

GENENTECH INC
Form 10-Q
May 05, 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 March 31, 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	531,789,029 Outstanding at April 28, 2004

GENENTECH, INC.
TABLE OF CONTENTS

	<u>Page No.</u>
	<u>PART I - FINANCIAL INFORMATION</u>
Item 1.	3
	<u>Financial Statements</u>
	3
	<u>Condensed Consolidated Statements of Income - for the three months ended March 31, 2004 and 2003</u>
	4
	<u>Condensed Consolidated Statements of Cash Flows - for the three months ended March 31, 2004 and 2003</u>
	5
	<u>Condensed Consolidated Balance Sheets - March 31, 2004 and December 31, 2003</u>
	6-17
	<u>Notes to Condensed Consolidated Financial Statements</u>
	18
	<u>Independent Accountants' Review Report</u>
Item 2.	19-48
	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
Item 3.	49
	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
Item 4.	49
	<u>Controls and Procedures</u>

PART II - OTHER INFORMATION

Item 1.		50
	<u>Legal Proceedings</u>	
Item 6.		50
	<u>Exhibits and Reports on Form 8-K</u>	
		51
	<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.

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, formerly Xanelim™) 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.

Page 2

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

GENENTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2004	2003
Revenues		

Edgar Filing: GENENTECH INC - Form 10-Q

Product sales (including amounts from related parties: 2004-\$27,824; 2003-\$29,409)	\$ 763,700	\$ 598,482
Royalties (including amounts from related party: 2004-\$71,297; 2003-\$46,887)	154,097	113,275
Contract revenue (including amounts from related parties: 2004-\$36,621; 2003-\$2,288)	57,338	37,915
Total operating revenues	975,135	749,672
Costs and expenses		
Cost of sales (including amounts for related parties: 2004-\$22,645; 2003-\$24,829)	114,480	114,842
Research and development (including related parties amounts of: 2004-\$46,464; 2003-\$12,129)		157,433
(including contract related: 2004-\$36,924; 2003-\$9,473)	190,345	
Marketing, general and administrative	247,314	137,222
Collaboration profit sharing (including related party amounts of: 2004-\$11,822; 2003-\$0)	126,431	96,547
Recurring charges related to redemption	38,209	38,586
Special charges: litigation-related	13,399	13,245
Total costs and expenses	730,178	557,875
Operating margin	244,957	191,797
Other income, net	22,321	15,703
Income before taxes	267,278	207,500
Income tax provision	90,691	56,029
Net income	\$ 176,587	\$ 151,471
Earnings per share		
Basic	\$ 0.33	\$ 0.30
Diluted	\$ 0.33	\$ 0.29
Weighted-average shares used to compute earnings per share		
Basic	527,599	511,909
Diluted	540,814	517,266

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

*(In thousands)**(Unaudited)*

	Three Months Ended March 31,	
	2004	2003
Cash flows from operating activities		
Net income	\$ 176,587	\$ 151,471
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	78,975	73,016
Deferred income taxes	(14,842)	(17,889)
Deferred revenue	(12,570)	5,047
Litigation-related liabilities	12,856	15,077
Net gain on sales of securities available-for-sale and other	(649)	(369)
Write-down of securities available-for-sale	-	3,764
Changes in assets and liabilities:		
Receivables and other current assets	(31,651)	27,205
Inventories	(55,089)	(17,565)
Investments in trading securities	(6,781)	11,148
Accounts payable and other current liabilities	(50,406)	(5,406)
Net cash provided by operating activities	96,430	245,499
Cash flows from investing activities		
Purchases of securities available-for-sale	(452,150)	(253,742)
Proceeds from sales and maturities of securities available-for-sale	172,845	120,699
Capital expenditures	(97,707)	(73,460)
Change in other assets	10,075	(6,317)
Net cash used in investing activities	(366,937)	(212,820)
Cash flows from financing activities		
Stock issuances	231,552	21,064
Stock repurchases	-	(113,172)
Net cash provided by (used in) financing activities	231,552	(92,108)

Net decrease in cash and cash equivalents	(38,955)	(59,429)
Cash and cash equivalents at beginning of period	372,152	208,130
Cash and cash equivalents at end of period	\$ 333,197	\$ 148,701

See Notes to Condensed Consolidated Financial Statements.

Page 4

GENENTECH, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	March 31, 2004	December 31, 2003
Assets		
Current assets		
Cash and cash equivalents	\$ 333,197	\$ 372,152
Short-term investments	1,304,624	1,139,620
Accounts receivable - product sales, net (including amounts from related parties: 2004-\$12,871; 2003-\$16,018)	379,492	315,097
Accounts receivable - royalties, net (including amounts from related party: 2004-\$100,635; 2003-\$113,739)	174,497	184,163
Accounts receivable - other, net (including amounts from related parties: 2004-\$65,531; 2003-\$71,863)	56,815	74,831
Inventories	524,729	469,640
Prepaid expenses and other current assets	176,912	201,327
Total current assets	2,950,266	2,756,830
Long-term marketable debt and equity securities	1,654,985	1,422,886
Property, plant and equipment (net of accumulated depreciation of: 2004-\$918,978; 2003-\$883,556)	1,679,549	1,617,912
Goodwill	1,315,019	1,315,019
Other intangible assets (net of accumulated amortization of: 2004-\$1,792,217; 2003-\$1,749,234)	765,415	810,810
Restricted cash and other long-term assets	769,221	812,714

Total assets	\$ 9,134,455	\$ 8,736,171
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 24,296	\$ 59,700
Other current liabilities (including amounts owed to related parties: 2004-\$54,939; 2003-\$58,138)	663,312	813,331
Total current liabilities	687,608	873,031
Long-term debt	412,250	412,250
Other long-term liabilities	927,347	930,592
Total liabilities	2,027,205	2,215,873
Commitments and contingencies		
Stockholders' equity		
Preferred stock	-	-
Common stock	10,612	10,495
Additional paid-in capital	7,751,394	7,370,261
Accumulated deficit, since June 30, 1999	(980,904)	(1,157,491)
Accumulated other comprehensive income	326,148	297,033
Total stockholders' equity	7,107,250	6,520,298
Total liabilities and stockholders' equity	\$ 9,134,455	\$ 8,736,171

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

We prepared the condensed consolidated financial statements following the requirements of the Securities and Exchange Commission (or SEC) 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.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Genentech and all subsidiaries. Genentech also consolidated a variable interest entity in 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 recorded 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. 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, although we may grant options with different vesting terms from time to time. No stock purchase rights or incentive stock options have been granted under our current plan to date.

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 plan.

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 March 31,	
	2004	2003
Risk-free interest rate	3.0 %	2.8 %
Dividend yield	0.0 %	0.0 %
Volatility factors of the expected market price of our Common Stock	45.0 %	36.0 %
Weighted-average expected life of option (years)	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. Because 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, 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.

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 March 31,	
	2004	2003
Net income as reported	\$ 176,587	\$ 151,471
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	45,883	40,208
Pro forma net income	\$ 130,704	\$ 111,263

Earnings per share:		
Basic-as reported	\$ 0.33	\$ 0.30
Basic-pro forma	\$ 0.25	\$ 0.22
Diluted-as reported	\$ 0.33	\$ 0.29
Diluted-pro forma	\$ 0.24	\$ 0.22

On March 31, 2004, the FASB issued an Exposure Draft (ED), "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95." The proposed Statement 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 Statement 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. As proposed, the new rules would be applied on a modified prospective basis as defined in the ED, and would be effective for public companies for fiscal years beginning after December 15, 2004. We are currently evaluating option valuation methodologies and assumptions in light of the evolving accounting standards 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. Three of our operating leases are commonly referred to as "synthetic leases." Under FIN 46R, each synthetic 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.

The most significant 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 two remaining leases were entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us various buildings that we occupy in South San Francisco, California. Under one of these leases, we are required to maintain cash collateral of \$56.6 million, which we have included in our condensed consolidated balance sheets as restricted cash and other long-term assets. We have evaluated our accounting for these leases under the provisions of FIN 46R, and we determined that, as of July 1, 2003 and through March 31, 2004, we are not required to consolidate

either the leasing entity or the specific assets that we lease under the BNP leases.

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 ⁽¹⁾	\$ 6.2	\$ 6.2	\$ 5.6	\$ -	\$ -	\$ -	\$ 18.0
South San Francisco synthetic leases	2.7	2.6	1.1	-	-	-	6.4
Other operating leases	6.5	6.9	5.8	5.8	5.8	24.1	54.9
Total	<u>\$ 15.4</u>	<u>\$ 15.7</u>	<u>\$ 12.5</u>	<u>\$ 5.8</u>	<u>\$ 5.8</u>	<u>\$ 24.1</u>	<u>\$ 79.3</u>

(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 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 1	56.6	07/2004	48.1
South San Francisco lease 2	160.0	06/2007	136.0
Total	<u>\$ 641.6</u>		<u>\$ 555.9</u>

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 indemnifications 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. In the case of South San Francisco lease 1, we have pledged cash collateral of \$56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

Contingencies

In August 2002, we entered into an agreement with Serono S.A., which, in addition to granting Serono marketing rights in specific areas of the world, includes an arrangement to collaborate on co-developing additional indications of Raptiva and to share certain global development costs. We also have a supply agreement with Serono, under which we may have a loss exposure up to a maximum of \$10.0 million.

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

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 March 31, 2004 and December 31, 2003. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. The appeal process is ongoing. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

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 has not yet given its decision on the Petition.

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 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.

We and Tanox Biosystems, Inc. (or Tanox) are parties to a July 1996 Settlement and Cross-Licensing Agreement relating to the development and manufacture of certain antibody products directed towards immunoglobulin E, including Xolair and Hu-901. On February 20, 2002, Tanox filed an amended demand in an ongoing arbitration proceeding between Genentech and Tanox that is being conducted by the American Arbitration Association in San Francisco. In its amended demand, Tanox has claimed breach of the July 1996 Agreement, conversion, tortious interference, unjust enrichment, and unfair competition by Genentech, and requests injunctive relief as well as monetary damages "many times in excess of \$100,000,000." On March 14, 2002, Genentech denied all of Tanox's claims, and counterclaimed for breach of contract, theft of trade secrets, misappropriation, breach of confidence,

interference with contract, and interference with economic expectancies by Tanox. Genentech requested injunctive relief and monetary damages. On October 16, 2002, Tanox announced that in a dispute between it and Novartis, an arbitration panel ruled that Tanox is not entitled to develop independently the Hu-901 antibody product. The

Novartis/Tanox panel also ruled that Tanox is entitled to receive certain know-how from Novartis. Tanox contends in its dispute against Genentech that it is entitled to similar information from Genentech. The effect of the October 16 ruling from the Novartis/Tanox arbitration, if any, on Tanox's claims against Genentech cannot be determined since the arbitrators in the Tanox/Genentech proceedings have not yet resolved it. As a general matter, the claims are divided into two categories: (1) compensation for lost rights under agreements with Genentech and Novartis, and (2) additional royalties on future sales. On February 25, 2004, the parties settled and agreed to dismiss with prejudice all claims from the arbitration that began on January 13, 2003. On February 26, 2004, we announced that we, Novartis Pharma AG and Tanox, Inc. have settled all litigation among us and finalized the detailed terms of our three-party collaboration, begun in 1996, to develop, commercialize and manufacture certain anti-IgE antibodies including Xolair® (Omalizumab) and TNX-901. Genentech and Novartis each reimbursed Tanox \$3.3 million in an upfront payment; Tanox will relinquish any rights to manufacture Xolair and will receive payments tied to certain quantities of Xolair produced by Genentech and/or Novartis; and Tanox will benefit from an accelerated forgiveness of a loan from Novartis to finance the construction of its biologics manufacturing plant in the mid-1990s. As in the original agreement, Genentech and Novartis share U.S. marketing rights for all collaboration products, while Novartis has marketing rights outside the United States. The existing royalty and profit-sharing percentages will remain unchanged. Committees with representatives from all three companies have been established to cooperatively oversee further development and commercialization of Xolair, and possibly other collaboration products.

On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, City of Hope National Medical Center (or 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. Because the appeal process is ongoing, the final outcome of this matter cannot be determined at this time.

We recorded \$13.4 million and \$13.3 million in the first quarters of 2004 and 2003, respectively, for accrued interest and bond costs related to the COH trial judgment. 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 \$600.0 million surety bond and as part of this arrangement, we were required to pledge \$630.0 million in cash and investments to secure the bond. In addition, we accrued \$2.4 million in the first quarter of 2003 of royalty expenses related to the City of Hope judgment, which was reflected in marketing, general and administrative expenses. There was no such expense in the first quarter of 2004. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the 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 March 31, 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. The amount of cash, if any, paid in connection with the City of Hope matter will depend on the outcome of the appeal.

Note 3. RELATED PARTIES

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

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 509,194,352 (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 and October 2000. We repurchased shares of our common stock in 2003 (see Note 10, "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 also has issued zero-coupon notes (which were offered publicly in January 2000) exchangeable for an aggregate of 13,034,618 shares of our common stock held by Roche. As of March 31, 2004, a total of 9,840,309 shares of our common stock owned by Roche have been issued in exchange for the zero-coupon notes, decreasing Roche's ownership to 55.9%. The Minimum Percentage at March 31, 2004 was 58.3% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be no lower than 56.3%. See Note 10 "Capital Stock" for information regarding our stock repurchase program.

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 its existing licensing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 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.

Page 12

In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. (other than territory previously licensed to others) under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of subsequent global development costs related to PRO70769 unless Roche opts out of the development of certain other indications. We will receive royalties on net sales of Avastin and PRO70769 in countries outside of the U.S.

As part of our licensing and marketing agreement, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$25.8 million and \$2.0 million in the first quarters of 2004 and 2003, respectively. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$98.9 million and \$76.3 million in the first quarters of 2004 and 2003, respectively. In 2003, Hoffmann-La Roche's Penzberg, Germany facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Our ex-U.S. sales of Herceptin to Hoffmann-La Roche were \$4.8 million in the first quarter of 2004. We had no such sales in the first quarter of 2003. Cost of sales included amounts related to Roche of \$22.4 million and \$24.8 million in the first quarters of 2004 and 2003, respectively. R&D expenses included amounts related to Roche of \$36.8 million and \$8.4 million in the first quarters of 2004 and 2003, respectively.

Relationship and Transactions With Novartis AG (or 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 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. Novartis plans to assume primary manufacturing responsibilities in the future.

Contract revenue from Novartis was \$10.8 million in the first quarter of 2004 and not material in the first quarter of 2003. Collaboration profit sharing expenses were \$11.8 million in the first quarter of 2004 and not material in the first quarter of 2003. R&D expenses included amounts related to Novartis of \$9.7 million in the first quarter of 2004 and \$3.7 million in the first quarter of 2003.

Note 4. OTHER INTANGIBLE ASSETS

The components of our acquisition-related other intangible assets, including those arising from the Redemption and push-down accounting, at March 31, 2004 and December 31, 2003, were as follows (*in millions*):

	March 31, 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	\$ 789.1	\$ 405.0	\$ 1,194.1	\$ 769.5	\$ 424.6
Core technology	443.5	335.1	108.4	443.5	329.8	113.7
Tradenames	144.0	67.5	76.4	144.0	65.1	78.9
Patents	119.5	46.7	72.9	116.6	44.5	72.1
Other	656.5	553.8	102.7	661.8	540.3	121.5
Total	\$ 2,557.6	\$ 1,792.2	\$ 765.4	\$ 2,560.0	\$ 1,749.2	\$ 810.8

Amortization expense of our other intangible assets was \$43.0 million in each of the first quarters of 2004 and 2003.

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 nine months)	\$ 121.8
2005	141.9
2006	122.0
2007	120.7
2008	118.8

2009 and thereafter	140.2
Total expected future annual amortization	\$ 765.4

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 quarters of 2004 or 2003.

At March 31, 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 \$3.9 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 first quarters of 2004 and 2003 was as follows (*in millions*):

	Three Months Ended March 31,	
	2004	2003
Net income	\$ 176.6	\$ 151.5
Change in unrealized gains (losses) on securities available-for-sale	25.7	(8.6)
Change in unrealized gains on derivatives	3.4	1.1
Comprehensive income	\$ 205.7	\$ 144.0

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

	March 31, 2004	December 31, 2003
Unrealized gains on securities available-for-sale	\$ 320.0	\$ 294.3
Unrealized gains on derivatives	6.1	2.7
Accumulated other comprehensive income	\$ 326.1	\$ 297.0

Edgar Filing: GENENTECH INC - Form 10-Q

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

	Three Months Ended March 31,	
	2004	2003
Unrealized gains (losses) on securities available-for-sale (net of tax effect of \$17.1 in 2004, (\$7.1) in 2003)	\$ 25.7	\$ (10.6)
Reclassification adjustment for net gains included in net income (net of tax effect of \$0 in 2004, \$1.4 in 2003)	-	2.0
Change in net unrealized gains (losses) on securities available-for-sale	\$ 25.7	\$ (8.6)

The activity in OCI, net of taxes, during the first quarters 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 first quarters of 2004 and 2003 (*in thousands*):

	Three Months Ended March 31,	
	2004	2003
Numerator:		
Net income	\$ 176,587	\$ 151,471
Denominator:		
Weighted-average shares outstanding used for basic earnings per share	527,599	511,909
Effect of dilutive securities:		
Stock options	13,215	5,357
Weighted-average shares and dilutive stock options used for diluted earnings per share	540,814	517,266

Options to purchase 0.1 million shares of common stock between \$99.41 and \$113.27 per share were outstanding in the first quarter of 2004, and options to purchase 24.1 million shares of common stock between \$35.87 and \$95.66 per share were outstanding in the first quarter of 2003. These options were excluded from the computation of diluted EPS because such options were anti-dilutive in the respective periods presented.

Note 8. INVENTORIES

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

	March 31, 2004	December 31, 2003
Raw materials and supplies	\$ 40.4	\$ 37.1
Work in process	443.6	383.8
Finished goods	40.7	48.7
Total	<u>\$ 524.7</u>	<u>\$ 469.6</u>

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

Note 9. DEBT OBLIGATIONS

Our long-term debt at March 31, 2004 and December 31, 2003 consisted of \$412.3 million of debt related to a variable interest entity (or VIE), which we consolidated on July 1, 2003, with minimum interest payable at 1.2%, due in November 2006. See discussion on this VIE in Note 2 above.

Note 10. CAPITAL STOCK

Stock Repurchase Program

Under a stock repurchase program approved by our Board of Directors on December 5, 2003, Genentech is authorized to repurchase up to 12,500,000 shares for an aggregate purchase price of up to \$1 billion of its common stock through December 31, 2004. 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 maintaining Roche's minimum ownership percentage. That minimum ownership percentage which is equal to the Minimum Percentage described in Note 3 less 2% is 56.3%. Under a previous stock repurchase program approved by our Board of Directors, Genentech was authorized to repurchase up to \$1 billion of our common stock through the period ended June 30, 2003.

Under our current stock repurchase program, we had no repurchases during the first quarter of 2004. The only shares repurchased under this plan were 70,900 shares repurchased in December 2003 at an average price per share of \$85.63. At March 31, 2004, the approximate dollar value of shares that may yet be purchased under this program is \$993.9 million.

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 11. TAXES

The effective tax rate was 34% in the first quarter of 2004 compared to 27% in the first quarter of 2003. The increase in the tax rate reflects a decrease in benefits related to changes in estimates of prior year items. The tax provision for the first quarter of 2004 included a benefit of \$6.5 million related to a favorable change in estimates of research credits.

Note 12. SUBSEQUENT EVENTS

On April 16, 2004, at our annual meeting, our shareholders approved an increase in our authorized common stock. Based on stockholder approval of the increase in authorized common stock, the Board approved a two-for-one stock split of our common stock in the form of a stock dividend of one share of Genentech common stock for each share held at the close of business on April 28, 2004. Our stock will begin trading on a split-adjusted basis on May 13, 2004. All information in this report relating to the number of shares, price per share and per share amounts of common stock are presented on a pre-split basis.

Page 16

Under our stock repurchase program approved by our Board of Directors on December 5, 2003, we have repurchased 800,000 shares of our common stock at a cost of approximately \$93.2 million during the period from April 1, 2004 through April 23, 2004. For more information on our stock repurchase program, see the "Capital Stock" note above.

Page 17

INDEPENDENT ACCOUNTANTS' REVIEW REPORT

The Board of Directors and Stockholders of Genentech, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of Genentech, Inc. as of March 31, 2004, and the related condensed consolidated statements of income and cash flows for the three-month periods ended March 31, 2004 and 2003. These financial statements are the responsibility of Genentech's management.

We conducted our reviews in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data, and making inquiries of persons responsible for financial and accounting matters. It is substantially less

in scope than an audit conducted in accordance with auditing standards generally accepted in the United States, which will be performed for the full year with the objective of expressing an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

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

We have previously audited, in accordance with auditing standards generally accepted in the 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
April 6, 2004, except for the
eleventh paragraph of Note 2
and all of Note 12, as to which the
date is April 23, 2004

Page 18

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. We manufacture and commercialize in the United States 13 biotechnology products and license 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 2004, we expect the growth of our business 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 first quarter of 2004, our total operating revenues were \$975.1 million, our net income was \$176.6 million and our current assets at March 31, 2004 were approximately \$3.0 billion.

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 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 U.S. oncology company in 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 FDA approval, clinical trial success, and advantageous government reimbursement rates.
- To position ourselves for continued leadership in our oncology franchise by bringing five new oncology products or indications for existing products into clinical development and into the market.
- To build a leading immunology franchise by expanding the fundamental understanding of immune disorders, bringing at least five new immunology products or indications into clinical development, and obtaining U.S. Food and Drug Administration (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 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 influence the practice of medicine, 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.

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. Physician reaction to the Medicare Act may have caused some disruption in the ordering of Rituxan in the first few weeks of 2004. However, orders for February and March of 2004 have met our expectations.

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. However, we believe growth hormone may be one of the first likely products for which a generic approval route will be attempted.

This past year we experienced the largest annual growth in employee numbers in our history, recruiting and hiring more than 1,500 new employees. 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.

We have ramped up manufacturing efforts in both our South San Francisco and Vacaville facilities to meet increased product demand. 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. In addition, we entered into 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. We also made progress on our facility in Porriño, Spain (Genentech España) and now expect to bring it online in 2004 to produce Avastin for clinical trials. All of these projects are critical to providing sufficient capacity to meet expected demand for our products.

Intellectual property protection of our products is also crucial to our business. We are often involved in challenges over contracts and intellectual property and we work to resolve these disputes in confidential negotiations. 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 first quarter of 2004, we saw growth in our operating revenues, net income and earnings per share as compared to the first quarter of 2003. Sales of Avastin, launched on February 26, 2004, were \$38.1 million. Our initial sales data suggests that Avastin use is consistent with its broad label, including use in combination with both oxaliplatin and irinotecan based regimens. Sales of Xolair were \$30.0 million. This is an increase of 63% as compared to the fourth quarter of 2003. This growth reflects good market penetration and high patient compliance. Sales of Raptiva were \$6.3 million. More than 80% of patients being identified for Raptiva therapy have not been previously treated with a biologic and over one-fourth of patients moved to Raptiva therapy after being treated with topical agents only. This is an important indicator that Raptiva is not being reserved for use only in patients failing to respond to systemic or other biologic therapies. Rituxan sales increased 17% from the first quarter of 2003 and decreased 3% from the fourth quarter of 2003. This reflects a slowing of the Rituxan growth rate, inventory adjustments made by wholesalers at the beginning of the year and possible reaction to the Medicare legislation. We believe the opportunities for long-term Rituxan sales growth lie in potential new indications, particularly in immunology, and in the potential for use of Rituxan in the maintenance setting in treating non-Hodgkin's lymphoma. Sales of Herceptin increased 21% from the first quarter of 2003 and decreased 1% from the fourth quarter of 2003. We believe the opportunity for long-term Herceptin sales growth lies in the adjuvant setting. Sales for the growth hormone and Pulmozyme products grew slowly, while sales of thrombolytics declined slightly. Royalties and contract revenues increased due to higher sales by licensees, recognition of product opt-in revenue and reimbursements for on-going

collaborations. Operating expenses increased as a result of increased MG&A and R&D expenses and we expect this trend to continue this year. Cost of sales as a percentage of sales have declined due to higher sales of more favorable margin products, lower royalty expenses and lower production costs.

We, OSI Pharmaceuticals, Inc. and Roche announced on April 25, 2004, that a Phase III study of Tarceva in previously treated patients with non-small cell lung cancer met its primary endpoint of improving overall survival, with patients receiving Tarceva living longer than those in the placebo arm of the study. The trial also met secondary endpoints including improving time to symptomatic deterioration, progression-free survival and response rate. OSI will work with the FDA to complete the filing of the NDA for Tarceva.

Marketed Products

Rituxan

(rituximab) anti-CD20 antibody 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 Inc. (or Biogen Idec), formerly known as IDEC Pharmaceuticals Corporation, one of the predecessor companies, from whom we licensed Rituxan.

Herceptin

(trastuzumab) anti-HER2 antibody is the 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 (or Bristol-Myers), and other drugs, 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.

Nutropin

[somatotropin (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 the first half of 2004 or until inventory is depleted.

Nutropin AQ

[somatotropin (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 (or t-PA) approved for the treatment of acute myocardial infarction (heart attack), acute ischemic stroke (blood clots in the brain) within three hours of the onset of symptoms and acute massive pulmonary embolism (blood clots in the lungs).

Cathflo Activase

(alteplase, recombinant) is a 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. We received FDA approval in June 2003.

Raptiva

(efalizumab) is an anti-CD11a antibody co-developed with XOMA Ltd. It was approved by the FDA in October 2003 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 approved by the FDA on February 26, 2004 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. We began shipping Avastin on February 26, 2004.

Licensed Products

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

- Rituxan, Herceptin and Pulmozyme outside of the United States (or U.S.), and
- growth hormone products, Rituxan, Pulmozyme, Activase, Cathflo Activase and TNKase in Canada.

We receive royalties from third parties on sales of:

- Activase outside of the U.S. and Canada, and
- TNKase outside of the U.S., Canada and Japan.

We also receive worldwide 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.

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 \$20.63 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 accounting principles generally accepted in the United States (or 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 below 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.

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 509,194,352 (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 and October 2000. We repurchased shares of our common stock in 2003 (see discussion in Note 10, "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 also has issued zero-coupon notes (which were offered publicly in January 2000) exchangeable for an aggregate of 13,034,618 shares of our common stock held by Roche. As of March 31, 2004, a total of 9,840,309 shares of our common stock owned by Roche have been issued in exchange for the zero-coupon notes, decreasing Roche's ownership to 55.9%. The Minimum Percentage at March 31, 2004 was 58.3% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be no lower than 56.3%. See Note 10 "Capital Stock" for information regarding our stock repurchase program.

Available Information

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

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and 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 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. 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 March 31, 2004, we have accrued \$621.2 million, which represents our estimate of the costs for the current 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, milestone payments, 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 and post-marketing costs are recognized as revenue as the related costs are incurred.

Income Taxes

Income tax expense (benefit) is based on pretax financial accounting income under the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision (benefit) 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 its impaired 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.

RESULTS OF OPERATIONS

(in millions, except per share amounts)

Edgar Filing: GENENTECH INC - Form 10-Q

	Three Months Ended March 31,		% Change
	2004	2003	
Product sales	\$ 763.7	\$ 598.5	28 %
Royalties	154.1	113.3	36
Contract revenue	57.3	37.9	51
Total operating revenues	975.1	749.7	30
Cost of sales	114.5	114.8	-
Research and development	190.3	157.4	21
Marketing, general and administrative	247.3	137.2	80
Collaboration profit sharing	126.4	96.6	31
Recurring charges related to redemption	38.2	38.6	(1)
Special items: litigation-related	13.4	13.3	1
Total costs and expenses	730.1	557.9	31
Operating margin	245.0	191.8	28
Other income, net	22.3	15.7	42
Income tax provision	90.7	56.0	62
Net income	\$ 176.6	\$ 151.5	17
Operating margin as a % of operating revenues	25 %	26 %	
COS as a % of product sales	15	19	
R&D as a % of operating revenues	20	21	
MG&A as a % of operating revenues	25	18	
NI as a % of operating revenues	18	20	

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

Total Operating Revenues

Total operating revenues increased 30% in the first quarter of 2004 from the comparable period in 2003. This increase was due to higher product sales, royalty income and contract revenues. These increases are further discussed below.

Total Product Sales

Product Sales	Three Months Ended March 31,		% Change
	2004	2003	
Rituxan	\$ 400.6	\$ 341.0	17 %
Herceptin	113.5	93.7	21

Avastin	38.1	-	-
Growth Hormone	85.5	76.7	11
Thrombolytics	46.3	47.5	(3)
Pulmozyme	43.4	39.6	10
Xolair	30.0	-	-
Raptiva	6.3	-	-
Total product sales	<u>\$ 763.7</u>	<u>\$ 598.5</u>	28

Total net product sales increased 28% in the first quarter of 2004 from the comparable period in 2003. The increase was due to higher sales across most of our existing products, in particular Rituxan, and sales of our new products, specifically Avastin, Xolair and Raptiva. Increased volume, including new product shipments, accounted for a 21% sales increase, or \$127.5 million, in the first quarter of 2004. Higher sales prices across the entire product suite accounted for \$37.7 million of the increase in the first quarter of 2004.

Rituxan

Net sales of Rituxan increased 17% to \$400.6 million in the first quarter of 2004 from the comparable period 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 front line indolent NHL, front line CLL, and maintenance use), and to a lesser extent the ongoing impact of a price increase implemented in March 2003. Also contributing to the increase was growth in ex-U.S. sales to our partner Roche.

Although sales were strong for the year over year period, net sales of Rituxan decreased 3% from the prior quarter. This decrease was a result of inventory adjustments made by wholesalers at the beginning of 2004 and also reflected initial caution among some physicians as they adjusted to the new reimbursement methodology under the Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003 (or the Medicare Act). Future sales of Rituxan may be adversely affected if physicians prescribe less of Rituxan in light of the decrease in the Rituxan reimbursement rate under the Medicare Act. However, our February and March 2004 orders and our first quarter adoption data appear to reflect continuing demand for Rituxan, albeit at a slower rate of growth than we have previously seen. Given Rituxan's unique clinical benefits and lack of a direct substitute therapy, we currently believe there will be limited impact on its usage. However, we will continue to monitor the Medicare situation closely.

Herceptin

Net sales of Herceptin increased 21% in the first quarter of 2004 from the comparable period in 2003. The continued growth was primarily driven by physicians' extending the average treatment duration for two reasons. First, physicians have been using Herceptin in more than one line of therapy. Second, there is a growing interest in the combination of Herceptin, carboplatin and a taxane otherwise known as TCH; this particular regimen has an improved time to disease progression and can therefore lead to a longer treatment duration. The adoption rate of this regimen among oncologists has shown growth in the first quarter of 2004 from the comparable period in 2003. Although future sales of Herceptin may be adversely affected if physicians prescribe less Herceptin in light of the decrease in the Herceptin reimbursement rate under the Medicare Act, we currently believe there will be limited impact on Herceptin's usage,

particularly in light of the increase in drug administration services reimbursement rates. Also impacting our future sales growth is a price increase 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 achieved total net sales of \$38.1 million in the five weeks it was available in the first quarter of 2004. Of this, \$13.9 million represents the initial distribution to drug wholesalers. Among all accounts ordering Avastin from drug wholesalers, more than 50% have placed reorders. Future sales and the adoption 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 Depot, Nutropin AQ, Nutropin, and Protropin, increased 11% in the first quarter of 2004 from the comparable period in 2003. The net sales growth resulted from continued strong demand for the Nutropin products and, to a lesser extent, price increases. The price increase on a

number of growth hormone products in October 2003 accounted for a significant portion of the growth in the first quarter of 2004 as compared to the first quarter of 2003. The continued strong demand reflects our focus on new patient starts using our Nutropin AQ Pen (which is a delivery system for Nutropin AQ), continued growth in the adult patient market, higher dosing during puberty and an incremental increase in the length of therapy. Nutropin Depot is a long-acting dosage form of recombinant growth hormone approved for pediatric growth hormone deficiency. Positive data results from our Nutropin Depot study in patients with adult growth hormone deficiency will be presented at a medical meeting in June 2004. 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.

Thrombolytics

Combined net sales of our three thrombolytic products, Activase, TNKase and Cathflo Activase, decreased 3% in the first quarter of 2004 from the comparable period in 2003. Sales were impacted by continued competition from Centocor, Inc.'s Retavase® (reteplase) and adoption of mechanical reperfusion strategies to treat acute myocardial infarction. A price increase in February 2004 on certain thrombolytic products and higher sales of Cathflo Activase for catheter clearance partially offset the decline in overall sales volume.

However, competition and declines in the acute myocardial infarction market are expected to be offset by growth in the area of catheter clearance.

Pulmozyme

Net sales of Pulmozyme increased 10% in the first quarter of 2004 from the comparable period in 2003. This increase primarily reflects an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and, to a lesser extent, a price increase in August 2003.

Xolair

We received FDA approval to market Xolair in June 2003 and began shipping Xolair in July 2003. Xolair achieved total net sales of \$30.0 million in the first quarter of 2004, reflecting continued acceptance of the product and positive physician adoption rates. Future sales and related expenses are subject to risks and uncertainties, including continued physician adoption rates, third-party payer reimbursement and coverage decisions.

Raptiva

We received FDA approval to market Raptiva in October 2003 and began shipping Raptiva in November 2003. Raptiva achieved total net sales of \$6.3 million in the first quarter of 2004, reflecting continued acceptance of the product and effective reimbursement processing. Future sales and the continued acceptance of this biologics class are subject to risks and uncertainties, including how well Raptiva is able to compete with other new and established therapies for moderate-to-severe psoriasis.

Royalties

Royalty income increased 36% in the first quarter of 2004 from the comparable period in 2003. The increase was due to higher third-party sales by various licensees, primarily Hoffmann-La Roche (see "Related Party Transactions" below) for higher sales of Herceptin and Rituxan products, and to higher sales by various licensees for other products. We expect that in 2004 the increase in royalty income will be at a slower rate than 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 term of these options is 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 increased 51% in the first quarter of 2004 from the comparable period in 2003. The increase was primarily driven by revenues from our collaborators for amounts earned on development efforts related to Avastin, Rituxan and Lucentis. See "Related Party Transactions" below for more information on contract revenue from Hoffmann-La Roche and Novartis.

We expect that contract revenues will increase in 2004, but at a more modest pace than in 2003. We also expect contract revenues to fluctuate 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 was 15% and 19% in the first quarters of 2004 and 2003, respectively. This decrease primarily reflects higher sales of more favorable margin products (primarily sales of Rituxan and Herceptin, and to a lesser extent, sales of previously reserved products), lower royalty expenses and lower production costs due to manufacturing efficiencies primarily related to Herceptin. We do not expect this trend to continue and as such, our COS as a percentage of sales for the full year 2004 is expected to be higher than our first quarter of 2004 rate of 15%.

We entered into an arrangement with Lonza Biologics, a subsidiary of Lonza Group Ltd, to provide additional manufacturing capacity for Rituxan. We do not expect this arrangement to have a significant impact on our overall cost of sales as a percentage of product sales.

Research and Development

R&D expenses increased 21% in the first quarter of 2004 from the comparable period in 2003. This increase was largely due to higher spending on clinical development of products, including Lucentis, Rituxan and Omnitarg, partially offset by lower spending on Raptiva; increased post-marketing clinical studies for Raptiva, Avastin and Rituxan; and increased headcount and related expenses in support of research activities. We expect increases in R&D expenses over time to be driven mainly by the development of our pipeline products. 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 for the quarters ended March 31, 2004 and 2003 were as follows (*in millions*):

Research and Development	Three Months Ended March 31,		% Change
	2004	2003	
Product development	\$ 112.3	\$ 101.8	10 %
Post-marketing studies	28.3	15.6	81
Total development	140.6	117.4	20
Research	43.4	34.3	27
In-licensing	6.3	5.7	11
Total	\$ 190.3	\$ 157.4	21

Marketing, General and Administrative

Overall marketing, general and administrative (or MG&A) expenses increased 80% in the first quarter of 2004 from the comparable period in 2003. This increase was due to: (i) a \$44.4 million increase in marketing and promotional programs and headcount growth in support of commercial and pipeline products, primarily Avastin, Raptiva, Xolair and Herceptin; (ii) a \$21.0 million increase related to headcount growth and increased commercial training programs

in support of all products, including increases in field sales incentive compensation; (iii) a \$27.1 million increase in the corporate bonus program and corporate functional expenses (primarily related to an increase in information systems technologies), and (iv) a \$17.6 million increase in royalty expenses, primarily related to Biogen Idec.

MG&A expenses could trend higher in the near term as we continue to launch Avastin. However, as we expect revenues to rise, MG&A as a percentage of operating revenues will likely decline over the longer term.

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 31% in the first quarter of 2004 from the comparable period in 2003. This increase was driven by increased Rituxan profit sharing with Biogen Idec due to higher Rituxan sales and increased Xolair profit sharing with Novartis due to higher Xolair sales.

Collaboration profit sharing expense is expected 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 first quarters of 2004 and 2003 were \$38.2 million and \$38.6 million, respectively, and were comprised of the amortization of other intangible assets in all periods presented.

Special Items: Litigation-Related

We recorded charges of \$13.4 million and \$13.3 million in the first quarters of 2004 and 2003, respectively, for accrued interest and associated bond costs related to the 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). We expect that we will continue to incur interest charges on the COH trial judgment and service fees on a related \$600.0 million surety bond each quarter through the process of appealing the COH trial results. 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 March 31, 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. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

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	Three Months Ended March 31,		
	2004	2003	% Change
<i>(in millions)</i>			
Gains on sales of biotechnology equity securities and other	\$ 0.7	\$ 0.5	40 %
Write-downs of biotechnology debt and equity securities	-	(3.7)	(100)
Interest income	23.0	18.9	22
Interest expense	(1.4)	-	-
Total other income, net	\$ 22.3	\$ 15.7	42

Page 30

"Other income, net" increased 42% in the first quarter of 2004 from the comparable period in 2003, primarily due to higher interest income, as a result of higher average cash balances, and no write-downs of our biotechnology securities due to overall improved market conditions. Although we have had no biotechnology marketable equity securities write-downs to-date in 2004, we 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

Our effective tax rate was 34% in the first quarter of 2004 compared to 27% in the first quarter of 2003. The increase in the tax rate reflects a decrease in benefits related to changes in estimates of prior year items. The tax provision for the first quarter of 2004 included a benefit of \$6.5 million related to a favorable change in estimates of research credits.

We anticipate that our effective tax rate for the entire year 2004 will be higher than that for the first quarter of 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

Net Income and Earnings Per Share	Three Months Ended March 31,		
	2004	2003	% Change
<i>(in millions)</i>			
Net income	\$ 176.6	\$ 151.5	17 %

Earnings per share:

Basic	0.33	0.30	10
Diluted	0.33	0.29	14

Net income and diluted earnings per share in the first quarter of 2004 increased from the comparable period 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.

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 \$190.0 million, 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. We began shipping Avastin on February 26, 2004.

Our Overview and Results of Operations contain forward-looking statements regarding the number of products in late-stage development, timeframe of Avastin manufacturing in Porrino, costs for completion of in-process projects, expected amount of capital expenditures, the impact of Medicare legislation on our sales of Rituxan and Herceptin, increases in sales of Rituxan and Xolair, and increases in royalty income, contract revenues and total revenues and our growth in non-GAAP EPS through 2005. Actual results could differ materially. For a discussion of the risks and uncertainties associated with late-stage development, timeframe for manufacturing in Porrino, costs for completion of in-process projects and 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 sales of Rituxan and Xolair, 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 higher revenues, see all of the foregoing and for non-GAAP EPS growth, see all of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below. The Company disclaims any obligation and does 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>	March 31, 2004	December 31, 2003
Cash, cash equivalents, short-term investments and long-term marketable securities	\$ 3,292.8	\$ 2,934.7
Working capital	2,262.7	1,883.8

We used cash generated from operations, income from investments and proceeds from stock issuances to fund operations, purchase marketable securities, and invest in capital and equity instruments during the first quarters of both 2004 and 2003. During the first quarter of 2003, we also used cash to repurchase stock. See Note 10, "Capital Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for a discussion of our stock repurchase program.

Cash flows from operations can vary significantly due to various factors including changes in accounts receivable and deferred revenues related to large opt-in payments and new arrangements with collaborators. The average collection period of our accounts receivable as measured in days sales outstanding (or DSO) can vary and is dependent on various factors including, whether the related revenue was recorded in the beginning or at the end of a period, the type of revenue and the payment terms related to those revenues.

Capital expenditures of \$97.7 million in the first quarter of 2004 increased from \$73.5 million in the comparable period of 2003 primarily due to higher spending in 2004 for the purchase of land and office buildings in South San Francisco, including the repayment of one of our synthetic leases. In 2004, we expect to spend approximately \$800.0 million on property, plant and equipment. The increase over 2003 will primarily support our expected future manufacturing capacity needs, increases in property, equipment and information systems related purchases, and provide for synthetic lease repayments.

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. 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" section below 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. Three of our operating leases are commonly referred to as "synthetic leases." Under Interpretation No. 46R (or FIN 46R), each synthetic 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.

The most significant 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. See above in the "Critical Accounting Policies -- Changes in Accounting Principles" section for further information on our adoption of FIN 46R.

Our two remaining leases were entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us various buildings that we occupy in South San Francisco, California. Under certain of these leases, we are required to maintain cash collateral of \$56.6 million, which we have included in our condensed consolidated balance sheets as restricted cash and other long-term assets. We have evaluated our accounting for these leases under the provisions of FIN 46R, and we determined that, as of July 1, 2003 and through March 31, 2004, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP leases.

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 1	56.6	07/2004	48.1
South San Francisco lease 2	160.0	06/2007	136.0
Total	<u>\$ 641.6</u>		<u>\$ 555.9</u>

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 indemnifications 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. In the case of South San Francisco lease 1, we have pledged cash collateral of \$56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

Contractual Obligations

During the first quarter of 2004, there were no significant changes in our reported payments due under contractual obligations at December 31, 2003.

CONTINGENCIES

We have an agreement with Serono S.A.; our agreement, in addition to granting marketing rights to Serono in specific areas of the world, includes an arrangement to collaborate on co-developing additional indications of Raptiva and to share certain global development costs. We also have a supply agreement with Serono, under which we may have a loss exposure up to a maximum of \$10.0 million.

We are a party to various legal proceedings, including patent infringement litigation relating to our antibody products, 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, in the ordinary course of business. The accounting policies we apply to our transactions with our related parties are consistent with those used in transactions with independent third-parties.

Roche Holdings, Inc. (or Roche)

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 its existing licensing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 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 PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. (other than territory previously licensed to others) under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of subsequent global development costs related to PRO70769 unless Roche opts out of the development of certain other indications. We will receive royalties on net sales of Avastin and PRO70769 in countries outside of the U.S.

As part of our licensing and marketing agreement, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$25.8 million and \$2.0 million in the first quarters of 2004 and 2003, respectively. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$98.9 million and \$76.3 million in the first quarters of 2004 and 2003, respectively. In 2003, Hoffmann-La Roche's Penzberg, Germany facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Our ex-U.S. sales of Herceptin to Hoffmann-La Roche were \$4.8 million in the first quarter of 2004. We had no such sales in the first quarter of 2003. Cost of sales included amounts related to Roche of \$22.4 million and \$24.8 million in the first quarters of 2004 and 2003, respectively. R&D expenses included amounts related to Roche of \$36.8 million and \$8.4 million in the first quarters of 2004 and 2003, respectively.

Novartis AG (or 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 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 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. Novartis plans to assume primary manufacturing responsibilities in the future.

Contract revenue from Novartis was \$10.8 million in the first quarter of 2004 and not material in the first quarter of 2003. Collaboration profit sharing expenses were \$11.8 million in the first quarter of 2004 and not material in the first quarter of 2003. R&D expenses included amounts related to Novartis of \$9.7 million in the first quarter of 2004 and \$3.7 million in the first quarter of 2003.

STOCK OPTIONS

Option Program Description

Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our program primarily consists of our amended and restated 1999 Stock Plan (the "Plan"), a broad-based plan under which stock options are granted to employees, directors and other service providers. Substantially all of our employees participate in our stock option program. In the past, we granted options under our amended and restated 1996 Stock Option/Stock Incentive Plan, our amended and restated 1994 Stock Option Plan and our amended and restated 1990 Stock Option/Stock Incentive Plan.

Page 35

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. See "The Compensation Committee Report" appearing in our 2004 Proxy Statement on file with the Securities and Exchange Commission for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

General Option Information

Summary of Option Activity

(Shares in thousands)

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
December 31, 2002	4,049	55,419	\$ 38.37
Grants	(10,890)	10,890	81.09
Exercises	-	(16,039)	68.27
Cancellations ⁽¹⁾	2,207	(2,207)	47.59

Edgar Filing: GENENTECH INC - Form 10-Q

Additional shares reserved	25,000	-	-
December 31, 2003	20,366	48,063	50.36
Grants	(251)	251	99.23
Exercises	-	(5,634)	39.45
Cancellations ⁽¹⁾	196	(196)	49.53
March 31, 2004 (Year to date)	20,311	42,484	52.10

(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.

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

(Shares in thousands)

As of March 31, 2004	Exercisable		Unexercisable		Total	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
In-the-Money	20,037	\$ 44.11	22,401	\$ 59.12	42,438	\$ 52.03
Out-of-the-Money ⁽¹⁾	-	-	46	113.27	46	113.27
Total Options Outstanding	20,037		22,447		42,484	

(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, \$105.82, at the close of business on March 31, 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	0.01 %	1.68 %	1.98 %
Grants to Named Executive Officers* during the period as % of outstanding shares	0.00 %	0.18 %	0.25 %

Grants to Named Executive Officers during the year	0.00 %		
as % of total options granted		8.57 %	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 or scaling the manufacturing process.
- 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 NDA) 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.

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 of available product inventory. A number of factors could cause 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 the Company 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 and damage our reputation.

We may also experience insufficient available capacity to manufacture or have manufactured for us existing or new products which 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.

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. In addition, 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.

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 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 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 institutions and key distributors. Competition for these types of personnel and relationships is intense.

Page 40

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. As a result of that competition, we have experienced a loss in market share in the past. Competitors have also received approval to market their existing growth hormone products for additional indications. As a result of this competition, market share of our growth hormone products may decline. 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 biologic therapy Amevive® (alefacept), approved by the FDA in January 2003 for the treatment of moderate-to-severe psoriasis. Raptiva also competes with drugs approved for other indications that are used in psoriasis. Additional biologic therapies are expected to enter the psoriasis market in the next several years. ENBREL® (etanercept), marketed by Amgen and Wyeth in the U.S., is already approved for psoriatic arthritis, a condition associated with psoriasis. On April 30, 2004, Amgen announced that the FDA had approved ENBREL® for the treatment of adult patients with chronic moderate-to-severe plaque 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.

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 and use of our products for approved indications and additional indications. Among other things, the rate of adoption 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 these programs, 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 on December 5, 2003, Genentech is authorized to repurchase up to 12,500,000 shares of our common stock for an aggregate price of up to \$1 billion of its common stock through December 31, 2004. A total of 70,900 shares at a cost of approximately \$6.1 million has been purchased under the plan through December 31, 2003 and we had no repurchases in the first quarter of 2004.

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. See also item below regarding our affiliation agreement with Roche.

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 10, "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 March 31, 2004, Roche owned 296,754,043 shares of our common stock or 55.9% 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 10, "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 \$3,495.5 million or 38% of total assets at March 31, 2004. Interest income related to this portfolio was \$23.0 million in the first quarter 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 \$483.9 million or 5% of total assets at March 31, 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

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, there are a number of rule changes and proposed legislative initiatives following the recent corporate bankruptcies and failures which could result in changes in accounting rules, including the accounting for employee stock options as an expense. On March 31, 2004, the FASB issued an Exposure Draft (ED), "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95." The proposed Statement 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 Statement 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 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. As proposed, the new rules would be applied on a modified prospective basis as defined in the ED, and would be effective for public companies for fiscal years beginning after December 15, 2004. We are currently evaluating our option valuation methodologies and assumptions in light of these evolving accounting standards related to employee stock options. These and other potential changes could materially impact our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at March 31, 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

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

In the arbitration proceeding between Genentech and Tanox, Genentech, Novartis Pharma AG and Tanox, Inc. announced on February 26, 2004 that they settled all litigation among them and finalized the detailed terms of their three-party collaboration, begun in 1996, to develop and commercialize certain anti-IgE antibodies, including Xolair and TNX-901.

Genentech announced on April 6, 2004 that the U.S. Court of Appeals for the Federal Circuit unanimously affirmed the 2002 judgment of the U.S. District Court that found in favor of Genentech that all claims of Chiron Corporation's U.S. Patent No. 6,054,561 asserted against Genentech are invalid. Chiron sued Genentech for alleged infringement of its patent by Genentech's metastatic breast cancer drug, Herceptin. 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 has not yet given its decision on the Petition.

MedImmune filed a notice of appeal of the U.S. District Court's summary judgment in Genentech's favor on all of MedImmune's antitrust and unfair competition claims relating to U.S. Patent No. 6,331,415 that is co-owned by Genentech and City of Hope National Medical Center. 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. The appeal process is ongoing.

See also Item 3 of our report on Form 10-K for the period ended December 31, 2003.

See also Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I.

Item 6. Exhibits and Reports on Form 8-K

(a)	Exhibits		
	(i)	10.18	2004 Equity Incentive Plan.
	(ii)	15.1	Letter regarding Unaudited Interim Financial Information.
	(iii)	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.
	(iv)	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.

(v) 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.

(b) Reports on Form 8-K.

On January 14, 2004, we filed a Report on Form 8-K under Item 5 - Other Events, reporting the issuance of a press release, announcing our earnings for the year ended December 31, 2003.

Page 50

SIGNATURES

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

GENENTECH, INC.

Date: May 3, 2004

/s/ARTHUR D. LEVINSON

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

Date: May 3, 2004

/s/LOUIS J. LAVIGNE, JR.

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

Date: May 3, 2004

/s/JOHN M. WHITING

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

