

Edgar Filing: GENENTECH INC - Form 10-Q

GENENTECH INC  
Form 10-Q  
May 01, 2001

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

(Mark One)

X Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. For the quarterly period ended March 31, 2001.

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 (I.R.S. employer  
incorporation or organization) identification number)

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

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

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

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

Class	Number of Shares Outstanding
-----	-----
Common Stock \$0.02 par value	526,397,367 Outstanding at March 31, 2001

# Edgar Filing: GENENTECH INC - Form 10-Q

## GENENTECH, INC. INDEX

PART I.	FINANCIAL INFORMATION	PAGE NO.
	Condensed Consolidated Statements of Operations - for the three months ended March 31, 2001 and 2000	3
	Condensed Consolidated Statements of Cash Flows - for the three months ended March 31, 2001 and 2000	4
	Condensed Consolidated Balance Sheets - March 31, 2001 and December 31, 2000	5
	Notes to Condensed Consolidated Financial Statements	6-13
	Independent Accountants' Review Report	14
	Financial Review	15-35
	Quantitative and Qualitative Disclosures About Market Risk	36
PART II.	OTHER INFORMATION	37
	SIGNATURES	39

In this report, "Genentech," "we," "us" and "our" refer to Genentech, Inc. "Common Stock" refers to Genentech's common stock, par value \$0.02 per share, "Special Common Stock" refers to Genentech's callable puttable common stock, par value \$0.02 per share. All numbers related to the number of shares, price per share and per share amounts of Common Stock and Special Common Stock give effect to the two-for-one split of our Common Stock that was effected in October 2000.

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Actimmune, registered trademark, interferon gamma-1b; Activase, registered trademark, (Alteplase, recombinant) tissue-plasminogen activator; Herceptin, registered trademark, (Trastuzumab) anti-HER2 antibody; Nutropin, registered trademark, (somatropin (rDNA origin) for injection) growth hormone; Nutropin AQ, registered trademark, (somatropin (rDNA origin) injection) liquid formulation growth hormone; Nutropin Depot, trademark, (somatropin (rDNA origin) for injectable suspension) encapsulated sustained-release growth hormone; Protropin, registered trademark, (somatrem for injection) growth hormone; Pulmozyme, registered trademark, (dornase alfa, recombinant) inhalation solution; TNKase, trademark, (Tenecteplase) single-bolus thrombolytic agent; Xolair, trademark, (Omalizumab) anti-IgE antibody; Xanelim, trademark, (Efalizumab) anti-CD11a antibody. Rituxan, registered trademark, (Rituximab) antibody is a registered trademark of IDEC Pharmaceuticals Corporation. This report also includes trademarks, service marks and trade names of other companies.

## PART I. FINANCIAL INFORMATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended March 31,	
	2001	2000
		(Restated)
<b>Revenues:</b>		
Product sales (including amounts from related parties: 2001-\$22,037; 2000-\$24,127)	\$ 391,904	\$ 283,178
Royalties (including amounts from related parties: 2001-\$23,619; 2000-\$10,805)	74,631	47,344
Contract and other (including amounts from related parties: 2001-\$2,199; 2000-\$500)	38,483	35,854
Interest	35,064	21,474
	540,082	387,850
<b>Costs and expenses:</b>		
Cost of sales (including amounts from related parties: 2001-\$18,506; 2000-\$19,890)	83,796	106,135
Research and development (including contract related: 2001-\$2,948; 2000-\$4,557)	136,340	111,406
Marketing, general and administrative	127,920	83,613
Collaboration profit sharing	46,373	18,333
Recurring charges related to redemption	81,516	98,548
Interest	1,491	1,287
	477,436	419,322
Income (loss) before taxes and cumulative effect of accounting change	62,646	(31,472)
Income tax provision (benefit)	30,258	(6,862)
	32,388	(24,610)
Income (loss) before cumulative effect of accounting change	32,388	(24,610)
Cumulative effect of accounting change, net of tax	(5,638)	(57,800)
	26,750	(82,410)
Net income (loss)	\$ 26,750	\$ (82,410)
	=====	=====
<b>Earnings (loss) per share:</b>		
Basic: Earnings (loss) before cumulative effect of accounting change	\$ 0.06	\$ (0.05)
Cumulative effect of accounting change, net of tax	(0.01)	(0.11)

Edgar Filing: GENENTECH INC - Form 10-Q

Net earnings (loss) per share	\$ 0.05	\$ (0.16)
	=====	=====
Diluted: Earnings (loss) before cumulative effect of accounting change	\$ 0.06	\$ (0.05)
Cumulative effect of accounting change, net of tax	(0.01)	(0.11)
	-----	-----
Net earnings (loss) per share	\$ 0.05	\$ (0.16)
	=====	=====
Weighted average shares used to compute earnings (loss) per share:		
Basic	525,795	519,131
	=====	=====
Diluted	535,209	519,131
	=====	=====

See Notes to Condensed Consolidated Financial Statements.

Page 3

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(thousands)  
(unaudited)

	Three Months Ended March 31,	
	2001	2000
	-----	-----
		(Restated)
Cash flows from operating activities:		
Net income (loss)	\$ 26,750	\$ (82,410)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	105,954	118,595
Deferred income taxes	34,526	(85,409)
Gain on sales of securities available-for-sale	(22,245)	(26,572)
Loss on sales of securities available-for-sale	909	2,502
Write-down of securities available-for-sale	19,850	-
Loss on fixed asset dispositions	747	-
Changes in assets and liabilities:		
Investments in trading securities	(69,631)	(3,656)
Receivables and other current assets	(10,546)	1,477
Inventories, including inventory write-up effect in 2000	(28,789)	20,324
Accounts payable, other current liabilities and other long-term liabilities	(25,484)	(60,298)
	-----	-----
Net cash provided by (used in) operating activities	32,041	(115,447)
Cash flows from investing activities:		

Edgar Filing: GENENTECH INC - Form 10-Q

Purchases of securities available-for-sale	(270,086)	(98,152)
Proceeds from sales of securities available-for-sale	277,157	146,224
Purchases of non-marketable equity securities	(5,550)	(1,450)
Capital expenditures	(36,324)	(28,243)
Change in other assets	(2,038)	(5,214)
	-----	-----
Net cash (used in) provided by investing activities	(36,841)	13,165
Cash flows from financing activities:		
Stock issuances	35,355	71,589
	-----	-----
Net cash provided by financing activities	35,355	71,589
	-----	-----
Net increase (decrease) in cash and cash equivalents	30,555	(30,693)
Cash and cash equivalents at beginning of period	551,384	337,682
	-----	-----
Cash and cash equivalents at end of period	\$ 581,939	\$ 306,989
	=====	=====

See Notes to Condensed Consolidated Financial Statements.

Page 4

CONDENSED CONSOLIDATED BALANCE SHEETS  
(thousands)

	March 31, 2001 (unaudited)	December 31, 2000 (1)
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 581,939	\$ 551,384
Short-term investments	750,134	642,475
Accounts receivable, net (including amounts from related party: 2001-\$31,996; 2000-\$36,299)	269,570	261,682
Inventories	294,620	265,830
Deferred tax assets	51,021	40,619
Prepaid expenses and other current assets	35,815	26,821
	-----	-----
Total current assets	1,983,099	1,788,811
Long-term marketable securities	974,873	1,265,515
Property, plant and equipment (net of accumulated depreciation: 2001-\$627,512; 2000-\$604,332)	765,176	752,892
Goodwill (net of accumulated amortization: 2001-\$881,815; 2000-\$843,494)	1,417,457	1,455,778
Other intangible assets (net of accumulated amortization: 2001-\$1,326,165; 2000-\$1,282,090)	1,239,335	1,280,359
Other long-term assets	220,415	168,458

Edgar Filing: GENENTECH INC - Form 10-Q

Total assets	----- \$ 6,600,355 =====	----- \$ 6,711,813 =====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 149,692	\$ -
Accounts payable	24,321	34,503
Other accrued liabilities (including amounts from related party: 2001-\$17,358; 2000-\$12,265)	374,304	414,178
	-----	-----
Total current liabilities	548,317	448,681
Long-term debt	-	149,692
Deferred tax liabilities	285,661	349,848
Other long-term liabilities	90,535	89,389
	-----	-----
Total liabilities	924,513	1,037,610
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	10,528	10,510
Additional paid-in capital	6,686,765	6,651,428
Accumulated deficit, since June 30, 1999	(1,292,603)	(1,319,353)
Accumulated other comprehensive income	271,152	331,618
	-----	-----
Total stockholders' equity	5,675,842	5,674,203
	-----	-----
Total liabilities and stockholders' equity	\$ 6,600,355 =====	\$ 6,711,813 =====

(1) Amounts obtained from audited financial statements.

See Notes to Condensed Consolidated Financial Statements.

Page 5

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)

Note 1. Statement of Accounting Presentation and Significant Accounting Policies

Basis of Presentation

In the opinion of management, the accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of

## Edgar Filing: GENENTECH INC - Form 10-Q

management, all adjustments (consisting only of adjustments of a normal recurring nature) considered necessary for a fair presentation have been included. Operating results for the three-month periods ended March 31, 2001 and 2000 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. The condensed consolidated balance sheet as of December 31, 2000 has been derived from the audited financial statements as of that date. For further information, refer to the consolidated financial statements and notes thereto included in our Annual Report to Stockholders on Form 10-K for the year ended December 31, 2000.

**Collaboration Profit Sharing:** Collaboration profit sharing includes the net operating profit sharing with IDEC Pharmaceuticals Corporation on Rituxan sales, and the sharing of costs with collaborators related to commercialization and development of future products.

**Use of Estimates:** The preparation of financial statements in conformity with generally accepted accounting principles 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.

**Reclassification:** Certain reclassifications of prior year amounts have been made to conform with the current year presentation.

### Changes in Accounting Principle

**Securities and Exchange Commission's Staff Accounting Bulletin No. 101:** We adopted the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, in the fourth quarter of 2000, effective January 1, 2000, and recorded a \$57.8 million charge, net of tax, as a cumulative effect of the change in accounting principle. The cumulative effect was initially recorded as deferred revenue that will be recognized as revenue over the remaining term of the research and development collaboration or distribution agreements, as appropriate. The results for the first quarter of 2000 were restated to reflect the effects of the accounting change. For the quarter ended March 31, 2000, the impact of the change in accounting principle was to increase net loss by \$56.5 million, or \$0.11 per share, comprised of the \$57.8 million cumulative effect of the change (net of tax impact) as described above (\$0.11 per share), net of \$1.3 million of the related deferred revenue (net of tax) that was recognized as revenue during the

Page 6

quarter ended March 31, 2000 (\$0.0 per share). For the quarter ended March 31, 2001, we recognized \$2.3 million (net of tax impact) of the related deferred revenue.

**Statement of Financial Accounting Standards No. 133 (FAS 133):** In June 1998, the Financial Accounting Standards Board issued Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities." FAS 133 requires us to recognize all derivatives on the balance sheet at fair value. Derivatives that are not hedges must be adjusted to fair value through income. If the derivative is a hedge, depending on the nature of the hedge, changes in the fair value of derivatives are either offset against the change in fair value of assets, liabilities, or firm commitments through earnings or recognized in other comprehensive income until the hedged item is recognized in earnings. The ineffective portion of a derivative's change in fair value

## Edgar Filing: GENENTECH INC - Form 10-Q

will be immediately recognized in earnings. The adoption of FAS 133 on January 1, 2001 resulted in a \$5.6 million charge, net of tax, (\$0.01 per share) as a cumulative effect of an accounting change in the statement of operations and an increase of \$8.4 million in other comprehensive income.

### Derivative and Hedging Activities

**Accounting Policy for Derivative Instruments:** We use derivatives to partially offset our market exposure to foreign currencies, U.S. interest rates and marketable equity investments. We record all derivatives on the balance sheet at fair value. For derivative instruments that are designated and qualify as fair value hedge (i.e., hedging the exposure to changes in the fair value of an asset or a liability or an identified portion thereof that is attributable to a particular risk), the gain or loss on the derivative instrument as well as the offsetting loss or gain on the hedged item attributable to the hedged risk are recognized in current earnings during the period of the change in fair values. For derivative instruments that are designated and qualify as a cash flow hedge (i.e., hedging the exposure to variability in expected future cash flows that is attributable to a particular risk), the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. The remaining gain or loss on the derivative instrument in excess of the cumulative change in the present value of future cash flows of the hedged item, if any, is recognized in current earnings during the period of change. For derivative instruments not designated as hedging instruments, the gain or loss is recognized in current earnings during the period of change.

**Fair Value Hedging Strategy:** Our marketable equity securities portfolio consists primarily of investments in biotechnology companies whose risk of market fluctuations is greater than the stock market in general. To manage a portion of this risk, we enter into derivative instruments such as costless collar instruments and forward contracts to hedge equity securities against changes in market value. As of March 31, 2001, all collars have matured and have been settled.

During the quarter ended March 31, 2001, we recognized a net gain of \$10.0 million related to the change in the time value of certain hedging instruments. All gains are recorded in contract and other revenues and losses are recorded in marketing, general and administrative expenses in the statement of operations.

**Cash Flow Hedging Strategy:** To protect against currency exchange risks on forecasted foreign currency cash flows from royalties to be received from licensees' international product sales over the next one to three years and expenses related to our foreign facility and our collaboration development expenses denominated in foreign currencies, we have instituted a foreign currency cash flow hedging program. We hedge portions of our forecasted foreign currency revenues with option contracts and we hedge our foreign currency expenses from our foreign facility with forward contracts. When the dollar strengthens significantly against the foreign currencies, the decline in value of future foreign currency revenues or expenses is offset by gains or losses, respectively, in the value of the option or forward contracts



## Edgar Filing: GENENTECH INC - Form 10-Q

designated as hedges. Conversely, when the dollar weakens, the increase in the value of future foreign currency expenses is offset by gains in the value of the forward contracts. In accordance with FAS 133, hedges related to anticipated transactions are designated and documented at hedge inception as cash flow hedges and evaluated for hedge effectiveness at least quarterly.

We enter into interest-rate swap agreements to limit our exposure to fluctuations in U.S. interest rates. Our material interest bearing assets, or interest bearing portfolio, consisted of cash equivalents, restricted cash, short-term investments, convertible preferred stock investments, convertible loans and long-term investments. Our interest-rate swap agreements effectively convert a portion of our short-term investments in our interest bearing portfolio to a fixed-rate basis for the next three years, thus reducing the impact of interest-rate changes on future interest income. Our interest rate swaps meet the criteria for accounting under the short-cut method defined in FAS 133 for cash flow hedges. Interest income from approximately \$200.0 million of our interest bearing portfolio was designated as the hedged item to interest-rate swap agreements at March 31, 2001.

During the quarter ended March 31, 2001, the ineffective portion of our hedging instruments was not material. Gains and losses related to option and forward contracts that hedge future cash flows are recorded against the hedged revenues or expenses in the statement of operations. Gains and losses related to early termination of interest rate swaps are included in interest income in the statement of operations.

At March 31, 2001, we expect to reclassify \$3.3 million of net gains on derivative instruments from accumulated other comprehensive income to earnings during the next twelve months due to the receipt of net revenues denominated in foreign currencies and the receipt of variable interest associated with floating rate investments.

### Derivative Activity in Accumulated Other Comprehensive Income

The following table summarizes activity in other comprehensive income related to derivatives held by us during the period from January 1, 2001 through March 31, 2001 (in thousands):

Cumulative effect of adopting FAS 133	\$ 8,367
Changes in fair value of derivatives	6,148
Gains reclassified from other comprehensive income	(1,402)
	-----
Accumulated derivative gains	\$13,113
	=====

### Note 2. 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., commonly known as Roche, with funds deposited by Roche for that purpose. This event, referred to as the "Redemption," caused Roche to own 100% on that date. The Redemption was reflected as a purchase of a business which under U.S.

## Edgar Filing: GENENTECH INC - Form 10-Q

generally accepted accounting principles required push-down accounting 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. In 1990 and 1991 through 1997 Roche purchased 60% and 5%, respectively, of the outstanding stock of Genentech.

### Push-Down Accounting Adjustments

The following is a description of accounting adjustments that reflect push-down accounting in our financial statements. These adjustments were based on management's estimates of the value of the tangible and intangible assets acquired:

- The estimated useful life of an inventory adjustment to fair value resulting from the Redemption was approximately one year based upon the expected time to sell inventories on hand at June 30, 1999. Those inventories have been sold as of December 31, 2000. We recorded expense of \$43.2 million in cost of sales in the first quarter of 2000 related to the inventory adjustment. The entire inventory adjustment related to Roche's 1990 through 1997 purchases was reflected as an adjustment to paid-in capital.
- We recorded \$1,091.2 million of goodwill less accumulated amortization of \$613.6 million through June 30, 1999, as a result of Roche's 1990 through 1997 purchases. The accumulated amortization was recorded as an adjustment to additional paid-in capital at June 30, 1999. We also recorded \$1,208.1 million of goodwill as a result of the Redemption.
- We recorded \$1,040.0 million of other intangible assets less accumulated amortization of \$911.5 million through June 30, 1999, as a result of Roche's 1990 through 1997 purchases. The accumulated amortization was recorded as an adjustment to additional paid-in capital at June 30, 1999. We also recorded \$1,370.5 million of other intangible assets as a result of the Redemption.
- We recorded amortization expense related to goodwill and other intangible assets of \$79.4 million during the first quarter of 2001 and \$95.3 million during the first quarter of 2000.
- In connection with the Redemption, options under the 1996 Stock Option/Stock Incentive Plan, or the Plan, were cancelled. Alternative arrangements were provided for certain holders of some of the unvested options under the Plan. We recorded compensation expense related to these alternative arrangements of \$2.1 million in the first quarter of 2001 and \$3.3 million in the first quarter of 2000.

### Note 3. Relationship with Roche

Roche's Right 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

## Edgar Filing: GENENTECH INC - Form 10-Q

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 October 2000 and November 1999. 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's percentage ownership of our common stock was 58.24% at March 31, 2001.

#### Note 4. Comprehensive Income

Comprehensive income is comprised of net income and other comprehensive income. Other comprehensive income includes certain changes in stockholders' equity that are excluded from net income. Other comprehensive income includes changes in fair value of derivatives designated as and effective as cash flow hedges, and unrealized gains and losses on our available-for-sale securities. Comprehensive income (loss) and its components for the quarter ended March 31, 2001 and 2000 are as follows (in thousands):

	Three Months Ended March 31,	
	2001	2000
	(Restated)	
Net income (loss)	\$ 26,750	\$(82,410)
Changes in unrealized (loss) gain on securities available-for-sale, net of tax	(68,334)	36,756
Changes in fair value of derivative instruments, net of tax of \$5,245	7,868	-
Comprehensive loss	\$ (33,716)	\$(45,654)

## Edgar Filing: GENENTECH INC - Form 10-Q

### Note 5. Earnings (Loss) Per Share

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share (EPS) computations for the quarters ended March 31, 2001 and 2000 (in thousands).

	Three Months Ended March 31,	
	2001	2000
		(Restated)
<b>Numerator:</b>		
Net income (loss) - numerator for basic and diluted earnings (loss) per share:	\$ 26,750	\$(82,410)
<b>Denominator:</b>		
Denominator for basic earnings (loss) per share - weighted-average shares	525,795	519,131
Effect of dilutive securities:		
Stock options	9,414	-
Denominator for diluted earnings (loss) per share - adjusted weighted-average shares and assumed conversions	535,209	519,131

Options to purchase 9,828,383 shares of common stock between \$56.50 per share and \$95.66 per share were outstanding in the three-month period ended March 31, 2001, but were not included in the computation of diluted EPS because the options were anti-dilutive.

### Note 6. Legal Proceedings

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

On May 28, 1999, GlaxoSmithKline plc (formerly Glaxo Wellcome, Inc.), or Glaxo, filed a patent infringement lawsuit against us in the U.S. District Court in Delaware. The suit asserts that we infringe four U.S. patents owned by Glaxo. Two of the patents relate to the use of specific kinds of antibodies for the treatment of human disease, including cancer. The other two patents asserted against us relate to preparations of specific kinds of antibodies which are made more stable and the methods by which such preparations are made. Although the complaint failed to specify which of our products or methods of manufacture are allegedly infringing the four patents at issue, we believe that the suit relates to the manufacture, use and sale of our Herceptin and Rituxan antibody products. On July 19, 1999, we filed our answer to Glaxo's complaint, and in our answer we also stated counterclaims against Glaxo. On or about October 27, 2000, Glaxo filed a motion for summary judgment that our Herceptin and Rituxan antibody products

infringe two of the patents asserted against us in this suit. Genentech has filed multiple summary judgment motions relating to non-infringement and invalidity. All of those motions are currently pending before the judge. The trial of this suit began on April 17, 2001 and is ongoing.

On September 14, 2000, Glaxo filed another patent infringement lawsuit against us in the U.S. District Court in Delaware, alleging that we are infringing U.S. Patent No. 5,633,162 owned by Glaxo. The patent relates to specific methods for culturing Chinese Hamster Ovary cells. The complaint fails to specify which of our products or methods of manufacture are allegedly infringing that patent. However, the complaint makes a general reference to Genentech's making, using, and selling "monoclonal antibodies", and so we believe that the suit relates to our Herceptin and Rituxan antibody products. On October 4, 2000, we filed our answer to Glaxo's complaint, and in our answer we also stated counterclaims against Glaxo. The trial of this suit is scheduled to begin January 25, 2002. This lawsuit is separate from and in addition to the Glaxo suit mentioned above.

We and the City of Hope Medical Center are parties to a 1976 agreement relating to work conducted by two City of Hope 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 City of Hope filed a complaint against us in the Superior Court in Los Angeles County, California alleging that we owe royalties to the City of Hope in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. The complaint states claims for declaratory relief, breach of contract, breach of implied covenant of good faith and fair dealing, and breach of fiduciary duty. On December 15, 1999, we filed our answer to the City of Hope's complaint. On or about December 22, 2000, City of Hope filed a dismissal of its declaratory relief claims. The trial of this suit has been rescheduled to begin on August 22, 2001.

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 relates to certain antibodies that bind to breast cancer cells and/or other cells. On August 4, 2000, we filed our answer to Chiron's complaint, and in our answer we also stated counterclaims against Chiron. The judge has scheduled the trial of this suit to begin June 25, 2002.

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. Genentech has filed a motion to dismiss this second lawsuit, and the Court has scheduled a hearing on the motion for May 21, 2001. No trial date has yet been scheduled for this second lawsuit. This lawsuit is currently separate from and in addition to the Chiron suit mentioned above.

We and Pharmacia AB (formerly Pharmacia & Upjohn AB) are parties to a 1978

## Edgar Filing: GENENTECH INC - Form 10-Q

agreement relating to Genentech's development of recombinant human growth hormone products, under which Pharmacia is obligated to pay Genentech

Page 12

royalties on sales of Pharmacia's growth hormone products throughout the world. On January 5, 1999, Pharmacia filed a Request for Arbitration with the International Chamber of Commerce ("ICC") to resolve several disputed issues between Genentech and Pharmacia under the 1978 agreement. One of the claims made by Pharmacia is for a refund of some of the royalties previously paid to Genentech for sales of Pharmacia's growth hormone products in certain countries. Although the ICC has not yet given a decision on that claim, we do not believe its decision is likely to have a material adverse effect on our financial position, result of operations or cash flows.

On March 13, 2001, Genentech filed a complaint in the United States District Court in Delaware against Genzyme Corporation seeking a declaratory judgment that Genentech does not infringe Genzyme's U.S. Patent No. 5,344,773 and that Genentech has not breached a 1992 Patent License and Interference Settlement Agreement between Genentech and Genzyme relating to that patent. Genentech's filing followed communications earlier in 2001 from Genzyme claiming that Genentech's TNKase product infringes Genzyme's patent. Genentech is seeking a declaration that Genzyme's patent is not infringed by any Genentech product, that the patent is invalid, that Genzyme be enjoined from further legal action against Genentech regarding the patent, and that Genentech has not breached the 1992 Agreement. Genzyme has not yet filed its answer to our complaint.

On or about April 6, 2001, Genzyme filed a complaint in the same court against Genentech alleging that our TNKase product infringes the Genzyme patent and that Genentech is in breach of the 1992 Agreement referred to above. Genzyme's complaint also alleges willful infringement and reckless breach of contract by Genentech. Genzyme filed an amended complaint on or about April 11, 2001 that added no new substantive allegations or new claims. Genzyme is seeking to enjoin Genentech from infringing the patent, and also is seeking attorneys fees and costs. Genentech has not yet filed its answer to this complaint. Although this lawsuit is currently separate from and in addition to the declaratory judgment suit referred to above, it is possible that the suits will be consolidated in some respect.

Based upon the nature of the claims made and the information available to date to us and our counsel through investigations and otherwise, we believe the outcome of these actions is not likely to have a material adverse effect on our financial position, result of operations or cash flows. However, were an unfavorable ruling to occur in any quarterly period, there exists the possibility of a material impact on the operating results of that period.

### Note 7. Inventories

Inventories are summarized below (in thousands):

	March 31, 2001	December 31, 2000
	-----	-----
Raw materials and supplies	\$ 18,163	\$ 17,621

Edgar Filing: GENENTECH INC - Form 10-Q

Work in process	258,620	233,121
Finished goods	17,837	15,088
	-----	-----
Total	\$294,620	\$265,830
	=====	=====

Page 13

INDEPENDENT ACCOUNTANTS' REVIEW REPORT

The Board of Directors and Stockholders  
Genentech, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of Genentech, Inc. as of March 31, 2001, and the related condensed consolidated statements of operations for the three-month periods ended March 31, 2001 and 2000 and the condensed consolidated statements of cash flows for the three-month periods ended March 31, 2001 and 2000. 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 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, 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended (not presented herein) and in our report dated January 17, 2001, 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, 2000, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

ERNST & YOUNG LLP

## Edgar Filing: GENENTECH INC - Form 10-Q

Palo Alto, California  
April 10, 2001

Page 14

### GENENTECH, INC. FINANCIAL REVIEW

#### Overview

Genentech is a leading biotechnology company using human genetic information to discover, develop, manufacture and market human pharmaceuticals that address significant unmet medical needs. Fourteen of the approved products of biotechnology stem from or are based on our science. We manufacture and market nine protein-based pharmaceuticals listed below, and license several additional products to other companies.

- Herceptin (trastuzumab) antibody for the treatment of certain patients with metastatic breast cancer whose tumors overexpress the human epidermal growth factor receptor2, or HER2, protein;
- Rituxan (rituximab) antibody which we market together with IDEC Pharmaceuticals Corporation, commonly known as IDEC, for the treatment of patients with relapsed or refractory low-grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma;
- TNKase (tenecteplase) single-bolus thrombolytic agent for the treatment of acute myocardial infarction;
- Activase (alteplase, recombinant) tissue plasminogen activator, or t-PA, for the treatment of acute myocardial infarction, acute ischemic stroke within three hours of the onset of symptoms and acute massive pulmonary embolism;
- Nutropin Depot [somatropin (rDNA origin) for injectable suspension] long-acting growth hormone for the treatment of growth failure associated with pediatric growth hormone deficiency;
- Nutropin AQ [somatropin (rDNA origin) injection] liquid formulation growth hormone for the same indications as Nutropin;
- Nutropin [somatropin (rDNA origin) for injection] 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;
- Protropin (somatrem for injection) growth hormone for the treatment of



## Edgar Filing: GENENTECH INC - Form 10-Q

inadequate endogenous growth hormone secretion, or growth hormone deficiency, in children; and

- Pulmozyme (dornase alfa, recombinant) inhalation solution for the treatment of cystic fibrosis.

We receive royalties on sales of rituximab outside of the United States (excluding Japan), on sales of Pulmozyme and Herceptin outside of the United States and on sales of certain products in Canada from F. Hoffmann-La Roche Ltd, an affiliate of Roche Holdings, Inc., that is commonly known as Hoffmann-La Roche. We receive royalties on sales of growth hormone products and t-PA outside of the United States and Canada, and we will receive royalties on sales of rituximab in Japan through other licensees. We also receive worldwide royalties on seven additional licensed products that are

Page 15

marketed by other companies. Six of these products originated from our technology.

### 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., commonly known as Roche. This event, referred to as the "Redemption," caused Roche to own 100% of our common stock on that date. Consequently, under U.S. generally accepted accounting principles, 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. For more information about push-down accounting, you should read the "Redemption of Our Special Common Stock" note in the Notes to Condensed Consolidated Financial Statements.

### Roche's Right 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 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

## Edgar Filing: GENENTECH INC - Form 10-Q

adjusted for the two-for-one splits of Genentech common stock in November 1999 and October 2000. 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's percentage ownership of our common stock was 58.24% at March 31, 2001.

### RESULTS OF OPERATIONS

(dollars in millions, except per share amounts)

Page 16

	Three Months Ended March 31,		
	2001	2000	% Change
REVENUES			
Revenues	\$540.1	\$387.9	39%
	=====	=====	=====

Revenues increased 39% in the first quarter of 2001 from the comparable period in 2000 primarily as a result of higher product sales and royalty income and, to a lesser extent, higher interest income. These increases are further discussed below.

	Three Months Ended March 31,		
	2001	2000	% Change
PRODUCT SALES			
Herceptin	\$ 81.4	\$ 68.7	18%
Rituxan	172.1	85.1	102
Activase/TNKase	52.1	47.5	10
Growth Hormone	55.5	55.1	1
Pulmozyme	29.9	26.8	12
Actimmune	0.9	-	-
Total product sales	\$391.9	\$283.2	38%
	=====	=====	=====

Total product sales increased 38% in the first quarter of 2001 from the comparable period in 2000 primarily as a result of higher sales from our biotechnology products, Rituxan and Herceptin.

## Edgar Filing: GENENTECH INC - Form 10-Q

Herceptin: Net sales of Herceptin increased 18% in the first quarter of 2001 from the comparable period in 2000. Since launch, an increase in penetration into the metastatic breast cancer market has contributed to a positive sales trend. To a lesser extent, the increase was also due to a slight increase in price.

Rituxan: Net sales of Rituxan increased 102% in the first quarter of 2001 from the comparable period in 2000. This increase was primarily due to increased use of the product in the treatment of B-cell non-Hodgkin's lymphoma.

Activase/TNKase: Net sales of our two cardiovascular products, Activase and TNKase, were \$52.1 million in the first quarter of 2001 compared to \$47.5 million of Activase sales in the first quarter of 2000. The increase reflects the steady growth of TNKase sales due to the ease of administering the product through a single, 5-second injection. TNKase received U.S. Food and Drug Administration, or FDA, approval in early June 2000 and was launched in mid-June 2000.

Growth Hormone: Net sales of our four growth hormone products, Nutropin Depot, Nutropin AQ, Nutropin and Protropin, increased slightly in the first quarter of 2001 from the comparable period in 2000. Nutropin Depot was launched on June 28, 2000.

Page 17

Pulmozyme: Net sales of Pulmozyme increased 12% in the first quarter of 2001 from the comparable period in 2000. This increase was primarily as a result of programs to encourage patient compliance with therapy, and to a lesser extent, a price increase.

	Three Months Ended March 31,		
ROYALTIES, CONTRACT AND OTHER, AND INTEREST INCOME	2001	2000	% Change
Royalties	\$ 74.6	\$ 47.3	58%
Contract and other	38.5	35.9	7
Interest income	35.1	21.5	63

Royalties: Royalty income increased 58% in the first quarter of 2001 from the comparable period in 2000. The increase was due to higher third-party sales from various licensees. During the quarter we received approximately \$5.0 million of retroactive royalties on an interferon product from Roche.

Contract and Other Revenues: Contract and other revenues in the first quarter of 2001 increased 7% from the comparable period in 2000 due to the recognition of \$10.0 million in gains related to the change in the time value of certain hedging instruments, offset in part by lower gains from the sale of biotechnology equity securities. (See Note 1, "Statement of Accounting Presentation and Significant Accounting Policies," in the Notes to Condensed Consolidated Statements for more information on our derivative and hedging activities.)

## Edgar Filing: GENENTECH INC - Form 10-Q

Interest Income: Interest income in the first quarter 2001 increased 63% from the first quarter of 2000. The increase was due to a higher average portfolio balance and higher returns in our cash and investment portfolio.

COSTS AND EXPENSES	Three Months Ended March 31,		
	2001	2000	% Change
Cost of sales	\$ 83.8	\$106.1	(21)%
Research and development	136.3	111.4	22
Marketing, general and administrative	127.9	83.6	53
Collaboration profit sharing	46.4	18.3	154
Recurring charges related to redemption	81.5	98.6	(17)
Interest expense	1.5	1.3	15
Total costs and expenses	\$477.4	\$419.3	14%
	=====	=====	=====

Cost of Sales: Cost of sales in the first quarter of 2001 decreased to \$83.8 million compared to \$106.1 million in the first quarter of 2000. Cost of sales as a percent of product sales decreased to 21% in the first quarter of 2001 from 37% in the prior year. The decrease in the ratio primarily reflects a decline in the costs recognized on the sale of inventory that was written up at the Redemption due to push-down accounting. This inventory had been sold at December 31, 2000.

Page 18

Research and Development: Research and development, or R&D, expenses increased 22% in the first quarter of 2001 from the comparable period in 2000. The increase was primarily due to an increase in expenses related to late-stage clinical trials and the termination of a collaboration arrangement. In addition, R&D expenses in each of the first quarters of 2001 and 2000 include a \$15.0 million upfront payment for the purchase of in-process research and development, or IPR&D, under in-licensing agreements with collaborators. We determined that the acquired IPR&D was not yet technologically feasible and that it had no future alternative uses.

Marketing, General and Administrative: Overall marketing, general and administrative, or MG&A, expenses increased 53% in the first quarter from the comparable period in 2000. This increase was due to the write-down of certain biotech investments due to current market conditions, preparation for the Xolair market introduction, an increase in the marketing and selling expenses in continuing support of our oncology products, and increased royalty expenses associated with licensee sales.

Collaboration Profit Sharing: Collaboration profit sharing includes the net operating profit sharing with IDEC on Rituxan sales, and the sharing of costs with collaborators related to commercialization and development of future products. Collaboration profit sharing expenses increased to \$46.4 million in the first quarter of 2001, from \$18.3 million in the first quarter of 2000. The increase was primarily due to increased Rituxan profit sharing due to higher Rituxan sales.

## Edgar Filing: GENENTECH INC - Form 10-Q

Recurring Charges Related to Redemption: We began recording recurring charges related to the Redemption and push-down accounting in the third quarter of 1999. These charges were approximately \$81.5 million in the quarter ended March 31, 2001, and were comprised of \$79.4 million for the amortization of intangibles and goodwill, and \$2.1 million of compensation expense. These charges were approximately \$98.6 million in the first quarter of 2000 and were comprised of \$95.3 million for the amortization of intangibles and goodwill, and \$3.3 million of compensation expense. The compensation expense was related to alternative arrangements provided at the time of the Redemption for certain holders of some of the unvested options under the 1996 Stock Option/Stock Incentive Plan.

Interest Expense: Interest expense will fluctuate depending on the amount of capitalized interest related to the amount of construction projects. Interest expense, net of amounts capitalized, relates to interest on our 5% convertible subordinated debentures.

INCOME (LOSS) BEFORE TAXES AND CUMULATIVE EFFECT OF ACCOUNTING CHANGE, INCOME TAXES AND CUMULATIVE EFFECT OF ACCOUNTING CHANGE	Three Months Ended March 31,		
	2001	2000	% Change
Income (loss) before taxes and cumulative effect of accounting change	\$ 62.7	\$(31.4)	300%
Income tax provision (benefit)	30.3	(6.8)	546
Income (loss) before cumulative effect of accounting change	32.4	(24.6)	232
Cumulative effect of accounting change, net of tax	(5.6)	(57.8)	-

Page 19

Changes in Accounting Principle: We adopted the Statement of Financial Accounting Standards No. 133, or FAS 133, "Accounting for Derivatives and Hedging Activities," on January 1, 2001. Upon adoption, we recorded a \$5.6 million charge, net of tax, as a cumulative effect of a change in accounting principle and an increase of \$8.4 million in other comprehensive income related to recording derivative instruments at fair value. See Note 1, "Statement of Accounting Presentation and Significant Accounting Policies" in the Notes to Condensed Consolidated Financial Statements for further information on our adoption of FAS 133.

We adopted the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, or SAB 101, on revenue recognition effective January 1, 2000 and recorded a \$57.8 million charge, net of tax, as a cumulative effect of a change in accounting principle related to contract revenues recognized in prior periods. The related deferred revenue is being recognized over the term of the agreements. For the quarter ended March 31, 2000, the impact of the change in accounting was to increase net loss by \$56.5 million, comprised of the \$57.8 million cumulative effect of the change (net of tax) as described above, net of \$1.3 million of the related deferred revenue (net of tax) that was recognized as revenue during the quarter ended March 31, 2000. For the quarter ended March 31, 2001, we recognized \$2.3 million (net of tax)

## Edgar Filing: GENENTECH INC - Form 10-Q

of the related deferred revenue. See Note 1, "Statement of Accounting Presentation and Significant Accounting Policies," in the Notes to Condensed Consolidated Financial Statements for further information on our adoption of SAB 101.

**Income Tax:** The tax provision of \$30.3 million for the first quarter of 2001 increased over the tax benefit of \$6.8 million for the first quarter of 2000 primarily due to increased pretax income and decreased charges related to the Redemption.

Our effective tax rates were approximately 48% for the first quarter of 2001 and 22% for the first quarter of 2000, which reflect the non-deductibility of goodwill amortization.

The effective tax rate of 32% in the first quarter of 2001 on pretax income, excluding charges related to the Redemption and cumulative effect of accounting change, is higher than the comparative tax rate of 31% in the first quarter of 2000 primarily due to decreased R&D tax credits.

NET INCOME (LOSS)	Three Months Ended March 31,		% Change
	2001	2000	
	(Restated)		
Net income (loss)	\$ 26.8	\$ (82.4)	133%
Earnings (loss) per share:			
Basic: Earnings (loss) before cumulative effect of accounting change	\$ 0.06	\$ (0.05)	220%
Cumulative effect of accounting change, net of tax	(0.01)	(0.11)	-
Net earnings (loss) per share	\$ 0.05	\$ (0.16)	131%
Diluted: Earnings (loss) before cumulative effect of accounting change	\$ 0.06	\$ (0.05)	220%
Cumulative effect of accounting change, net of tax	(0.01)	(0.11)	-
Net earnings (loss) per share	\$ 0.05	\$ (0.16)	131%

**Net Income (Loss):** The net income of \$26.8 million, or earnings of \$0.05 per share in 2001, primarily reflects an increase in product sales, royalties, contract revenue and interest income and a decrease in cost of sales, offset in part by increased R&D, MG&A and Collaboration profit sharing expenses.

**In-Process Research and Development:** At June 30, 1999, the Redemption date, we determined that the acquired in-process technology was not technologically

## Edgar Filing: GENENTECH INC - Form 10-Q

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 retained earnings, 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 projects since December 31, 2000. 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 estimate, however, that the research and development expenditures that will be required to complete the in-process projects will total at least \$600.0 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 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.

The following are the only significant changes that occurred during the quarter ended March 31, 2001 to the projects included in the IPR&D charge at the Redemption:

- Dornase alfa AERx - project has been discontinued.
- Herceptin antibody for non-small cell lung cancer (NSCLC) - project has been discontinued in this indication.

LIQUIDITY AND CAPITAL RESOURCES	March 31, 2001	December 31, 2000
Cash and cash equivalents, short-term investments and long-term marketable securities	\$ 2,306.9	\$ 2,459.4
Working capital	1,434.8	1,340.1

We used cash generated from operations, income from investments and proceeds from stock issuances to fund operations, purchase marketable securities and make capital and equity investments.

Cash and cash equivalents, short-term investments and long-term marketable securities at March 31, 2001 decreased from December 31, 2000 by \$152.5 million. Working capital increased by \$94.7 million in the first three months of 2001 from December 31, 2000.

Capital expenditures totaled \$36.3 million in the first quarter of 2001 compared to \$28.2 million in the comparable period of 2000. The increase in 2001 compared to 2000 was primarily due to an increase in leasehold improvements.

We believe that our cash, cash equivalents and short-term investments,

together with funds provided by operations and leasing arrangements, will be sufficient to meet our foreseeable operating cash requirements. In addition,

## Edgar Filing: GENENTECH INC - Form 10-Q

we believe we could access additional funds from the debt and, under certain circumstances, capital markets. See also "Forward-Looking Information and Cautionary Factors that May Affect Future Results - Affiliation Agreement with Roche Could Adversely Affect Our Cash Position" below for factors that could negatively affect our cash position.

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

The following section 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 and net income.

#### 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.

For example, sales of our Activase product decreased in 2000, 1999 and 1998 primarily due to competition from Centocor Inc.'s Retavase and more recently to a decreasing size of the thrombolytic marketplace as other forms of acute myocardial infarction treatment gain acceptance.

- The amount and timing of sales to customers in the United States.

For example, sales of our Growth Hormone products increased in 2000 and 1999 due to fluctuations in distributor ordering patterns.

- The amount and timing of our sales to Hoffmann-La Roche of products for sale outside of the United States and the amount and timing of its sales to its customers, which directly impact both our product sales and royalty revenues.

For example, in the third quarter of 2000, Hoffmann-La Roche's approval of Herceptin in Europe increased our sales of Herceptin product.

- The timing and volume of bulk shipments to licensees.
- The availability of third-party reimbursements for the cost of therapy.
- 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 it is approved by the FDA for sale.
- The rate of adoption and use of our products for approved indications and additional indications.

For example, sales of Pulmozyme increased in 1998 due, in part, to new



## Edgar Filing: GENENTECH INC - Form 10-Q

patients who were attracted to our product as a result of an FDA approval for a label extension to include cystic fibrosis patients under the age of five.

For example, sales of Rituxan increased in the last quarter of 2000 and the first quarter of 2001 due to the announcement at the American Society of Clinical Oncology of the results of a study conducted by the Groupe d'Etude des Lymphomes de l'Adulte, or GELA, reporting on the benefits of using Rituxan, combined with standard chemotherapy, for treating aggressive non-Hodgkins lymphoma.

- The potential introduction of new products and additional indications for existing products in 2001 and beyond.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.
- The number and size of any product price increases we may issue.

### The Successful Development of Pharmaceutical Products Is Highly Uncertain

Successful pharmaceutical product development is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- Preclinical and clinical trial results that may show the product to be less effective than desired or to have harmful problematic side effects;

For example:

- In June 2000, we announced that the preliminary results from our 415-patient Phase II clinical trial of our recombinant humanized anti-CD18 monoclonal antibody fragment, which is known as rhuMAB CD18, for the treatment of myocardial infarction, more commonly known as a heart attack, did not meet its primary objectives.
  - In 1999, our Phase III clinical trial of recombinant human nerve growth factor, which is known as rhNGF, for use in diabetic peripheral neuropathy did not meet its objectives and we decided not to file for product approval with the FDA.
  - In 1999, our Phase II clinical study of recombinant human vascular endothelial growth factor, which is known as VEGF, protein failed to meet the primary endpoints of the study.
  - In April 2001, we announced that a Phase III clinical trial of Veletri, trademark, (tezosentan) - an intravenous dual endothelin receptor antagonist for the treatment of symptoms (dyspnea, or shortness of breath) associated with acute heart failure (AHF)- did not meet its primary objectives.
- Failure to receive the necessary regulatory approvals or delay in receiving such approvals;
  - Manufacturing costs or other factors that make the product uneconomical;  
or

- The proprietary rights of others and their competing products and technologies that may prevent the product from being 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, we have experienced an increase in R&D expenses in the first quarter of 2001 due to 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, promising candidates have not yielded 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, in February 2000, we entered into an agreement with Actelion Ltd. for the purchase of rights for the development and co-promotion in the United States of tezosentan and paid Actelion an upfront fee of \$15.0 million which was recorded as an R&D expense.

For example, in January 2001, we entered into an agreement with OSI Pharmaceuticals, Inc. for the global co-development and commercialization of an anti-cancer drug, OSI-774, and paid OSI an upfront fee of \$15.0 million for the purchase of IPR&D which was recorded as an R&D expense.

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

Roche, Our Controlling Stockholder, May Have Interests That Are Adverse to Other Stockholders

## Edgar Filing: GENENTECH INC - Form 10-Q

Roche, as our majority stockholder, controls the outcome of actions requiring the approval of our stockholders. Our bylaws provide, among other things,

Page 24

that the composition of our board of directors shall consist of two Roche directors, three independent directors nominated by a nominating committee and one Genentech employee 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; and
- Establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock.

These provisions may have the effect of limiting our ability to make acquisitions and while the dollar amounts associated with the stock repurchase program cannot currently be estimated, these stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access 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; and
- 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

## Edgar Filing: GENENTECH INC - Form 10-Q

competition with Roche, conflicts of interest with Roche, the offer of corporate opportunities to Roche and intercompany agreements with Roche. This deemed consent may restrict your 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

Page 25

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. Two of our directors, Dr. Franz B. Humer and Dr. Jonathan K.C. Knowles, currently serve as directors, officers and employees of Roche Holding Ltd and its affiliates.

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.

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 right of Roche may limit our flexibility as to 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 Growing and New Competition

We face growing competition in two of our therapeutic markets and expect new competition in a third market. First, in the thrombolytic market, Activase has lost market share and could lose additional market share to Centocor's Retavase, either alone or in combination with the use of another Centocor product, ReoPro, registered trademark, (abciximab) and to the use of other mechanical therapies to treat acute myocardial infarction; the resulting adverse effect on sales has been and could continue to be material. Retavase received approval from the FDA in October 1996 for the treatment of acute myocardial infarction. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow.

Second, in the growth hormone market, we continue to face increased competition from four other companies currently selling growth hormone and an additional company which may enter the market in the near future. As a result of that competition, we have experienced a loss in market share. The four competitors have also received approval to market their existing human growth hormone products for additional indications. As a result of this competition, sales of our Growth Hormone products may decline, perhaps significantly.

Third, in the non-Hodgkin's lymphoma market, Corixa Corporation, formerly Coulter Pharmaceutical, Inc., has filed and received an expedited review of a revised Biologics License Application, or BLA, in 2000 for Bexxar, trademark, (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan and IDEC has filed a BLA for Zevalin, trademark, (ibratumomab tiuxetan), a product which could also potentially compete with Rituxan. Both Bexxar and Zevalin are radiolabeled molecules while Rituxan is not. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

Page 26

#### Other Competitive Factors Could Affect Our Product Sales

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

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

For example, in June 2000 one of our competitors, Novo, received FDA approval for a liquid formulation of its growth hormone product that will directly compete with our liquid formulation, Nutropin AQ. Also in June 2000, another of our competitors, Serono S.A., received FDA approval to deliver its competitive growth hormone product in a needle-free device.

- Our pricing decisions and the pricing decisions of our competitors.

For example, we raised the prices of Rituxan in May 2000 and Pulmozyme in June 2000 by approximately 5%.

For example, we raised the prices of Herceptin by 3% and on Growth Hormone Product by 5% in January 2001.

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

For example, in January 2000, a federal court judge lifted a preliminary injunction that had been in effect since 1995 against Bio-Technology General Corporation, or BTG. Although an appeal of the judge's decision is pending, BTG is now permitted to sell its competitive growth hormone product in the United States.

- 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 further described in "Protecting Our Proprietary Rights Is Difficult and Costly," in May 1999, June 2000 and September 2000, several companies filed patent infringement lawsuits against us alleging that we are infringing certain of 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, in the past, we have lost market share to new competitors in the thrombolytic and growth hormone markets.

In Connection With the Redemption of Our Special Common Stock, We Recorded Substantial Goodwill and Other Intangibles, the Amortization of Which May Adversely Affect Our Earnings

As a result of the redemption of our special common stock, Roche owned all of our outstanding common stock. Consequently, push-down accounting under generally accepted accounting principles was required. Push-down accounting

Page 27

required us to establish a new accounting basis for our assets and liabilities, based on Roche's cost in acquiring all of our stock. In other words, Roche's cost of acquiring Genentech was "pushed down" to us and reflected on our financial statements. Push-down accounting required us to record goodwill and other intangible assets of approximately \$1,685.7 million and \$1,499.0 million, respectively, on June 30, 1999. The amortization of this goodwill and other intangible assets will have a significant negative impact on our financial results in future years. In addition, we will continuously evaluate whether events and circumstances have occurred that indicate the remaining balance of this and other intangible assets may not be recoverable. If our assets need to be evaluated for possible impairment, we may have to reduce the carrying value of our intangible assets. This could have a material adverse effect on our financial condition and results of operations during the periods in which we recognize a reduction. We may have to write down intangible assets in future periods. For more information about push-down accounting, see the Note 2, "Redemption of Our Special Common Stock," in the Notes to Condensed Consolidated Financial Statements of Part I.

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.

For example, we began receiving royalty revenues from Immunex Corporation's sale of Enbrel, registered trademark, in 1999.

- The conclusion of existing arrangements with other companies and Hoffmann-La Roche.

For example, royalty revenues decreased in 1999 from 1998 due to the expiration of royalty payments primarily on sales of human insulin, from

## Edgar Filing: GENENTECH INC - Form 10-Q

Eli Lilly and Company in August 1998.

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

For example, we expect the approval of Herceptin outside the United States which occurred in third quarter of 2000 to have a continuing positive impact on royalties.

- Fluctuations in foreign currency exchange rates.
- The initiation of new contractual arrangements with other companies.

For example, license fees from Immunex and Schwarz Pharma AG increased contract revenues in 1999.

- Whether and when contract benchmarks are achieved.

Page 28

For example, milestone payments from Pharmacia increased contract revenue in 1997.

- The failure of or refusal of a licensee to pay royalties.
- The expiration or invalidation of patents or licensed intellectual property.

### 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 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. 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 product in dispute. For example, in late 1999 we settled a patent infringement lawsuit brought against us by the Regents of the University of California in which the University alleged that the manufacture and sale of our Protropin and Nutropin growth hormone products infringed a patent owned by the University. In connection with that settlement we paid the University of California \$150.0 million and donated \$50.0 million for the construction of a new life sciences building on the University of California, San Francisco campus.

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, the courts will determine the ultimate strength of patent protection of our products and those on which we earn royalties.

## Edgar Filing: GENENTECH INC - Form 10-Q

Three lawsuits have been filed against us in which the companies involved allege that we have infringed their patents by the manufacture and sale of certain of our products:

- In May 1999, GlaxoSmithKline plc, or Glaxo, filed a complaint in which it appears to claim that our manufacture, use and sale of Rituxan and Herceptin antibody products infringe four Glaxo patents that relate to certain uses and preparations of antibodies.
- In June 2000, Chiron Corporation filed a complaint in which it claims that our manufacture and sale of Herceptin infringe a patent it owns.
- In September 2000, Glaxo filed another complaint in which it appears to claim that our manufacture, use and sale of Rituxan and Herceptin antibody products infringe a Glaxo patent that relates to certain cell culture methods.

### We May Incur Material Litigation Costs

Litigation to which we are currently or have been subjected relates to, among

Page 29

other things, our patent and intellectual property rights, licensing arrangements with other persons, product liability and financing activities. We cannot predict with certainty the eventual outcome of pending litigation, and we might have to incur substantial expense in defending these lawsuits. We have in the past taken substantial special charges relating to litigation, including \$230.0 million in 1999.

### We May Incur Material Product Liability Costs

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

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

The pharmaceutical industry is subject to stringent regulation with respect to product safety and efficacy by various 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 pharmaceutical product 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 their label, written advisements to physicians and product recall.

We cannot be sure that we can obtain necessary regulatory approvals on a



## Edgar Filing: GENENTECH INC - Form 10-Q

timely basis, if at all, for any of the products we are developing 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.
- Loss of or changes to previously obtained approvals.

For example, in May 2000, we issued letters to physicians advising them of some serious adverse events associated with the administration of Herceptin. In October 2000, we issued a new package insert for Herceptin including this information.

- Failure to comply with existing or future regulatory requirements.

For example, in 1999, we paid a \$50.0 million settlement to the federal government in connection with a federal investigation of our former clinical, sales and marketing activities associated with our human growth hormone products.

Moreover, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development, which may affect our ability to obtain approval of our products.

Difficulties or Delays in Product Manufacturing Could Harm Our Business

Page 30

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 product defects, which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all.

For example, in March 2000, we issued an important drug notification regarding a defect in the packaging of our Pulmozyme product. During a quality assurance inspection, we had discovered that there was a defect in the packaging of Pulmozyme which occasionally caused a small puncture in ampules of that product. We suspended shipping the product while we determined the source and extent of the defect. We ultimately recalled some of the product.

In April 2001, we issued another important drug notification regarding a separate defect in the manufacture of a Pulmozyme product lot which was causing a small puncture in a small number of ampules of the product. We suspended shipping the product upon discovery of this defect and recalled the few cases of the product lot that had been distributed.

On December 27, 2000, we received a Warning Letter from the FDA regarding our quality control at our South San Francisco manufacturing plant. The products cited were for Pulmozyme, Herceptin and Activase. On February 7, 2001, we received a letter from the FDA accepting our responses and corrective actions with respect to the Warning Letter. If we were to experience additional quality control or other related manufacturing problems

## Edgar Filing: GENENTECH INC - Form 10-Q

in the future, the FDA could take more significant action, including causing us to cease manufacturing of one or more products for a period of time.

In addition, any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments or loss of product in the process of being manufactured. A number of factors could cause interruptions, including equipment malfunctions or failures, or damage to a facility due to natural disasters, rolling blackouts imposed by Pacific Gas & Electric Company or otherwise. 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 and our contractors' manufacturing of existing or new products could increase our costs, cause us to lose revenue or market share and damage our reputation.

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, due to the absence of the put and call that were associated with our special common stock, the market price of our common stock has been and may continue to be more volatile than our special common stock was in the past.

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.

Page 31

For example, our stock increased by approximately 19% on the day we announced FDA approval for our TNKase product.

- Developments concerning proprietary rights, including patents.

For example, our stock price decreased by approximately 4% on the day one of our competitors, Chiron, announced a patent infringement suit against us.

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

For example, our stock price increased by approximately 9% on the day we announced positive preliminary Phase III results from the Anti-IgE asthma clinic.

For example, our stock price decreased by approximately 9% on the day we announced negative Phase III results from the clinical trials of Velettri.

- Regulatory developments in the United States and foreign countries.
- Public concern as to the safety of biotechnology products.

## Edgar Filing: GENENTECH INC - Form 10-Q

For example, on May 8, 2000, we issued a warning concerning our Herceptin drug after 15 deaths resulted from the administration of Herceptin. Our stock price decreased by approximately 2% at that time.

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

For example, our stock reached a high of \$122.50 per share in March 2000 and decreased, as the biotech sector and stock market in general decreased, to a low of \$38.50 per share in March 2001.

- Period-to-period fluctuations in financial results.

For example, our stock price has historically been affected by whether we met or exceeded analyst expectations, and accordingly, our stock increased by more than 6% after we announced that our first quarter 2001 earnings had met analysts' expectations.

### Our Affiliation Agreement With Roche Could Adversely Affect Our Cash Position

Our affiliation agreement with Roche provides that we will establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. While the dollar amounts associated with these future purchases cannot currently be estimated, those stock repurchases could have a material adverse effect on our cash position and may have the effect of limiting our ability to use our capital stock as consideration for acquisitions.

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

Page 32

### Future Sales by Roche Could Cause the Price of Our Common Stock to Decline

As of March 31, 2001, Roche owned 306,594,352 shares of our common stock or approximately 58.24% 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. We have agreed to use our best efforts to facilitate the registration and offering of those shares designated for sale by Roche. 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.

### 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 investment transactions pursuant to our investment and risk management

## Edgar Filing: GENENTECH INC - Form 10-Q

policies and procedures in areas such as hedging and counterparty exposure practices. 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.

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

Our material interest bearing assets, or interest bearing portfolio, consisted of cash equivalents, restricted cash, short-term investments, convertible preferred stock investments, convertible loans and long-term investments. The balance of our interest bearing portfolio was \$1,879.6 million or 28% of total assets at December 31, 2000. Interest income related to this portfolio was \$90.4 million or 5% of total revenues at December 31, 2000. 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 have entered into swap transactions, which involve the receipt of fixed rate interest and the payment of floating rate interest without the exchange of the underlying principal.

### 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

Page 33

in Europe, Asia (primarily Japan) and Canada. Our exposure to foreign exchange rates primarily exists with the Euro. When the dollar strengthens against the currencies in these countries, the dollar value of non-dollar-based revenue decreases; when the dollar weakens, the dollar value of the non-dollar-based 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. Increasingly however, these royalties are being offset by expenses arising from our foreign facility as well as non-dollar expenses incurred in our collaborations. Currently, our foreign royalty revenues exceed our 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

## Edgar Filing: GENENTECH INC - Form 10-Q

hedge certain of our anticipated revenues by purchasing option contracts with expiration dates and amounts of currency that are based on 25% 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. Currently, the term of these options is generally one to two years. To hedge the non-dollar expenses arising from our foreign facility, we may enter into forward contracts to lock in the dollar value of a portion of these anticipated expenses.

### 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 \$652.7 million or 10% of total assets at December 31, 2000. These investments are subject to fluctuations from market value changes in stock prices. For example, in the first quarter of 2001, we took a significant charge on an equity security investment that had an other than temporary impairment.

To mitigate the risk of market value fluctuation, certain equity securities are hedged with costless collars and forward contracts. A costless 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 pay the counterparty the total return of the security above the current spot price and receive interest income on the notional amount for the contract term. 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. In addition, as part of our strategic alliance efforts, we hold dividend-bearing convertible preferred stock and have made interest-bearing loans that are convertible into the equity securities of the debtor.

Page 34

### We Are Exposed to Credit Risk of Counterparties

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

### New Accounting Pronouncement Could Impact Our Financial Position and Results of Operations

The Financial Accounting Standards Board, or FASB, is expected to issue a new accounting standard on Business Combinations in June 2001. If the proposed accounting standard is adopted, it would require that goodwill not be

## Edgar Filing: GENENTECH INC - Form 10-Q

amortized, but rather be subject to an impairment test. In addition, separately identified and recognized intangibles resulting from business combinations completed prior to the adoption of the proposed accounting standard that do not meet the new criteria for separate recognition of intangible assets will be subsumed into goodwill upon adoption. If adopted, the proposed accounting standard could have a significant impact on our financial position and results of operations.

Page 35

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Genentech's market risk disclosures set forth in the Form 10-K for the period ended December 31, 2000, have not changed significantly.

Page 36

GENENTECH, INC.  
PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In connection with the patent infringement lawsuit filed against us by

## Edgar Filing: GENENTECH INC - Form 10-Q

GlaxoSmithKline plc on May 28, 1999, Genentech has filed multiple summary judgment motions relating to non-infringement and invalidity. All of those motions are currently pending before the judge. The trial of this suit began on April 17, 2001 and is ongoing.

On March 13, 2001, Chiron Corporation filed a second 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. Genentech has filed a motion to dismiss this second lawsuit, and the Court has scheduled a hearing on the motion for May 21, 2001. No trial date has yet been scheduled for this second lawsuit. This lawsuit is currently separate from and in addition to the patent infringement lawsuit filed against us by Chiron on June 7, 2000.

On March 13, 2001, Genentech filed a complaint in the United States District Court in Delaware against Genzyme Corporation seeking a declaratory judgment that Genentech does not infringe Genzyme's U.S. Patent No. 5,344,773 and that Genentech has not breached a 1992 Patent License and Interference Settlement Agreement between Genentech and Genzyme relating to that patent. Genentech's filing followed communications earlier in 2001 from Genzyme claiming that Genentech's TNKase product infringes Genzyme's patent. Genentech is seeking a declaration that Genzyme's patent is not infringed by any Genentech product, that the patent is invalid, that Genzyme be enjoined from further legal action against Genentech regarding the patent, and that Genentech has not breached the 1992 Agreement. Genzyme has not yet filed its answer to our complaint.

On or about April 6, 2001, Genzyme filed a complaint in the same court against Genentech alleging that our TNKase product infringes the Genzyme patent and that Genentech is in breach of the 1992 Agreement referred to above. Genzyme's complaint also alleges willful infringement and reckless breach of contract by Genentech. Genzyme filed an amended complaint on or about April 11, 2001 that added no new substantive allegations or new claims. Genzyme is seeking to enjoin Genentech from infringing the patent, and also is seeking attorneys fees and costs. Genentech has not yet filed its answer to this complaint. Although this lawsuit is currently separate from and in addition to the declaratory judgement suit referred to above, it is possible that the suits will be consolidated in some respect.

See also Item 3 of the our report on Form 10-K for the period ended December 31, 2000.

See also Note 6, "Legal Proceedings," in the Notes to Condensed Consolidated Financial Statements of Part I.

Page 37

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

#### (a) Exhibits

10.1 Change in Control Agreement, dated as of January 20,



## Edgar Filing: GENENTECH INC - Form 10-Q

2001, by and between Genentech, Inc. and Myrtle S. Potter.

10.2 Promissory Note, dated as of December 22, 2000, issued to Genentech, Inc. by Myrtle S. Potter.

15.1 Letter regarding Unaudited Interim Financial Information.

(b) Reports on Form 8-K

There were no other reports on Form 8-K filed during the quarter ended March 31, 2001.

Edgar Filing: GENENTECH INC - Form 10-Q

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.

Date: May 1, 2001

GENENTECH, INC.

/s/ARTHUR D. LEVINSON

/s/LOUIS J. LAVIGNE, JR.

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

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

/s/JOHN M. WHITING

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