matters and are included in other long-term liabilities in the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. We developed these estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. We

currently believe that if our petition for review of the COH verdict is granted, the process will likely take longer than one year. In the event that our petition for review is not granted or that the appeal process is resolved earlier, the pledged assets and associated liability may be reclassified as a current asset and liability, respectively. 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 our planned petition for a rehearing by the Court of Appeal and/or a review by the California Supreme Court.

### Note 3. RELATED PARTIES

We enter into transactions with our related parties, Roche Holdings, Inc. (including Hoffmann-La Roche and other affiliates) and Novartis AG (or Novartis), which has an investment in Roche, 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.

#### Relationship and Transactions with Roche Holdings, Inc. (or Roche)

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche with funds deposited by Roche for that purpose. This event, referred to as the "Redemption," caused Roche to own 100% of our common stock on that date. The Redemption was reflected as a purchase of a business, which under GAAP required us to reflect in our financial statements the amount paid for our stock in excess of our net book value plus Roche's transaction costs at June 30, 1999. See Note 4, "Other Intangible Assets," for the amortization of our other intangible assets.

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 will 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 2004 and 2003 (see Note 9, "Stock Repurchases Program"). 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. Roche publicly offered zero-coupon notes in January 2000, which were exchangeable for Genentech common stock held by Roche. Roche called these notes in March 2004. Through April 5, 2004, the expiration date for investors to tender these notes, a total of 25,999,324 shares were issued in exchange for the notes, thereby reducing Roche's ownership of Genentech common stock to 587,189,380 shares. At September 30, 2004, Roche's ownership percentage was 55.7%. The Minimum Percentage at September 30, 2004 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be no lower than 55.7%. See Note 9 "Capital Stock" for information regarding our stock repurchase program.

In April 2004, we further amended our July 1999 licensing and marketing agreement with Hoffmann-La Roche and its affiliates under which we grant them an option to license, use and sell our products in non-U.S. markets. This

amendment added certain Genentech products under Hoffman-La Roche's commercialization and marketing rights for Canada but did not modify any material financial terms of the licensing and marketing agreement, which are described in our Annual Report on Form 10-K for the year ended December 31, 2003.

We have a July 1998 licensing and marketing agreement relating to anti-HER2 antibodies (Herceptin and Omnitarg) with Hoffmann-La Roche, providing them with exclusive marketing rights outside of the United States. Under the agreement, Hoffmann-La Roche contributes equally with us on global development costs. Either Genentech or Hoffmann-La Roche has the right to "opt-out" of developing an additional indication for a product and would not share the costs or benefits of the additional indication, but could "opt-back-in" before approval of the indication by paying twice what would have been owed for development of the indication if no opt-out had occurred. Hoffmann-La Roche has also agreed to make royalty payments of 20% on aggregate net product sales outside the United States up to \$500 million in each calendar year and 22.5% on such sales in excess of \$500 million in each calendar year.

In April 2004, we entered into a research collaboration agreement with Hoffmann-La Roche that outlines the process by which Hoffmann-La Roche and Genentech will conduct and share in the costs of joint research on molecules in areas of mutual interest. The agreement further outlines how development and commercialization efforts will be

coordinated with respect to select molecules, including the financial provisions for a number of different development and commercialization scenarios undertaken by either or both parties.

In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under the July 1999 licensing and marketing agreement. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and pays 75% of subsequent global development costs related to the metastatic colorectal cancer indication of Avastin and all others unless Hoffmann-La Roche specifically opts out of the development of certain other indications. In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market a humanized anti-CD20 antibody for all countries outside of the U.S. (other than territory previously licensed to others) under the July 1999 licensing and marketing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and pays 50% of subsequent global development costs related to the humanized anti-CD20 antibody unless Hoffmann-La Roche opts out of the development of certain other indications. We will receive royalties on net sales of Avastin and the humanized anti-CD20 antibody in countries outside of the U.S.

We recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$4.3 million and \$23.9 million in the third quarters of 2004 and 2003, respectively, and \$53.9 million and \$33.5 million in the first nine months of 2004 and 2003, respectively. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$106.9 million and \$77.9 million in the third quarters of 2004 and 2003, respectively, and \$317.5 million and \$247.5 million in the first nine months of 2004 and 2003, respectively. Cost of sales included amounts related to Hoffmann-La Roche of \$22.5 million and \$20.5 million in the third quarters of 2004 and 2003, respectively, and \$70.8 million and \$75.3 million in the first nine months of 2004 and 2003, respectively. Research and development (or R&D) expenses included amounts related to Hoffmann-La Roche of \$25.7 million and \$28.9 million in the third quarters of 2004 and 2003, respectively, and \$93.0 million and \$43.5 million in the first nine months of 2004 and 2003, respectively.

#### Relationship and Transactions with Novartis

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

In June 2003, we entered into an agreement with Novartis Ophthalmics AG (subsequently merged into Novartis Pharma AG), under which Novartis Ophthalmics licensed the exclusive right to develop and market Lucentis outside of North America for diseases or disorders relating to the human eye, including the indication of age-related macular degeneration (or AMD). As part of this agreement, Novartis Ophthalmics paid us \$46.6 million and pays 50% of Genentech's expenses relating to certain AMD Phase III trials and related development expenses. Genentech may

share in a portion of the development costs incurred by Novartis outside of North America. We may also receive royalties on net sales of Lucentis products, which we will manufacture and supply to Novartis, outside of North America, and certain milestone payments.

In February 2004, Genentech, Inc., Novartis Pharma AG and Tanox, Inc. settled all litigation pending among them, and finalized the detailed terms of their three-party collaboration, begun in 1996, to govern the potential development and commercialization of certain anti-IgE antibodies including Xolair® (Omalizumab) and TNX-901. This

arrangement modifies the arrangement related to Xolair that we entered into with Novartis in 2000. All three parties are co-developing Xolair in the U.S., and Genentech and Novartis are co-promoting Xolair in the U.S. and both will separately make payments to Tanox; Genentech's will be in the form of royalties. Genentech records all sales and cost of sales in the U.S. and Novartis will market the product in and record all sales and cost of sales in Europe. Genentech and Novartis then share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. The existing royalty and profit-sharing percentages between the three parties remain unchanged. Genentech is currently supplying the product and receives cost plus a mark-up similar to other supply arrangements. Genentech and Novartis are finalizing the details of the supply and manufacturing planning of Xolair worldwide.

Contract revenue from Novartis was \$11.0 million and \$7.4 million in the third quarters of 2004 and 2003, respectively, and \$31.9 million and \$18.5 million in the first nine months of 2004 and 2003, respectively. Novartis collaboration profit sharing expenses were \$21.6 million and \$48.2 million in the third quarter and first nine months of 2004 and not material in the same periods of 2003. R&D expenses included amounts related to Novartis of \$11.2 million and \$7.5 million in the third quarters of 2004 and 2003, respectively, and \$31.0 million and \$16.3 million in the first nine months of 2004 and 2003, respectively.

#### Note 4. OTHER INTANGIBLE ASSETS

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

	September 30, 2004			December 31, 2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Developed product technology	\$ 1,194.1	\$ 828.2	\$ 365.9	\$ 1,194.1	\$ 769.5	\$ 424.6
Core technology	443.5	345.7	97.8	443.5	329.8	113.7
Tradenames	144.0	72.3	71.7	144.0	65.1	78.9
Patents	130.1	51.2	78.9	116.6	44.5	72.1
Other	626.5	563.8	62.7	661.8	540.3	121.5
Total	<u>\$ 2,538.2</u>	<u>\$ 1,861.2</u>	<u>\$ 677.0</u>	<u>\$ 2,560.0</u>	<u>\$ 1,749.2</u>	<u>\$ 810.8</u>

Amortization expense of our other intangible assets was \$38.7 million and \$42.7 million in the third quarters of 2004 and 2003, respectively, and \$143.1 million and \$128.0 million in the first nine months of 2004 and 2003, respectively. Included in the amortization expense in the second quarter of 2004 is an \$18.6 million charge to marketing, general and administrative (or MG&A) expense related to the unamortized portion of the license fee that was paid to Alkermes, Inc. in 2000 upon U.S. Food and Drug Administration approval of Nutropin Depot. This license fee was being amortized over a 10 year estimated life and was included in MG&A expense. Our decision to discontinue commercialization of Nutropin Depot resulted in an impairment to this license, as we do not anticipate any significant future cash flows attributable to this license.

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

For the Year Ending December 31,	Amortization Expense
2004 (remaining three months)	\$ 38.4
2005	139.8
2006	119.9
2007	118.6
2008	116.8
2009 and thereafter	143.5
Total expected future annual amortization	\$ 677.0

#### Note 5. DERIVATIVE FINANCIAL INSTRUMENTS

We record gains and losses on derivatives related to our equity hedging instruments in "other income, net" in the condensed consolidated statements of income. Such gains or losses were not material in the first nine months of 2004 or 2003.

At September 30, 2004, net losses on derivative instruments expected to be reclassified from accumulated other comprehensive income to "other income, net" during the next twelve months are \$6.9 million. These net losses are primarily due to the recognition of premiums related to maturing foreign currency exchange options.

#### Note 6. 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 taxes, during the third quarters and first nine months of 2004 and 2003 was as follows (*in millions*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	\$ 230.9	\$ 152.0	\$ 578.3	\$ 435.8
Change in unrealized gains (losses) on securities available-for-sale	(2.7)	16.1	(6.8)	28.8
Change in unrealized gains (losses) on derivatives	2.0	(0.6)	1.2	1.7
Comprehensive income	\$ 230.2	\$ 167.5	\$ 572.7	\$ 466.3

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

	September 30, 2004	December 31, 2003
Unrealized gains on securities available-for-sale	\$ 287.5	\$ 294.3
Unrealized gains on derivatives	3.9	2.7
Accumulated other comprehensive income	<u>\$ 291.4</u>	<u>\$ 297.0</u>

The activity in OCI, net of taxes, during the third quarters and first nine months of 2004 and 2003 related to our available-for-sale securities was as follows (*in millions*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Unrealized gains (losses) on securities available-for-sale (net of tax effect for third quarter of (\$2.1) in 2004 and \$10.3 in 2003; and for first nine months of (\$5.1) in 2004 and \$24.8 in 2003)	\$ (3.1)	\$ 15.5	\$ (7.6)	\$ 37.2
Reclassification adjustment for net gains included in net income (net of tax effect of (\$5.6) in the first nine months of 2003)	0.4	0.6	0.8	(8.4)
Change in net unrealized gains (losses) on securities available-for-sale	<u>\$ (2.7)</u>	<u>\$ 16.1</u>	<u>\$ (6.8)</u>	<u>\$ 28.8</u>

The activity in OCI, net of taxes, during the third quarters and first nine months of 2004 and 2003, related to our cash flow hedges was not material.

#### Note 7. EARNINGS PER SHARE

The following is a reconciliation of the denominator used in basic and diluted earnings per share (or EPS) computations for the third quarters and first nine months of 2004 and 2003 (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Numerator:				

Edgar Filing: GENENTECH INC - Form 10-Q

Net income	\$ 230,874	\$ 151,981	\$ 578,231	\$ 435,797
<b>Denominator:</b>				
Weighted-average shares outstanding used for basic earnings per share	1,055,140	1,040,762	1,057,006	1,030,140
<b>Effect of dilutive securities:</b>				
Stock options	21,953	24,810	25,075	21,509
Weighted-average shares and dilutive stock options used for diluted earnings per share	1,077,093	1,065,572	1,082,081	1,051,649

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 the respective periods presented (*in thousands, except for exercise prices*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Number of shares	19,619	21,310	19,128	34,461
Range of exercise prices	\$49.90-\$59.61	\$39.85-\$48.33	\$52.43-\$59.61	\$28.25-\$48.33

Note 8. INVENTORIES

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

	September 30, 2004	December 31, 2003
Raw materials and supplies	\$ 58.2	\$ 37.1
Work in process	415.3	383.8
Finished goods	86.4	48.7
Total	\$ 559.9	\$ 469.6

Work in process included pre-approval product candidate inventories, net of reserves, of \$86.7 million at December 31, 2003. Such inventories were sold during the quarter ended March 31, 2004. We had no inventories for pre-approval product candidates at September 30, 2004.

In the second quarter of 2004, in conjunction with our decision to discontinue commercialization and manufacture of Nutropin Depot, we expensed \$18.8 million of Nutropin Depot inventory, which was reflected in cost of sales. We determined that this inventory could not be used to manufacture any of our other growth hormone products.

In the third quarter and first nine months of 2004, we recorded charges of \$10.0 million and \$31.3 million, respectively, related to filling failures for certain other products, which were reflected in cost of sales.

## Note 9. CAPITAL STOCK

### Stock Repurchase Program

In September 2004, our Board of Directors authorized the extension of our current stock repurchase program for the repurchase of up to an additional \$1 billion of our common stock through December 31, 2005. The Board also extended the current repurchase plan by increasing the maximum number of shares that can be repurchased to 50 million from 25 million shares. The Board initially approved \$1 billion for repurchases of common stock under the stock repurchase program in December 2003. In this plan, as in previous stock repurchase plans, 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 Roche's minimum ownership percentage. That minimum ownership percentage, which is equal to the Minimum Percentage described in Note 3 less 2%, is 55.7%.

We have entered into a Rule 10b5-1 trading plan 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 trading plan covers approximately 2.7 million shares and will run through December 31, 2004.

Page 17

Under our current stock repurchase program, we had no repurchases during the first quarter of 2004. Our shares repurchased during the second and third quarters of 2004 were as follows:

	Total Number of Shares Purchased	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
April 1 - 30, 2004	1,600,000	\$ 58.21		
May 1 - 31, 2004	4,761,300	59.25		
June 1 - 30, 2004	3,582,500	55.90		

July 1 - 31, 2004	3,208,100	51.85		
August 1 - 31, 2004	-	-		
September 1 - 30, 2004	1,578,400	50.12		
Total	<u>14,730,300</u>	<u>\$ 55.73</u>	<u>14,872,100</u>	<u>35,127,900</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.

#### Note 10. TAXES

The effective tax rate was 36% in the third quarter and first nine months of 2004, which was comparable to the third quarter of 2003, but increased from 32% in the first nine months of 2003. The increase in the tax rate reflects increased income before taxes and a decrease in benefits from foreign sales and from various tax credits. The tax provision for the first nine months of 2004 included a benefit of \$6.5 million related to a favorable change in estimates of research credits.

#### Note 11. SUBSEQUENT EVENT

Under our stock repurchase program approved by our Board of Directors in December 2003, and extended in September 2004, we repurchased 5,130,200 shares of our common stock, with direct market purchases and purchases under our Rule 10b5-1 trading plan, at a cost of approximately \$248.7 million during the period from October 1, 2004 through October 28, 2004. For more information on our stock repurchase program, see Note 9 "Capital Stock" above.

---

#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Genentech, Inc.

We have reviewed the condensed consolidated balance sheet of Genentech, Inc. as of September 30, 2004, and the related condensed consolidated statements of income for the three and nine-month periods ended September 30, 2004 and 2003, and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2004 and 2003. These financial statements are the responsibility of Genentech's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and



making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

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

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Genentech, Inc. as of December 31, 2003, 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 January 13, 2004 (except for the second paragraph of the note titled Subsequent Events and the twenty-first paragraph of the note titled Leases, Commitments and Contingencies, as to which the date is February 25, 2004), 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, 2003, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
October 5, 2004 except for  
Note 11, as to which the  
date is October 28, 2004

Page 19

---

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

### **GENENTECH, INC. FINANCIAL REVIEW**

#### OVERVIEW

Genentech, Inc. is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products directly in the United States and licenses several additional products to other companies.

Genentech primarily earns revenues and income and generates cash from product sales, contract revenues and royalties. We also generate other income from gains on sales of stocks in our biotechnology equity portfolio and

interest from our investment portfolio. In the remainder of 2004, we expect the growth of our business to continue to be driven by sales of our new products, Avastin, Xolair and Raptiva and continued strong sales of our established oncology products, Rituxan and Herceptin. We also expect sales of our legacy products, contract revenues and royalties to continue to contribute to the bottom-line. In the third quarter of 2004, our total operating revenues were \$1,202.6 million, our net income was \$230.9 million and our current assets at September 30, 2004 were approximately \$3,376.5 million. In the first nine months of 2004, our total operating revenues were \$3,305.9 million and our net income was \$578.3 million.

Our short-term business objectives are driven by our 5x5 goals, which began in 1999 and continue through 2005. Our most important goal is to achieve 25 percent average annual non-GAAP EPS growth; we are tracking well toward this goal. Our goal of achieving 25 percent non-GAAP net income as a percentage of revenues will probably not be met, primarily due to our profit sharing arrangement for Rituxan. We have exceeded our goal of five new products or indications approved, as seven new products or indications have been approved since 1999. We are well positioned to exceed our goal of five significant products in late stage clinical development by the end of 2005. At this time, we are uncertain if we will meet our goal of \$500 million in new revenue from alliances and/or acquisitions; as, since the approval of Xolair and Avastin, we changed our strategic focus to pursue earlier stage rather than later stage opportunities.

Our long-term business objectives are reflected in our Horizon 2010 strategy and goals set forth below.

- To aim to become the number one United States (or U.S.) oncology company in U.S. sales by 2010. We recognize that this goal is highly ambitious and that there will be formidable competition from other companies, particularly given the rate of new business consolidations in our industry. We face many challenges in meeting this goal, such as U.S. Food and Drug Administration (or FDA) approval, clinical trial success, and levels of government reimbursement rates, which recognize the innovation of our products to patients.
- 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.
- 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 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 sufficient to be considered a growth company.

Achieving these goals depends on our ability to quickly capitalize on advances in basic research, to balance speed in clinical development with designing high quality trials, to shape the markets for our products, to increase our manufacturing capability and to maintain our unique corporate culture during a period of rapid growth.

As a business in a highly regulated and competitive industry, we face many opportunities, risks and challenges. There are many economic and industry-wide factors that affect our business, including increasing complexity and cost of pharmaceutical research and development, leadership changes at the FDA, increases in clinical development timeframes, declines in numbers of new products that the FDA is approving, changes in reimbursement under recent Medicare legislation and initiatives towards generic biologics and employee stock option expensing.

On October 4, 2004, we received a subpoena from the U.S. Department of Justice, requesting documents related to the promotion of Rituxan. We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature.

The Medicare Prescription Drug, Improvement and Modernization Act (or the Medicare Act) was enacted into law in December 2003. We are monitoring closely the impact on our business of the reform of the Average Wholesale Price (AWP) mechanism as the basis of oncology reimbursement under Medicare. To date, there has been minimal impact on physician prescribing.

With respect to generic biologics, we believe that current technology cannot prove a generic biotechnology product to be safe and effective outside the New Drug Application (or NDA) and Biologics License Application (or BLA) process. We have filed a Citizen Petition with the FDA requesting that the agency re-assess its approach to approvals of follow-on biologics and put processes in place to protect trade secret and confidential commercial data and information from use and disclosure by others. The FDA has initiated a public process to discuss the complex scientific issues surrounding generic or follow-on biologics, including a scientific workshop planned for early 2005, which we hope will be followed by a similar workshop to discuss the critical legal issues involved with establishing an approval pathway for follow-on biologics.

In regards to employee stock options, the Financial Accounting Standards Board (or FASB) has proposed a rule to expense employee stock options. We believe the FASB's direction towards requiring companies to expense these options may have unintended negative consequences. Recently the FASB has delayed the effective date of its proposed rule to the quarter beginning July 1, 2005. The proposed rule could materially impact our results of operations.

This past year we experienced the largest annual growth in employee numbers in our history. Our continued growth depends on our ability to bring highly qualified and talented people into all areas of our company. It also depends on our ability to retain our employees. Integrating this number of new employees into our company will be a significant challenge for management and we have focused our attention on this important area.

On our operations, we continue to plan for manufacturing needs in both the short- and long-term. We have increased manufacturing efforts in both our South San Francisco and Vacaville facilities in an effort to meet increased product demand. We received FDA approval in August 2004 for the manufacture of Avastin bulk drug substance at our Vacaville facility; this additional capacity will supplement our Avastin bulk drug substance manufactured in South San Francisco. We recently announced a decision to expand our Vacaville facility; the expansion of this facility is expected to cost approximately \$600 million over the next several years. That additional capacity is planned to be available in 2009. In addition, we have a long-term manufacturing agreement with Lonza Biologics, under which Lonza will manufacture commercial quantities of Rituxan at Lonza's production facility in Portsmouth, New Hampshire. In September 2004, we and Wyeth Pharmaceuticals, a division of Wyeth, entered into a manufacturing agreement for Herceptin. Under this agreement, Wyeth Pharmaceuticals will manufacture Herceptin bulk drug substance for Genentech at Wyeth's production facility in Andover, Massachusetts. Technology transfer activities have already begun and we anticipate that Wyeth will start production of Herceptin in 2006. We also made progress

on our facility in Porriño, Spain (Genentech España), which produced its first lot of Avastin bulk drug substance for clinical trials in July 2004. We are currently working to get authorizations from appropriate regulatory agencies in Spain and the U.S. to enable us to use the Porriño material in clinical trials in the near future. Finally, as part of our capacity planning to support our growth and expansion, and efforts to add additional capacity, we will continue to have ongoing dialogue with third-party manufacturers and evaluate potential sites with existing manufacturing capabilities, as well as sites where we can build new facilities. We also have additional avenues we are pursuing to attempt to meet future product supply needs for ourselves and our collaborators. All of these projects and efforts are critical to providing sufficient capacity to meet expected demand for our products. However, we recognize that there are some inherent uncertainties associated with forecasting future demand, especially for newly introduced products, and that manufacturing of biologics is a complex process. We have recently had equipment malfunctions in our filling facility and, consequently, several product lots were not able to be released and a scheduled facility maintenance shut-down was extended. This situation has resulted in decreased target inventory levels for certain of our products. We are working to rebuild our inventory to target levels and undertaking efforts to secure additional filling capacity in order to mitigate the current risk associated with having a single licensed filling facility for many of our products. Until that process is completed, we have potential supply risk for many of our products that are single-sourced from our own filling facility or from a single contract filling site.

Intellectual property protection of our products is also crucial to our business. We are often involved in disputes over contracts and intellectual property and we work to resolve these disputes in confidential negotiations or litigations. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position. The resources required to do this are significant.

In the third quarter and first nine months of 2004, we saw growth in our operating revenues, net income and earnings per share as compared to the third quarter and first nine months of 2003. Sales of Avastin, launched on February 26, 2004, were \$183.0 million in the third quarter of 2004, a 38% increase from the second quarter of 2004. Our sales data suggests that Avastin is being combined with a wide range of 5FU-based chemotherapies, reflecting Avastin's broad indication in metastatic colorectal cancer. Penetration in first-line metastatic cancer of the rectum or colon (or MCRC), which is our approved indication, was over 40% in the third quarter of 2004, a significant increase over our second quarter penetration of approximately 20%. First-line MCRC represents approximately 60% of all Avastin use. Adoption by physicians in the relapsed setting, which is an unapproved use, remained relatively constant at 34% in the third quarter of 2004. Sales of Xolair were \$53.9 million in the third quarter of 2004, a 23% increase from the second quarter of 2004. This growth reflects ongoing market penetration and high patient compliance. Sales of Raptiva were \$18.0 million in the third quarter of 2004, a 34% increase from the second quarter of 2004. Over 10,500 patients have been prescribed Raptiva since launch and approximately 80% of these patients have not been previously treated with biologics. The rate of growth in prescriptions for Raptiva has been affected by the recent approval of Enbrel for psoriasis. Specifically, a significant Enbrel trial that was launched earlier in the year took several thousand patients out of the market and impacted our third quarter revenues. Rituxan sales increased 18% in the third quarter and 17% in the first nine months of 2004 as compared to the same periods in 2003. Quarter over quarter, Rituxan sales increased only 3% from the second quarter. This trend reflects a slowing of the Rituxan growth rate, inventory adjustments made by wholesalers at the beginning of the year and limited reaction to the Medicare legislation. We believe the opportunities for long-term Rituxan sales growth lie in potential new FDA approved indications, for which we have conducted or are conducting label-enabling clinical trials, particularly in immunology, and in the potential use of Rituxan in the maintenance setting in treating non-Hodgkin's lymphoma. Sales of Herceptin increased 17% in the third quarter and 15% in the first nine months of 2004 as compared to the same periods in 2003. Quarter over quarter, Herceptin sales increased 7% from the second quarter. We believe the potential for long-term Herceptin sales growth lies in the adjuvant setting for HER2 positive breast cancer, for which label-enabling clinical studies are still ongoing. Thrombolytics sales increased 5% from the second quarter and Pulmozyme sales increased 11% from the second quarter. Royalties and contract revenues increased year over year due to higher sales by licensees and product

development reimbursements from collaborators, respectively.

Operating expenses increased as a result of increased marketing, general and administrative (or MG&A) and research and development (or R&D) expenses and we expect this trend to continue this year. Cost of sales as a

percentage of sales in the third quarter and first nine months of 2004 decreased over the comparable periods of 2003 primarily reflecting higher sales of more favorable margin products, partially offset by charges related to our decision to discontinue commercialization of Nutropin Depot in the second quarter of 2004 and filling failures for other products.

In September 2004, OSI Pharmaceutical announced that the FDA has accepted for filing and review the NDA for the use of Tarceva as a monotherapy for the treatment of patients with advanced non-small cell lung cancer (NSCLC) for whom chemotherapy has failed. The NDA filing for Tarceva is under the FDA's Pilot 1 Program for Continuous Marketing Application and was granted priority review status. Based on the timing of the filing, we anticipate FDA action by January 30, 2005. In August, Roche submitted a Marketing Authorization Application to the European Health Authorities for Tarceva as a monotherapy for the treatment of patients with advanced NSCLC for whom chemotherapy has failed.

Also in September 2004, we and our collaborators OSI Pharmaceuticals and Roche announced positive Phase III study results of Tarceva in patients with locally advanced or metastatic pancreatic cancer. We and our collaborators will discuss these data with the FDA and other regulatory agencies to determine the next steps for Tarceva in patients with pancreatic cancer.

#### Marketed Products

##### Rituxan

(rituximab) anti-CD20 antibody, which we commercialize with Biogen Idec Inc. (or Biogen Idec), is for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, a cancer of the immune system, including retreatment, times 8 dosing and bulky disease. We co-developed Rituxan with Biogen Idec, formerly known as IDEC Pharmaceuticals Corporation, one of the predecessor companies, from whom we licensed Rituxan.

##### Herceptin

(trastuzumab) anti-HER2 antibody is a humanized antibody for the treatment of certain patients with metastatic breast cancer whose tumors overexpress the Human Epidermal growth factor Receptor type 2 (or HER2) protein. 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.

##### Nutropin Depot

[somatotropin (rDNA origin) for injectable suspension] is a long-acting growth hormone for the treatment of growth failure associated with pediatric growth hormone deficiency. It uses ProLease®, an injectable extended-release drug delivery system, which was developed by our collaborator Alkermes, Inc. On June 1, 2004, we and Alkermes announced our decision to discontinue commercialization of Nutropin Depot. We expect sales of Nutropin Depot to continue through 2004 or until inventory is depleted.

##### Nutropin

[somatropin (rDNA origin) for injection] is a growth hormone 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 is similar to Protropin (see below); however, it does not have the additional N-terminal amino acid, methionine, found in the Protropin chemical structure.

### Protropin

(somatrem for injection) is a growth hormone approved for the treatment of growth hormone inadequacy in children. Manufacture of Protropin was discontinued at the end of 2002 because physicians are typically initiating therapy with one of the Nutropin family products and the demand for Protropin has declined, but sales are expected to continue through 2004 or until inventory is depleted.

### Nutropin AQ

[somatropin (rDNA origin) for injection] is a liquid formulation growth hormone for the same indications as Nutropin and is aimed at providing improved convenience in administration.

### TNKase

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

### Activase

(alteplase, recombinant) is a tissue plasminogen activator 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 thrombolytic agent for the restoration of function to central venous access devices that have become occluded due to a blood clot.

### Pulmozyme

(dornase alfa, recombinant) is an inhalation solution for the treatment of cystic fibrosis.

### Xolair

(omalizumab) is an anti-IgE antibody, which we commercialize with Novartis, for the treatment of moderate-to-severe persistent asthma in adults and adolescents.

### Raptiva

(efalizumab) is an anti-CD11a antibody, co-developed with XOMA Ltd., for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy.

### Avastin

(bevacizumab) is an antibody that binds to and inhibits vascular endothelial growth factor (VEGF) and 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.

## Licensed Products

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

- Herceptin and Pulmozyme 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. Some of our products are sold under different trademarks or trade names when sold outside of the U.S.

## 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 any 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 and senior financial officials; and
- the charter of the Audit Committee of our Board of Directors.

## CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States (or GAAP). The preparation of these 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 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. We assess the likelihood of any adverse judgments or outcomes to these legal matters as well as potential ranges of probable losses. As of September 30, 2004, we have accrued \$646.9 million, which represents our current estimate of the costs for the resolution of these matters. We developed these estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances known to us at that time. 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 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 uncollectible amounts, product returns and discounts.
- 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 costs and post-marketing costs.
  - Nonrefundable upfront fees, including milestone payments, for which no further performance obligations exist are recognized as revenue on the earlier of when payments are received or collection is assured.

- Nonrefundable upfront licensing fees, including product opt-ins, and certain guaranteed, time-based payments that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue:

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



- ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.
- Manufacturing payments are recognized as revenue as the related manufacturing services are rendered, generally on a straight-line basis over the longer of the manufacturing obligation period or the expected product life.
- Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
- Reimbursements of development, post-marketing and certain collaboration-related commercialization costs are recognized as revenue as the related costs are incurred.

#### Income Taxes

Income tax expense is based on pretax financial accounting income computed 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, future levels of capital expenditures, 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 assessment of the likelihood of the regulatory approval 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.

#### Nonmarketable Equity Securities

As part of our strategic efforts to gain access to potential new products and technologies, we invest in equity securities of certain private biotechnology companies. Our nonmarketable equity securities are carried at cost unless we determine that an impairment that is other than temporary has occurred, in which case we write the investment down to fair value. We periodically review our investments for impairment; however, the impairment analysis requires significant judgment in identifying events or circumstances that would likely have significant adverse effect on the fair value of the investment. The analysis may include assessment of the investee's (i) revenue and earnings trend, (ii) business outlook for its products and technologies, (iii) liquidity position and the rate at which it is using its cash, and (iv) likelihood of obtaining subsequent rounds of financing. If an investee obtains additional funding at

a valuation lower than our carrying value, we presume that the investment is other than temporarily impaired. We have experienced impairments in our portfolio due to the decline in equity markets over the past few years. However, we are not able to determine at the present time which specific investments are likely to be impaired in the future, or the extent or timing of the individual impairments.

#### 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 upon certain events, some of which are outside our control, to reassess the accounting treatment of our business development collaborations in future periods based on the nature and extent of our financial interests as well as our ability to exercise influence. Our reassessment may require that we exercise significant judgment in estimating future outcomes and may result in our consolidation of the company or related entities with which we have a collaborative arrangement and this may have a material impact on our financial condition or results of operation in future periods.

#### RESULTS OF OPERATIONS

(in millions, except per share amounts)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2004	2003	% Change	2004	2003	% Change
			*			*
Product sales	\$ 1,005.5	\$ 654.9	54 %	\$ 2,682.6	\$ 1,897.7	41 %
Royalties	153.9	116.5	32	459.9	352.6	30
Contract revenue	43.2	45.6	(5)	163.4	116.1	41
Total operating revenues	1,202.6	817.0	47	3,305.9	2,366.4	40
Cost of sales	166.0	115.7	43	467.2	353.9	32
Research and development	234.1	168.7	39	637.3	506.3	26
Marketing, general and administrative	264.6	209.8	26	788.6	531.3	48
Collaboration profit sharing	151.9	119.7	27	423.5	323.6	31
Recurring charges related to redemption	34.5	38.6	(11)	111.0	115.8	(4)
Special items: litigation-related	13.4	(131.6)	110	40.3	(105.0)	138
Total costs and expenses	864.5	520.9	66	2,467.9	1,725.9	43
Operating margin	338.1	296.1	14	838.0	640.5	31
Other income, net	23.5	15.9	48	61.3	72.5	(15)
Income before taxes and cumulative effect of	361.6	312.0	16	899.3	713.0	26

accounting change						
Income tax provision	130.7	112.4	16	321.0	229.6	40
Income before cumulative effect of accounting change	230.9	199.6	16	578.3	483.4	20
Cumulative effect of accounting change, net of tax	-	(47.6)	- **	-	(47.6)	- **
Net income	\$ 230.9	\$ 152.0	52	\$ 578.3	\$ 435.8	33
Operating margin as a % of operating revenues	28 %	36 %		25 %	27 %	
COS as a % of product sales	17	18		17	19	
R&D as a % of operating revenues	19	21		19	21	
MG&A as a % of operating revenues	22	26		24	22	
NI as a % of operating revenues	19	19		17	18	

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

\*\* Calculation not meaningful.

### Total Operating Revenues

Total operating revenues increased 47% in the third quarter and 40% in the first nine months of 2004 from the comparable periods in 2003. These increases were primarily due to higher product sales and royalty income. Also contributing to the increase for the nine-month period were higher contract revenues. These increases are further discussed below.

### Total Product Sales

Product Sales	Three Months Ended September 30,			Nine Months Ended September 30,		
	2004	2003	% Change	2004	2003	% Change
Rituxan	\$ 437.7	\$ 371.7	18 %	\$ 1,263.0	\$ 1,076.1	17 %
Herceptin	126.0	107.7	17	357.2	310.5	15
Avastin	183.0	-	-	354.1	-	-

Edgar Filing: GENENTECH INC - Form 10-Q

Growth Hormone	87.2	80.6	8	261.1	238.9	9
Thrombolytics	54.0	46.0	17	151.8	141.1	8
Pulmozyme	45.7	40.4	13	130.1	122.6	6
Xolair	53.9	6.8	693	127.6	6.8	1,776
Raptiva	18.0	-	-	37.7	-	-
Product manufactured under contract	-	1.7	(100)	-	1.7	(100)
Total product sales	\$ 1,005.5	\$ 654.9		\$ 2,682.6	\$ 1,897.7	

Total net product sales increased 54% in the third quarter and 41% in the first nine months of 2004 from the comparable periods in 2003. The increase was due to higher sales across all products, in particular Rituxan and Herceptin, and sales of our new products, specifically Avastin, Xolair and Raptiva. Increased volume, including new product shipments, accounted for 98%, or \$343.7 million, of the net sales increase in the third quarter of 2004 and an increase of 94%, or \$740.4 million, in the first nine months of 2004. Changes in net sales prices across the portfolio accounted for an increase of 2%, or \$6.9 million in the third quarter of 2004, and 6%, or \$44.5 million, in the first nine months of 2004.

#### Rituxan

Net sales of Rituxan increased 18% to \$437.7 million in the third quarter and 17% to \$1,263.0 million in the first nine months of 2004 from the comparable periods in 2003. This growth was driven by greater penetration of the non-Hodgkin's lymphoma (or NHL) and chronic lymphocytic leukemia (or CLL) markets in the U.S. (specifically use in front line indolent NHL, front line CLL, and indolent maintenance, which are all unapproved uses). Effective September 9, 2004, the price of Rituxan was increased by 4% in the U.S.

Roche announced earlier in the year the positive opinion of the European Union's Committee for Human Medicinal Products (or CHMP), for the frontline use of Rituxan in combination with CVP (cyclophosphamide, vincristine, prednisone) chemotherapy for the treatment of indolent NHL. In the aggressive NHL setting, Genentech and Biogen Idec have agreed upon a filing strategy with the FDA that includes both the ECG (Eastern Cooperative Oncology Group) 4494 data and the GELA (Groupe d'Etude des Lymphomes de l'Adulte) study, and now anticipate this filing to occur in 2005. We are in discussions with the FDA about additional data requirements needed to file an supplemental BLA for the use of Rituxan in front-line indolent NHL. The phase III study in relapsed CLL continues to enroll in Europe and is open for enrollment in the U.S.

Rituxan sales increased a modest 3% from the previous quarter, reflecting a slower growth rate than we have seen in previous years. We currently believe there will be limited impact on Rituxan's usage under the Medicare Act. The Centers for Medicare and Medicaid Services (CMS) recently published a Carrier Correction, which stipulates an increase in the 2004 Medicare physician office reimbursement rate for Rituxan from 81% to 83% of Average

Wholesalers Price (AWP). This correction is retroactive to April 1, 2004. We anticipate the current reimbursement rates for practice expenses will remain the same until 2005.

#### Herceptin

Net sales of Herceptin increased 17% to \$126.0 million in the third quarter and 15% to \$357.2 million in the first nine months of 2004 from the comparable periods in 2003. The continued growth was primarily driven by physicians' extending the average treatment duration. In 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. We currently believe there will be limited impact on Herceptin's usage under the new Medicare Act. Also impacting our third quarter increase and our future sales growth is a price increase of 4.2% that was effective on April 1, 2004.

#### Avastin

We received FDA approval to market Avastin on February 26, 2004 and made initial product shipments to distributors that same day. Avastin has achieved total net sales of \$183.0 million in the third quarter and \$354.1 million since it was launched in February. Our sales have been driven primarily by use in colorectal cancer, which represents more than 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, reflecting Avastin's broad indication. Early market penetration rates indicate that we may reach peak penetration sooner than expected, but estimates of the overall size of the market remain unchanged.

At present, all Medicare carriers and all of our targeted commercial payers are covering Avastin and reimbursement has proceeded as expected. On September 1, 2004, the Centers for Medicare and Medicaid Services added Avastin to its ongoing National Coverage Analysis (or NCA) of colorectal cancer therapies. We do not anticipate any interruption of Medicare coverage of Avastin during the NCA assessment period.

Future sales and the adoption by physicians of the use of Avastin are subject to a number of risks and uncertainties. Avastin is currently being studied in combination with 5-FU/ Leucovorin and Oxaliplatin (the "FOLFOX Regimen") in patients with relapsed, metastatic colorectal cancer in a large randomized study through the Eastern Cooperative Oncology Group (the "E3200 Trial"). If the results from the E3200 Trial are positive for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin or show a similar magnitude of benefit as previous colorectal cancer studies with Avastin, use of Avastin may increase as physicians increase their use of Avastin in combination with Oxaliplatin-based regimens in the relapsed, and also the first-line setting. However, if the results of the E3200 Trial are negative for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin, potential sales of Avastin may be materially adversely affected as physicians may limit their use of Avastin to 5-FU/Leucovorin and/or irinotecan regimens. Physicians may also restrict their use of Avastin to first-line patients only.

#### Growth Hormone

Combined net sales of our four growth hormone products, Nutropin AQ, Nutropin, Nutropin Depot, and Protropin, increased 8% in the third quarter and 9% in the first nine months of 2004 from the comparable periods in 2003. The net sales growth resulted from continued demand for the Nutropin products as well as a price increase of 5.5% in July 2004 on Nutropin and Nutropin AQ. At the end of 2002, manufacture of Protropin was discontinued as physicians had shifted their therapy preference toward other Nutropin family products. Protropin sales are expected to continue through 2004 or until inventory is depleted. On June 1, 2004, we and our collaborator Alkermes made a decision to discontinue commercialization of Nutropin Depot, a long-acting dosage form of recombinant growth hormone. We expect sales of Nutropin Depot to continue through 2004 or until inventory is depleted.

### Thrombolytics

Combined net sales of our three thrombolytic products, Activase, Cathflo Activase and TNKase, increased 17% in the third quarter and 8% in the first nine months of 2004 from the comparable periods in 2003. The sales increase was primarily driven by growth in our catheter clearance and stroke markets as well as a price increase of 8% in February 2004 on Activase. 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 acute myocardial infarction market has been offset by growth in our other markets.

### Pulmozyme

Our net sales of Pulmozyme increased 13% in the third quarter and 6% in the first nine months of 2004 from the comparable periods in 2003. These increases primarily reflect an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and, to a lesser extent, a price increase of 6% in July 2004.

### Xolair

We received FDA approval to market Xolair in June 2003 and began shipping Xolair in July 2003. Xolair achieved total U.S. net sales of \$53.9 million in the third quarter and \$127.6 million in the first nine months of 2004, and \$152.9 million since launch, reflecting continued acceptance of the product and strong growth in our prescriber base. Payer coverage and perceived clinical response remain high. A price increase of 5% effective on September 1, 2004 also positively impacted third quarter sales. Novartis Pharma AG, our collaborator on Xolair, recently announced that it had submitted its application for the European approval of Xolair to the European Agency for the Evaluation of Medicinal Products (EMEA) and CHMP. Future sales and related expenses are subject to risks and uncertainties, including patient fulfillment and retention rates.

### Raptiva

We received FDA approval to market Raptiva in October 2003 and began shipping Raptiva in November 2003. Raptiva achieved total net sales of \$18.0 million in the third quarter and \$37.7 million in the first nine months of 2004, reflecting continued acceptance of the product and effective reimbursement processing. Raptiva had a price increase of 5% effective on September 3, 2004. Future sales and the continued acceptance of Raptiva in this biologics class is subject to risks and uncertainties, including how well Raptiva is able to compete with other new and established therapies for moderate-to-severe psoriasis. The rate of growth in prescriptions and resulting revenue for Raptiva in the third quarter was affected by the recent approval of Enbrel for psoriasis and the initiation of a significant patient experience trial with that product that took several thousand patients out of the market.

In September 2004, Serono S.A., which has rights to market Raptiva in certain areas of the world, announced that it had received European Commission Marketing Authorization for Raptiva. In October 2004, Serono launched Raptiva in Germany. In addition, Serono has launched Raptiva in Switzerland and Argentina, and recently received approval for Raptiva in Mexico, Brazil and Australia.

### Royalties

Royalty income increased 32% in the third quarter and 30% in the first nine months of 2004 from the comparable periods in 2003. The increase was due to higher third-party sales by various licensees, primarily Hoffmann-La Roche (see "Related Party Transactions" below) of our Herceptin and Rituxan products. We expect that royalty income will

continue to increase in 2004, but at a lower rate than in 2003.

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 the "We Are Exposed to Risks Relating to Foreign Currency Exchange Rates and Foreign Economic Conditions" section of the Forward-Looking Information below for a discussion of market risks related to these financial instruments.

### Contract Revenues

Contract revenues decreased 5% in the third quarter and increased 41% in the first nine months of 2004 from the comparable periods in 2003. The decrease in the third quarter was primarily due to lower revenues from Hoffmann-La Roche on development efforts for Avastin and Omnitarg, partially offset by higher revenues earned for development efforts on Tarceva, Rituxan and Lucentis. The increase in the first nine months was primarily driven by revenues from our collaborators for amounts earned on development efforts related to Avastin, Tarceva, Rituxan and Lucentis. See "Related Party Transactions" below for more information on contract revenue from Hoffmann-La Roche and Novartis.

Based on a full year of revenues on arrangements put in place in 2003, we expect that contract revenues will continue to increase in 2004, but at a lower rate than in 2003. We also expect contract revenues to fluctuate each quarter depending on the level of revenues earned for ongoing development efforts, the level of milestones received, the number of new contract arrangements and Hoffmann-La Roche's potential opt-ins for products.

### Cost of Sales

Cost of sales (or COS) as a percentage of product sales in the third quarter was 17% in 2004 and 18% in 2003. COS as a percentage of product sales in the first nine months was 17% in 2004 and 19% in 2003. These decreases primarily reflect higher sales of more favorable margin products (primarily sales of Rituxan and Avastin) and lower production costs due to manufacturing efficiencies primarily related to Herceptin and Rituxan, partially offset by a second quarter 2004 charge of \$18.8 million related to Nutropin Depot inventory and our decision to discontinue its commercialization, and a provision of \$21.3 million in the second quarter and \$10.0 million in the third quarter related to filling failures for certain other products.

In the fourth quarter of 2003, we entered into an arrangement with Lonza Biologics, a subsidiary of Lonza Group Ltd, to provide additional manufacturing capacity for Rituxan. In September 2004, we and Wyeth Pharmaceuticals, a division of Wyeth, entered into a manufacturing agreement for Herceptin. Under this agreement, Wyeth Pharmaceuticals will manufacture Herceptin bulk drug substance for Genentech at Wyeth's production facility in Andover, Massachusetts. Technology transfer activities have already begun and we anticipate that Wyeth will start production of Herceptin in 2006. We do not expect the Lonza or the Wyeth arrangements to have a significant impact on our overall cost of sales as a percentage of product sales in the future. We expect our COS as a percentage of sales for the full year 2004 to be somewhat comparable to the rate in 2003.

### Research and Development

R&D expenses increased 39% in the third quarter and 26% in the first nine months of 2004 from the comparable periods in 2003. These increases were largely due to higher spending on clinical development of products, including

Lucentis, Rituxan and Omnitarg, partially offset by lower spending on Raptiva, Tarceva and Avastin; increased spending for post-marketing clinical studies, and increased headcount and related expenses to support research activities. We expect increases in R&D expenses over time to be driven mainly by the development of our pipeline products, including increases in clinical production as well as increases in our post-marketing clinical programs. Our expectations for higher revenues in the future will likely cause R&D as a percentage of operating revenues to decline over time.

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

Research and Development	Three Months Ended September 30,			Nine Months Ended September 30,		
	2004	2003	% Change	2004	2003	% Change
Product development	\$ 136.3	\$ 102.4	33 %	\$ 376.1	\$ 324.2	16 %
Post-marketing studies	33.7	22.3	51	92.3	55.6	66
Total development	170.0	124.7	36	468.4	379.8	23
Research	53.9	37.0	46	146.2	104.5	40
In-licensing	10.2	7.0	46	22.7	22.0	3
Total	\$ 234.1	\$ 168.7	39	\$ 637.3	\$ 506.3	26

#### Marketing, General and Administrative

Overall MG&A expenses increased 26% in the third quarter and 48% in the first nine months of 2004 from the comparable periods in 2003. The increases in both periods were primarily due to: (i) increases of \$36.7 million and \$111.8 million in the third quarter and first nine months of 2004, respectively, for marketing and promotional programs to support commercial and pipeline products, primarily Avastin, Raptiva, Xolair, Rituxan and Herceptin; (ii) increases of \$23.6 million and \$69.1 million in the third quarter and first nine months of 2004, respectively, related to headcount growth and increased commercial training programs to support all products, including increases in field sales incentive compensation; (iii) an increase of \$15.5 million in the first nine months of 2004 related primarily to spending on our information systems technologies and headcount growth in our corporate support functions, partially offset by fixed asset write-offs in 2003; (iv) a decrease of \$5.5 million in the third quarter of 2004 primarily related to fixed asset write-offs in the third quarter of 2003; (v) an increase of \$42.3 million in the first nine months of 2004 for our royalty expenses, primarily related to Biogen Idec; and (vi) a charge of \$18.6 million in the first nine months of 2004 related to the Nutropin Depot license and our decision to discontinue commercializing Nutropin Depot (see Note 4, "Other Intangible Assets," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on this charge).

MG&A expenses are expected to increase in the near term as we continue the launch of Avastin, Raptiva and Xolair, and as we prepare for the potential launch of Tarceva. However, as we expect revenues to rise, MG&A as a percentage of operating revenues is targeted to decline.



### Collaboration Profit Sharing

Collaboration profit sharing consists primarily of the net operating profit sharing with Biogen Idec on commercial activities underlying Rituxan sales and, to a much lesser extent, the sharing of the commercial net operating results of Xolair with Novartis. Collaboration profit sharing increased 27% in the third quarter and 31% in the first nine months of 2004 from the comparable periods in 2003. These increases were driven by increased Rituxan profit sharing with Biogen Idec due to higher Rituxan sales and new Xolair profit sharing with Novartis due to Xolair sales, which began in July 2003.

Collaboration profit sharing expense is expected to continue to increase in 2004 consistent with the expected collaboration operating results associated with increased Rituxan and Xolair sales.

### Recurring Charges Related to Redemption

We began recording recurring charges related to the Redemption and push-down accounting in the third quarter of 1999. The charges in the third quarter and first nine months of 2004 were comparable to the same periods of 2003 and were comprised of the Redemption-related amortization of other intangible assets in all periods presented.

### Special Items: Litigation-Related

Certain of the charges included in "Special Items: Litigation-Related" in the third quarter and first nine months of 2004 were comparable to the same periods of 2003 and were comprised of the accrued interest and associated bond costs related to the City of Hope National Medical Center (or COH) trial judgment (see Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for further information regarding our litigations). In conjunction with the City of Hope judgment, we arranged to post a surety bond of \$600.0 million. As part of this arrangement, we were required to pledge \$630.0 million in cash and investments to secure the bond. In the second quarter of 2004, we were required to increase the surety bond to \$650.0 million and pledged an additional \$52.0 million, or a total of \$682.0 million, in cash and investments to secure the bond. These amounts are reflected in "restricted cash and other long-term assets" on the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. We expect that we will continue to incur interest charges on the COH trial judgment and service fees on the related surety bond each quarter through the process of appealing the COH trial results. We recorded accrued interest and bond costs related to the COH trial judgment of \$13.4 million in the third quarters of 2004 and 2003, and \$40.3 million and \$40.0 million in the first nine months of 2004 and 2003, respectively. These special charges represent our best estimate of the costs for the current resolution of these matters and are included in other long-term liabilities in the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. We developed these estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. We currently believe that if our petition for review of the COH verdict is granted, the process will likely take longer than one year. In the event that our petition for review is not granted or that the appeal process is resolved earlier, the pledged assets and associated liability may be reclassified as a current asset and liability, respectively. 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 our planned petition for a rehearing by the Court of Appeal and/or a review by the California Supreme Court.

In the third quarter of 2003, in addition to the COH accrued interest and bond costs, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately \$0.09 in earnings per diluted share for the third quarter of 2003 and was reported as a litigation-related special item in our condensed consolidated statements of income.

#### Other Income, Net

As part of our strategic alliance efforts, we invest in debt and equity securities of certain biotechnology companies with which we have or have had collaborative agreements. "Other income, net" includes realized gains and losses from the sale of certain of these biotechnology equity securities as well as changes in the recoverability of our debt securities. In addition, "other income, net" includes write-downs for other-than-temporary declines in the fair value of certain of these biotechnology debt and equity securities, interest income and interest expense.

Other Income, Net <i>(in millions)</i>	Three Months Ended September 30,			Nine Months Ended September 30,		
	2004	2003	% Change	2004	2003	% Change
Gains on sales of biotechnology equity securities and other	\$ 10.5	\$ 0.8	1,213 %	\$ 11.6	\$ 21.0	(45) %
Write-downs of biotechnology debt and equity securities	(12.0)	-	-	(12.0)	(3.7)	224
Interest income	26.9	16.1	67	66.4	56.2	18
Interest expense	(1.9)	(1.0)	90	(4.7)	(1.0)	370
Total other income, net	\$ 23.5	\$ 15.9	48	\$ 61.3	\$ 72.5	(15)

"Other income, net" increased 48% in the third quarter and decreased 15% in the first nine months of 2004 from the comparable periods in 2003. The third quarter increase was primarily due to higher interest income (driven by

higher yields and a higher average cash balance) and recognition of a biotechnology stock gain when an investee was acquired; these increases were partially offset by an other-than-temporary write-down of one of our biotechnology equity security holdings. The decrease in the first nine months of 2004 was primarily due to lower gains for the year on sales of biotechnology equity securities, increased write-downs of our biotechnology equity security holdings, and higher interest expense related to our long-term variable interest entity debt, which we consolidated on July 1, 2003. These decreases were partially offset by higher interest income (driven by a higher average cash balance, partially offset by lower yields). We continually monitor our biotechnology marketable equity securities and may determine in

future periods, depending on market conditions, that certain of such unhedged securities are impaired and require a write-down to market value.

### Income Tax Provision

The effective tax rate was 36% in the third quarter and first nine months of 2004, which was comparable to the third quarter of 2003, but increased from 32% in the first nine months of 2003. The increase in the tax rate reflects increased income before taxes and a decrease in benefits from foreign sales and from various tax credits. The tax provision for the first nine months of 2004 included a benefit of \$6.5 million related to a favorable change in estimates of research credits.

We anticipate that our effective tax rate for the entire year 2004 will be slightly lower than that for the third quarter of 2004. The decrease in the tax rate reflects additional benefits as a result of recent legislation extending the R&D credit, retroactive to July 1, 2004. Various factors may have favorable or unfavorable effects on our effective tax rate during the remainder of 2004 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, future levels of capital expenditures, and changes in overall levels of pretax earnings.

### Net Income and Earnings Per Share

Income Before Taxes, Income Tax Provision, Cumulative Effect of Accounting Change, Net Income and Earnings Per Share	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Income before taxes and cumulative effect of accounting change	\$ 361.6	\$ 312.0	\$ 899.3	\$ 713.0
Income tax provision	130.7	112.4	321.0	229.6
Income before cumulative effect of accounting change	230.9	199.6	578.3	483.4
Cumulative effect of accounting change, net of tax	-	(47.6)	-	(47.6)
Net income	\$ 230.9	\$ 152.0	\$ 578.3	\$ 435.8
Earnings per share:				
Basic				
Earnings before cumulative effect of accounting change	\$ 0.22	\$ 0.19	\$ 0.55	0.47
Cumulative effect of accounting change, net of tax	-	(0.04)	-	(0.05)
Net earnings per share	\$ 0.22	\$ 0.15	\$ 0.55	\$ 0.42
Diluted				
Earnings before cumulative effect of accounting change	\$ 0.21	\$ 0.18	\$ 0.53	\$ 0.46
	-	(0.04)	-	(0.05)

Cumulative effect of accounting change, net of tax				
Net earnings per share	\$ 0.21	\$ 0.14	\$ 0.53	\$ 0.41

Net income and diluted earnings per share in the third quarter and first nine months of 2004 increased from the comparable periods in 2003. The increases were primarily due to higher operating revenues in 2004, driven mostly by higher product sales, offset only in part by higher operating expenses.

### Cumulative Effect of Accounting Change

FIN 46, issued in January 2003, requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE's expected losses, receives a majority of the entity's expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003, however, the FASB deferred the effective date for VIEs created before February 1, 2003 to the period ended December 31, 2003 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

We adopted FIN 46 on July 1, 2003, and consolidated the entity from which we lease our manufacturing facility located in Vacaville, California as of that date, as we determined that this entity is a VIE, as defined by FIN 46, and that we absorb a majority of its expected losses. Accordingly, we consolidated assets, which consist of the Vacaville manufacturing building and related equipment, net of accumulated depreciation. Such property and equipment had a carrying value of \$348.4 million at December 31, 2003 and was included in property, plant and equipment in the accompanying condensed consolidated balance sheet. We also consolidated the entity's debt of \$412.3 million and noncontrolling interests of \$12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, in the accompanying condensed consolidated balance sheet at September 30, 2003. We recorded a \$47.6 million charge, net of tax, (or \$0.04 per share) as a cumulative effect of the accounting change in the third quarter of 2003. We had previously accounted for our involvement with this entity as an operating lease. See also "Leases and Contingencies" below for a discussion of all of our leases.

### In-Process Research and Development

At June 30, 1999, the Redemption date, we determined that the acquired in-process technology was not technologically feasible and that the in-process technology had no future alternative uses. As a result, \$500.5 million of in-process research and development (or IPR&D) related to Roche's 1990 through 1997 purchases of our common stock was charged to additional paid-in capital, and \$752.5 million of IPR&D related to the Redemption was charged to operations at June 30, 1999.

Except as otherwise noted below, there have been no significant changes to the in-process projects since December 31, 2003. We do not track all costs associated with research and development on a project-by-project basis. Therefore, we believe a calculation of cost incurred as a percentage of total incurred project cost as of the FDA approval is not possible. We currently estimate, however, that the research and development expenditures that will be required to complete the in-process projects will total at least \$75 million as of September 30, 2004, as compared to \$700.0

million as of the Redemption date. This estimate reflects costs incurred since the Redemption date, discontinued projects, and decreases in the cost to complete estimates for other projects, partially offset by an increase in certain cost estimates related to early stage projects and changes in expected completion dates.

Significant changes to the in-process projects since December 31, 2003 are as follows:

- Avastin (bevacizumab) -- We announced on February 26, 2004, that the FDA approved Avastin to be used in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum.
- Rituxan (rituximab) -- Genentech, Inc. and Biogen Idec Inc. developed an updated filing strategy for Rituxan in aggressive NHL that has been agreed upon by the FDA and will result in a filing in 2005. Genentech, Inc., Biogen Idec Inc., and Roche announced on June 5, 2004, positive data from a randomized Phase III trial evaluating Rituxan, known as MabThera® in Europe, in combination with chemotherapy as a front-line treatment for aggressive NHL.
- Lucentis (ranibizumab) -- On September 16, 2004, the second Phase III clinical trial (ANCHOR) for Lucentis in age-related macular degeneration completed enrollment.

Our Overview, Results of Operations and Liquidity and Capital Resources, contain forward-looking statements regarding our research and clinical development timelines, including the expected number of products in late-stage development through 2005, the timeframe of a regulatory filing for Rituxan, expected Rituxan and Herceptin sales growth opportunities, the timeframe of Herceptin manufacturing by Wyeth, the impact of Medicare legislation on our sales of Rituxan and Herceptin, the impact of the Lonza and Wyeth arrangements on our cost of sales, the costs for completion of in-process projects and Vacaville expansion, the expected amount of capital expenditures, increases in product sales, total revenues, royalty income and contract revenues, and the expected growth in non-GAAP EPS through 2005. Actual results could differ materially. For a discussion of the risks and uncertainties associated with our research and clinical development, our Rituxan regulatory filing timeframe, Rituxan and Herceptin sales growth opportunities, timeframe for Herceptin manufacturing by Wyeth, impact of the Lonza and Wyeth arrangements on our cost of sales, the costs for completion of in-process projects and Vacaville expansion and our capital expenditures, 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 the impact of Medicare legislation, see "Decreases in Third Party Reimbursement Rates May Affect Our Product Sales"; for product sales, 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 royalty income and contract revenues, see "Our Royalty and Contract Revenues Could Decline"; and for total revenues, see all of the foregoing and for expected 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.

## LIQUIDITY AND CAPITAL RESOURCES

## Liquidity and Capital Resources

<i>(in millions)</i>	September 30, 2004	December 31, 2003
Cash, cash equivalents, short-term investments and long-term marketable securities	\$ 3,070.6	\$ 2,934.7
Working capital	2,295.4	1,883.8

Cash, cash equivalents, short-term investments and long-term marketable securities, excluding restricted cash, were \$3.1 billion at September 30, 2004, an increase of \$135.9 million or 4.6% from December 31, 2003. This increase was primarily a result of cash generated from operations, income from investments and proceeds from stock issuances, partially offset by cash used for the repurchase of common stock, purchase of marketable securities and for capital investments.

## 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:

Deferred revenues declined \$6.3 million during the first nine months of 2004 compared to an increase of \$251.9 million during the first nine months of 2003. The increase in 2003 was primarily due to a \$188.0 million opt-in payment from Hoffmann-La Roche on the development and commercialization of Avastin, and a \$46.6 million upfront payment and R&D reimbursement fee from Novartis AG on a new arrangement to develop and market Lucentis. Opt-in and upfront payments from collaborators are recognized in earnings over various number of years depending on the stage of the product and the contractual arrangement. Refer to our "Revenue Recognition" policy above for further information.

Our "accounts receivable - product sales" was \$570.4 million at September 30, 2004, an increase of \$255.3 million from December 31, 2003. The average collection period of our "accounts receivable-product sales" as measured in days sales outstanding (or DSO) was 52 days this quarter compared to 40 days as of December 31, 2003. The increase in our "accounts receivable-product sales" and our DSO was primarily due to higher sales of new products, in particular Avastin, and the related payment cycles. For new product launches, we offer, for a limited period, extended payment terms to allow customers and doctors purchasing the drug sufficient time to process reimbursements. The average collection period of our accounts receivable as measured in DSO can vary and is dependent on various factors, including the type of revenue (i.e., product sales, royalties, or contract revenue) and the payment terms related to those revenues and whether the related revenue was recorded at the beginning or at the end of a period.

Our inventories increased \$90.3 million in the first nine months of 2004 primarily due to the ongoing manufacture of our Rituxan, Pulmozyme, Activase, TNKase and Nutropin AQ products, partially offset by the charges related to our decision to discontinue commercializing Nutropin Depot and filling failures for other products. See Note 8, "Inventories," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for

further information on these charges.

#### 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 \$418.2 million in the first nine months of 2004 compared to \$211.2 million in the first nine months of 2003. Capital expenditures in 2004 were made to purchase land and office buildings in South San Francisco, including the repayment of two of our synthetic leases, and for equipment purchases and ongoing construction costs in support our manufacturing, R&D and corporate infrastructure needs. In 2004, we expect to spend approximately \$600.0 million on property, plant and equipment. This increase in spending over 2003 will primarily support our expected future manufacturing capacity needs, increases in property purchases, including repayments of our synthetic leases, and increases in equipment and information systems related purchases.

In addition, restricted cash decreased by \$4.6 million due to a release of \$56.6 million upon our buyout of a synthetic lease, partially offset by an increase of \$52.0 million related to the additional cash and investments we were required to pledge to secure the COH surety bond. Total cash and investments pledged to secure the COH surety bond was \$682.0 million at September 30, 2004, an increase from the \$630.0 million at December 31, 2003. These amounts are reflected in "restricted cash and other long-term assets" on the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. The associated liability for the COH judgment is classified in "other long-term liabilities" in the condensed consolidated balance sheets at September 30, 2004 and December 31, 2003. We currently believe that if our petition for review of the COH verdict is granted, the process will likely take longer than one year. In the event that our petition for review is not granted or that the appeal process is resolved earlier, the pledged assets and associated liability may be reclassified as a current asset and liability, respectively. 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 our planned petition for a rehearing by the Court of Appeal and/or a review by the California Supreme Court. See Note 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding the COH litigation and related surety bond.

#### 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. In the first nine months of 2004, we received \$421.1 million related to stock option exercises and stock issuances under our employee stock purchase plan. We also used cash for stock repurchases of \$821.4 million in the first nine months of 2004, pursuant to our stock repurchase program approved by our Board of Directors. Refer to Note 9, "Capital Stock," in the Notes to Condensed Consolidated Financial Statements for further information on our stock repurchase program approved by our Board of Directors.

Our total cash, cash equivalents, short-term investments and marketable securities are expected to decline over the next several years due to cash requirements for capital expenditures, share repurchases under our stock repurchase program, synthetic lease repayments and other uses of working capital. We believe these funds, together with funds provided by operations and leasing arrangements, will be sufficient to meet our foreseeable future operating cash requirements. In addition, we believe we could access additional funds from the debt and, under certain circumstances, capital markets. 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 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part

I, Item 1 of this Form 10-Q for factors that could negatively affect our cash position.

#### 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

We lease various real properties under operating leases. Two of our operating leases are commonly referred to as "synthetic leases." Under FIN 46R, each lease is evaluated to determine if it qualifies as a VIE and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

One of our synthetic leases relates to our manufacturing facility located in Vacaville, California. Under FIN 46R, we determined that the entity from which we lease the Vacaville facility qualified as a VIE and that we are the primary beneficiary of this VIE as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46R on July 1, 2003, we consolidated the entity.

Our other lease was entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us a building that we occupy in South San Francisco, California. We have evaluated our accounting for this lease under the provisions of FIN 46R, and have determined the following:

- as of July 1, 2003 and for each quarterly reporting period through September 30, 2004, our remaining synthetic lease entered into with BNP represents a variable interest in BNP;
- we are not the primary beneficiary of BNP as we do not absorb the majority of the entity's expected losses or expected residual returns. As part of this determination, we have received quarterly confirmations from BNP representing to us and we have reviewed their portfolio statements to confirm that the leased property does not represent greater than 50% of the fair value of BNP's assets; and
- we believe that the leased property is not a "specified asset" that represent essentially the only source of payment for our variable interest. As part of this determination, we have received quarterly confirmations from BNP representing to us and we have reviewed their portfolio statements to confirm that the leased property is not a "specified assets" held within a silo. That is, BNP has not financed an amount equal to or greater than 95% of the fair value of the leased assets with non-recourse debt, lessor participation, targeted equity or any other type of funding (silo funding) that would result in the leased property being the only source of payment. In addition, as part of BNP's representations and warranties, BNP has agreed not to incur additional indebtedness in the future or to change the character of other non-targeted equity or similar funding sources that in any way would result in the leased property being essentially the only source of repayment or to make any distributions from BNP that would result in silo funding equal to or exceeding 95% of the fair value of the leased property.



Accordingly, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP lease. See Note 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q, for our future minimum lease payments under all leases at December 31, 2003.

The following summarizes the approximate initial fair values of the facilities at the inception of the related leases, lease terms and residual value guarantee amounts for each of our synthetic leases (*in millions*):

	Approximate Initial Fair Value of Leased Property	Lease Expiration	Maximum Residual Value Guarantee
Vacaville lease	\$ 425.0	11/2006	\$ 371.8
South San Francisco lease 2	160.0	06/2007	136.0
Total	<u>\$ 585.0</u>		<u>\$ 507.8</u>

Two of our synthetic leases expired in the first nine months of 2004. Upon the expiration of these leases, we purchased the related properties from our lessor, BNP, and paid \$25.0 million in the first quarter and \$56.6 million in the third quarter of 2004 for the related properties.

We believe that there have been no impairments in the fair value or use of the properties that we lease under synthetic leases wherein we believe that we would be required to pay amounts under any of the residual value guarantees. We will continue to assess the fair values of the underlying properties and the use of the properties for impairment at least annually.

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnification in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses and expenses to be material.

#### Contractual Obligations

During the first nine months of 2004, the only significant change in our reported payments due under contractual obligations at December 31, 2003 was a payment of \$56.6 million in the third quarter of 2004 related to our buyout of a synthetic lease.

#### CONTINGENCIES

We are a party to various legal proceedings, including patent infringement litigation and licensing and contract disputes, and other matters. See Note 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information.

#### RELATED PARTY TRANSACTIONS

We enter into transactions with our related parties, Roche Holdings, Inc. (including Hoffmann-La Roche and other affiliates) and Novartis AG (or Novartis), in the ordinary course of business. The accounting policies we apply to our

transactions with our related parties are consistent with those applied in transactions with independent third-parties and all related party agreements are negotiated on an arm's-length basis.

#### 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 onto our balance sheet on June 30, 1999. See also above in the "Recurring Charges Related to Redemption" section of Results of Operations and Note 3, "Related Parties," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q.

#### 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 2004 and 2003 (see discussion in Note 9, "Stock Repurchases," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 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. Roche publicly offered zero-coupon notes in January 2000 which were exchangeable for Genentech common stock held by Roche. Roche called these notes in March 2004. Through April 5, 2004, the expiration date for investors to tender these notes, a total of 25,999,324 shares were issued in exchange for the notes, thereby reducing Roche's ownership of Genentech common stock to 587,189,380 shares. At September 30, 2004, Roche's ownership percentage was 55.7%. The Minimum Percentage at September 30, 2004 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be no lower than 55.7%. See Note 9 "Capital Stock" for information regarding our stock repurchase program.

Transactions with Roche

In April 2004, we further amended our July 1999 licensing and marketing agreement with Hoffmann-La Roche and its affiliates under which we grant them an option to license, use and sell our products in non-U.S. markets. This amendment added certain Genentech products under Hoffman-La Roche's commercialization and marketing rights for Canada but did not modify any material financial terms of the licensing and marketing agreement which are described in our Annual Report on Form 10-K for the year ended December 31, 2003.

Page 40

---

We have a July 1998 licensing and marketing agreement relating to anti-HER2 antibodies (Herceptin and more recently, Omnitarg) with Hoffmann-La Roche, providing them with exclusive marketing rights outside of the United States. Under the agreement, Hoffmann-La Roche contributes equally with us on global development costs. Either Genentech or Hoffmann-La Roche has the right to "opt-out" of developing an additional indication for a product and would not share the costs or benefits of the additional indication, but could "opt-back-in" before approval of the indication by paying twice what would have been owed for development of the indication if no opt-out had occurred. Hoffmann-La Roche has also agreed to make royalty payments of 20% on aggregate net product sales outside the United States up to \$500 million in each calendar year and 22.5% on such sales in excess of \$500 million in each calendar year.

In April 2004, we entered into a research collaboration agreement with Hoffmann-La Roche that outlines the process by which Hoffmann-La Roche and Genentech will conduct and share in the costs of joint research on molecules in areas of mutual interest. The agreement further outlines how development and commercialization efforts will be coordinated with respect to select molecules, including the financial provisions for a number of different development and commercialization scenarios undertaken by either or both parties.

In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under the July 1999 licensing and marketing agreement. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and pays 75% of subsequent global development costs related to the metastatic colorectal cancer indication of Avastin and all others unless Hoffmann-La Roche specifically opts out of the development of certain other indications. In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market, a humanized anti-CD20 antibody for all countries outside of the U.S. (other than territory previously licensed to others) under the July 1999 licensing and marketing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and pays 50% of subsequent global development costs related to the humanized anti-CD20 antibody unless Hoffmann-La Roche opts out of the development of certain other indications. We will receive royalties on net sales of Avastin and the humanized anti-CD20 antibody in countries outside of the U.S.

We recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$4.3 million and \$23.9 million in the third quarters of 2004 and 2003, respectively, and \$53.9 million and \$33.5 million in the first nine months of 2004 and 2003, respectively. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$106.9 million and \$77.9 million in the third quarters of 2004 and 2003, respectively, and \$317.5 million and \$247.5 million in the first nine months of 2004 and 2003, respectively. Cost of sales included amounts related to Hoffmann-La Roche of \$22.5 million and \$20.5 million in the third quarters of 2004 and 2003, respectively, and \$70.8 million and \$75.3 million in the first nine months of 2004 and 2003, respectively. R&D expenses included amounts related to Hoffmann-La Roche of \$25.7 million and \$28.9 million in the third quarters of 2004 and 2003, respectively, and \$93.0 million and \$43.5 million in the first nine

months of 2004 and 2003, respectively.

#### Transactions with Novartis AG

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

In June 2003, we entered into an agreement with Novartis Ophthalmics AG (subsequently merged into Novartis Pharma AG), under which Novartis Ophthalmics licensed the exclusive right to develop and market Lucentis outside of North America for diseases or disorders relating to the human eye, including the indication of age-related macular degeneration (or AMD). As part of this agreement, Novartis Ophthalmics paid us \$46.6 million and pays 50% of Genentech's expenses relating to certain AMD Phase III trials and related development expenses. Genentech may share in a portion of the development and commercialization costs incurred by Novartis outside of North America. We will also receive royalties on net sales of Lucentis products, which we will manufacture and supply to Novartis, outside of North America.

In February 2004, Genentech, Inc., Novartis Pharma AG and Tanox, Inc. settled all litigation pending among them, and finalized the detailed terms of their three-party collaboration, begun in 1996, to govern the potential development and commercialization of certain anti-IgE antibodies including Xolair® (Omalizumab) and TNX-901. This arrangement modifies the arrangement related to Xolair that we entered into with Novartis in 2000. All three parties are co-developing Xolair in the U.S., and Genentech and Novartis are co-promoting Xolair in the U.S. and both will separately make payments to Tanox; Genentech's will be in the form of royalties. Genentech records all sales and cost of sales in the U.S. and Novartis will market the product in and record all sales and cost of sales in Europe. Genentech and Novartis then share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. The existing royalty and profit-sharing percentages between the three parties remain unchanged. Genentech is currently supplying the product and receives cost plus a mark-up similar to other supply arrangements. Genentech and Novartis are finalizing the details of the supply and manufacturing planning of Xolair worldwide.

Contract revenue from Novartis was \$11.0 million and \$7.4 million in the third quarters of 2004 and 2003, respectively, and \$31.9 million and \$18.5 million in the first nine months of 2004 and 2003, respectively. Novartis collaboration profit sharing expenses were \$21.6 million and \$48.2 million in the third quarter and first nine months of 2004 and we had no such expenses in the same periods of 2003. R&D expenses included amounts related to Novartis of \$11.2 million and \$7.5 million in the third quarters of 2004 and 2003, respectively, and \$31.0 million and \$16.3 million in the first nine months of 2004 and 2003, respectively.

#### 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 consultants. 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 at the fair market value of the underlying stock at the date of grant after a review by, and with the approval of, the Compensation Committee of the Board of Directors.

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, 2002	8,098	110,838	\$ 19.19
Grants	(21,780)	21,780	40.55
Exercises	-	(32,078)	34.14
Cancellations <sup>(1)</sup>	4,414	(4,414)	23.80
Additional shares reserved	50,000	-	-
December 31, 2003	40,732	96,126	25.18
Grants	(20,302)	20,302	53.11
Exercises	-	(18,336)	20.54
Cancellations <sup>(1)</sup>	1,391	(1,391)	28.44
Additional shares reserved <sup>(2)</sup>	-	-	-
September 30, 2004 (Year to date)	21,821	96,701	31.88

(1) We currently only grant shares under our amended and restated 1999 Stock Plan. Cancellations from options granted under previous plans are not added back to the shares reserved for issuance under the 1999 Stock Plan.

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

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

*(Shares in thousands)*

As of September 30, 2004	Exercisable		Unexercisable		Total	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
In-the-Money	44,692	\$ 24.33	32,880	\$ 29.61	77,572	\$ 26.57
Out-of-the-Money <sup>(1)</sup>	4	53.23	19,125	53.41	19,129	53.41
Total Options Outstanding	44,696		52,005		96,701	

(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, \$52.42, at the close of business on September 30, 2004.

## Distribution and Dilutive Effect of Options

## Employee and Executive Officer Option Grants

	2004	2003	2002
Net grants during the year as % of outstanding shares	1.80 %	1.69 %	1.98 %
Grants to Named Executive Officers* during the period as % of outstanding shares	0.19 %	0.18 %	0.25 %
Grants to Named Executive Officers during the year as % of total options granted	9.95 %	8.54 %	10.27 %

\* "Named Executive Officers" refers to our CEO 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.

**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, many 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 Biologics License Application (or BLA) preparation, discussions with the U.S. Food and Drug Administration (or FDA), an FDA request for additional preclinical or clinical data, or unexpected safety 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 research and development (or 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.
- 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 research and development (or IPR&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.
- 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 United States until it has been approved by the FDA, and then can only be marketed for the indications and claims 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 and 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 at our manufacturing facilities located in South San Francisco, California and Vacaville, California 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.

We have had equipment malfunctions in our filling facility and, consequently, several product lots were not able to be released and a scheduled facility maintenance shut-down was extended. This situation resulted in decreased target

Page 45

---

inventory levels for certain of our products. 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 malfunctions or failures, damage to a 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 due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because our manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our or our 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 plan to expand our Vacaville facility, to build new facilities or enter into contracts for additional manufacturing capacity in the future. Any delay in the construction of the facilities, the ability to contract for additional manufacturing capacity or the receipt of FDA licensure may cause insufficient available capacity for the manufacture of our products. Insufficient available capacity to manufacture or have manufactured for us existing or new products could cause shortfalls of available product inventory and an inability to supply market demand of one or more of our products for either a short period of time or an extended period of time. Alternatively, we may have an excess of available capacity which could lead to an idling of a portion of our manufacturing facilities and incurring idle plant charges, resulting in an increase in our costs of sales. All of our efforts planning for additional manufacturing capacity are critical to providing for sufficient capacity to meet expected demand for our products, 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 United States are 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 the 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, namely Rituxan and especially with respect to 2004, could reduce physician usage of the product and have a material adverse effect on our product sales, results of operations and financial condition. We are unable to predict what impact the Medicare Act or other future regulation, if any, relating to third-party reimbursement, will have on sales of Rituxan or our oncology or other products.

#### 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 patent litigation, such as the matters discussed in Note 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. Patent litigation is costly in its 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 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, 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 potential changes in stock option accounting rules could have an 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 in certain of our therapeutic markets. First, in the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to Centocor's Retavase® (approved in 1996 for the treatment of acute myocardial infarction) and to the use of mechanical reperfusion therapies to treat acute myocardial infarction; the resulting adverse effect on sales has been and could continue to be material. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. In addition, we face potential competition in the catheter clearance market from the reintroduction of Abbott Laboratories' Abbokinase® (urokinase) in October 2002.

Second, 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. As a result of that competition, we have experienced and may continue to experience a loss in market share. In addition, we have certain patents related to the production of growth hormone that have expired and as a consequence those patents no longer exclude others from making growth hormone using the processes claimed by those patents. Any competitive entry as a result of expiration of our patents may cause further decline in our market share.

Third, 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 Biogen Idec's Amevive® (alefacept) and Amgen's ENBREL® (etanercept), co-marketed by Wyeth, both FDA approved for adult patients with moderate-to-severe psoriasis in January 2003 and April 2004, respectively. ENBREL® was previously approved and marketed for psoriatic arthritis, a condition associated with psoriasis. Other products are known to be in development for the psoriasis market.

Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil ("5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with an irinotecan-based regimen, 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 5-FU/Leucovorin alone. The use of these regimens is likely to decline as more physicians adopt Oxaliplatin-based regimens in the first-line setting. Avastin is currently being studied in combination with 5-FU/ Leucovorin and Oxaliplatin (the "FOLFOX Regimen") in patients with relapsed, metastatic colorectal cancer in a large randomized study through the Eastern Cooperative Oncology Group (the "E3200 Trial"). If the results from the E3200 Trial are positive for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin or show a similar magnitude of benefit as previous colorectal cancer studies with Avastin, use of Avastin may increase as physicians increase their use of Avastin in combination with Oxaliplatin-based regimens in the relapsed, and also the first-line setting. However, if the results of the E3200 Trial are negative for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin, potential sales of Avastin may be materially adversely affected as physicians may limit their use of Avastin to 5-FU/Leucovorin

and/or irinotecan regimens. Physicians may also restrict their use of Avastin to first-line patients only. An oral VEGF-inhibitor from Novartis is currently in Phase III clinical trials in combination with FOLFOX in both the first line and relapsed settings.

#### 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 data from new clinical studies could cause the utilization and sales of our products to decrease.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products. For example, as described in Note 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements in 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. For example, the overall size of the market for thrombolytic therapies, such as our Activase product, continues to decline as a result of the increasing use of mechanical reperfusion.
- The rate of market penetration by competing products. For example, we have lost market share to new competitors in the thrombolytic and, in the past, growth hormone markets.

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

### We May Incur Material Product Liability Costs

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

### Insurance Coverage Is Increasingly More Difficult 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.

### 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 United States. 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 United States and the amount and timing of sales to their respective customers, which directly impacts both our product sales and royalty revenues.
- The timing and volume of bulk shipments to licensees.

- The availability and extent of government and private third-party reimbursements for the cost of therapy.
- The extent of product discounts extended to customers.
- The effectiveness and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.

- The rate of adoption by physicians and use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
- The potential introduction of new products and additional indications for existing products.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.
- The number and size of any product price increases we may issue.

#### Our 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 United States 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.

#### Future Stock Repurchases Could Adversely Affect Our Cash Position

Our Board of Directors has authorized a stock repurchase program. Generally, under this program, Genentech can purchase its stock in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech can also engage in transactions in other Genentech securities in conjunction with the repurchase program, including derivative securities.

Under a stock repurchase program approved by our Board of Directors in December 2003 and extended in September 2004, Genentech is authorized to repurchase up to 50,000,000 shares of our common stock for an aggregate price of up to \$2 billion through December 31, 2005. A total of 14,872,100 shares at a cost of approximately \$827.4 million has been purchased under the plan through September 30, 2004. See also item below regarding our affiliation agreement with Roche and the potential impact of future stock repurchases.

#### 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 Note 9, "Capital Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q. See Note 3, "Related Parties" 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 September 30, 2004, Roche owned 587,189,380 shares of our common stock or 55.7% 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. 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 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 3, "Related Parties," 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 Note 9, "Capital Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.



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, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles, currently serve as officers and employees of Roche Holding Ltd and its affiliates.

We Are Exposed to Market Risk

We are exposed to market risk, including changes to interest rates, foreign currency exchange rates and equity investment prices. To reduce the volatility relating to these exposures, we enter into various derivative hedging transactions pursuant to our investment and risk management policies and procedures. We do not use derivatives for speculative purposes.

We maintain risk management control systems to monitor the risks associated with interest rates, foreign currency exchange rates and equity investment price changes, and our derivative and financial instrument positions. The risk management control systems use analytical techniques, including sensitivity analysis and market values. Though we intend for our risk management control systems to be comprehensive, there are inherent risks that may only be partially offset by our hedging programs should there be unfavorable movements in interest rates, foreign currency exchange rates or equity investment prices.

The estimated exposures discussed below are intended to measure the maximum amount we could lose from adverse

market movements in interest rates, foreign currency exchange rates and equity investment prices, given a specified confidence level, over a given period of time. Loss is defined in the value at risk estimation as fair market value loss. The exposures to interest rate, foreign currency exchange rate and equity investment price changes are calculated based on proprietary modeling techniques from a Monte Carlo simulation value at risk model using a 21-trading days holding period and a 95% confidence level. The value at risk model assumes non-linear financial returns and generates potential paths various market prices could take and tracks the hypothetical performance of a portfolio under each scenario to approximate its financial return. The value at risk model takes into account correlations and diversification across market factors, including interest rates, foreign currencies and equity prices. Hedge

instruments are modeled as positions on the actual underlying securities. No proxies were used. Market volatilities and correlations are based on a one-year historical times-series as of December 31, 2003.

#### Our Interest Income is Subject to Fluctuations in Interest Rates

Our material interest-bearing assets, or interest-bearing portfolio, consisted of cash, cash equivalents, restricted cash and investments, short-term investments, marketable debt securities, long-term investments and interest-bearing forward contracts. The balance of our interest-bearing portfolio, including restricted and unrestricted cash and investments, was \$3,268.8 million or 35% of total assets at September 30, 2004. Interest income related to this portfolio was \$66.4 million in the first nine months of 2004. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest-bearing portfolio. To mitigate the impact of fluctuations in U.S. interest rates, for a portion of our portfolio, we may enter into swap transactions that involve the receipt of fixed rate interest and the payment of floating rate interest without the exchange of the underlying principal.

Based on our overall interest rate exposure at December 31, 2003, including derivative and other interest rate sensitive instruments, a near-term change in interest rates, within a 95% confidence level based on historical interest rate movements could result in a potential loss in fair value of our interest rate sensitive instruments of \$19.5 million.

#### We Are Exposed to Risks Relating to Foreign Currency Exchange Rates and Foreign Economic Conditions

We receive royalty revenues from licensees selling products in countries throughout the world. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which our licensed products are sold. We are exposed to changes in exchange rates in Europe, Asia (primarily Japan) and Canada. Our exposure to foreign exchange rates primarily exists with the Swiss Franc. When the dollar strengthens against the currencies in these countries, the dollar value of foreign-currency denominated revenue decreases; when the dollar weakens, the dollar value of the foreign-currency denominated revenues increases. Accordingly, changes in exchange rates, and in particular a strengthening of the dollar, may adversely affect our royalty revenues as expressed in dollars. Expenses arising from our foreign manufacturing facility as well as non-dollar expenses incurred in our collaborations are offsetting exchange rate exposures on these royalties. Currently, our foreign royalty revenues exceed our foreign expenses. In addition, as part of our overall investment strategy, a portion of our portfolio is primarily in non-dollar denominated investments. As a result, we are exposed to changes in the exchange rates of the countries in which these non-dollar denominated investments are made.

To mitigate our net foreign exchange exposure, our policy allows us to hedge certain of our anticipated royalty revenues by purchasing option or forward contracts with expiration dates and amounts of currency that are based on up to 90% of probable future revenues so that the potential adverse impact of movements in currency exchange rates on the non-dollar denominated revenues will be at least partly offset by an associated increase in the value of the option or forward. Generally, the term of these options is one to five years. To hedge the non-dollar expenses arising from our foreign manufacturing facility, we may enter into forward contracts to lock in the dollar value of a portion of these anticipated expenses.

Based on our overall currency rate exposure at December 31, 2003, including derivative and other foreign currency sensitive instruments, a near-term change in currency rates within a 95% confidence level based on historical currency rate movements would not materially affect the fair value of our foreign currency sensitive instruments.

#### Our Investments in Equity Securities are Subject to Market Risks

As part of our strategic alliance efforts, we invest in equity instruments of biotechnology companies. Our biotechnology equity investment portfolio totaled \$483.8 million or 5% of total assets at September 30, 2004. These investments are subject to fluctuations from market value changes in stock prices. To mitigate the risk of market value fluctuation, certain equity securities are hedged with zero-cost collars and forward contracts. A zero-cost

collar is a purchased put option and a written call option in which the cost of the purchased put and the proceeds of the written call offset each other; therefore, there is no initial cost or cash outflow for these instruments at the time of purchase. The purchased put protects us from a decline in the market value of the security below a certain minimum level (the put "strike" level), while the call effectively limits our potential to benefit from an increase in the market value of the security above a certain maximum level (the call "strike" level). A forward contract is a derivative instrument where we lock-in the termination price we receive from the sale of stock based on a pre-determined spot price. The forward contract protects us from a decline in the market value of the security below the spot price and limits our potential benefit from an increase in the market value of the security above the spot price. Throughout the life of the contract, we receive interest income based on the notional amount and a floating-rate index. In addition, as part of our strategic alliance efforts, we hold convertible preferred stock, including dividend-bearing convertible preferred stock, and have made interest-bearing loans that are convertible into the equity securities of the debtor or repaid in cash. Depending on market conditions, we may determine that in future periods certain of our other unhedged equity security investments are impaired, which would result in additional write-downs of those equity security investments.

Based on our overall exposure to fluctuations from market value changes in marketable equity prices at December 31, 2003, a near-term change in equity prices within a 95% confidence level based on historic volatilities could result in a potential loss in fair value of our equity securities portfolio of \$22.4 million.

#### We Are Exposed to Credit Risk of Counterparties

We could be exposed to losses related to the financial instruments described above should one of our counterparties default. We attempt to mitigate this risk through credit monitoring procedures.

#### 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, future levels of capital expenditures, and changes in overall levels of pretax earnings.

#### New and Potential New Accounting Pronouncements May Impact Our Future Financial Position and Results of Operations

Under Financial Accounting Standards Board Interpretation No. 46R, a revision to Interpretation 46, "Consolidation of Variable Interest Entities," we are required upon certain events, some of which are outside our control, to reassess the accounting treatment of our business development collaborations in future periods based on the nature and extent of our financial interests as well as our ability to exercise influence. Our reassessment may require that we exercise significant judgment in estimating future outcomes and may result in our consolidation of the company or related entities with which we have a collaborative arrangement and this may have a material impact on our financial condition or results of operation 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 particular, the accounting for employee stock options and employee stock purchase plans as an expense. On March 31, 2004, the FASB issued an Exposure Draft, "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95" (proposed FAS 123R), which currently is expected to be effective for public companies in periods beginning after June 15, 2005. We would be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. FAS 123R would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," and would instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. The FASB expects to issue a final standard by December 31, 2004. The adoption of FAS 123R could materially impact our results of operations.

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

Our market risks at September 30, 2004 have not changed significantly from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2003 on file with the Securities and Exchange Commission. See Note 5, "Derivative Financial Instruments," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 and the "Forward-Looking Information and Cautionary Factors That May Affect Future Results -- We Are Exposed to Market Risk" section of Item 2 of this Form 10-Q for additional discussions of our market risks.

#### 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 and 15(d)-15) 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 timely providing them with material information relating to the Company, 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 our 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, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On October 4, 2004, we received a subpoena from the 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.

In connection with the Chiron patent infringement lawsuit relating to U.S. Patent No. 6,054,561, the Court of Appeals denied Chiron's Petition for Rehearing in its entirety on June 8, 2004. On October 4, 2004, Chiron filed a petition with the United States Supreme Court seeking review of the judgement in favor of Genentech.

In connection with the City of Hope lawsuit, on October 21, 2004 the Court of Appeal affirmed the verdict and damages award in all respects. Also, on October 21, Genentech announced that it will seek review by the California Supreme Court, which has discretion over which cases it will review.

See also Item 3 of our report on Form 10-K for the year ended December 31, 2003 and Part II, Item 1 of each of our reports on Form 10-Q for the quarters ended March 31, 2004 and June 30,2004.

See also Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q.

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

Our shares repurchased during the past quarter were as follows:

Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(1)</sup>	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs

July 1 - 31, 2004	3,208,100	\$ 51.85		
August 1 - 31, 2004	-	-		
September 1 - 30, 2004	1,578,400	50.12		
Total	<u>4,786,500</u>	<u>\$ 51.28</u>	<u>14,872,100</u>	<u>35,127,900</u>

- (1) Under a stock repurchase program approved by our Board of Directors in December 2003 and extended in September 2004, Genentech is authorized to repurchase up to 50,000,000 shares for an aggregate purchase price of up to \$2 billion of its common stock through December 31, 2005. See also Note 9, "Capital Stock," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q.

## Item 6. Exhibits

- (i) 10.22 1999 Stock Plan, Form of Stock Option Agreement.
- (ii) 10.23 1999 Stock Plan, Form of Stock Option Agreement (Director Version).
- (iii) 10.24 Promissory Note, dated as of April 5, 2001, issued to Genentech, Inc. by Richard H. Scheller.
- (iv) 15.1 Letter regarding Unaudited Interim Financial Information.
- (v) 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- (vi) 31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- (vii) 32.1 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

Edgar Filing: GENENTECH INC - Form 10-Q

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

GENENTECH, INC.

Date: October 28, 2004

/s/ARTHUR D. LEVINSON

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

Date: October 28, 2004

/s/LOUIS J. LAVIGNE, JR.

Louis J. Lavigne, Jr.  
Executive Vice President and  
Chief Financial Officer

Date: October 28, 2004

/s/JOHN M. WHITING

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