GENENTECH INC
Form 10-Q
October 12, 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 September 30, 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 incorporation or organization)	(I.R.S. employer identification number)

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

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

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

Indicate 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	527,203,090 Outstanding at September 30, 2001

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In this report, "Genentech," "we," "us" and "our" refer to Genentech, Inc. "Common Stock" refers to Genentech's common stock, par value $0.02 per share, "Special Common Stock" refers to Genentech's callable putable 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; Avastin, trademark, (Bevacizumab) anti-VEGF antibody; Cathflo, trademark, (Alteplase for catheter clearance); 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 AQ Pen, trademark, (pen injector for Nutropin AQ); Nutropin Depot, registered 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;

Xanelim, trademark, (Efalizumab) anti-CD11a antibody. Rituxan, registered trademark, (Rituximab) anti-CD20 antibody is a registered trademark of IDEC Pharmaceuticals Corporation; Tarceva, trademark, (Erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; Tracleer, trademark, (Bosentan) is a trademark of Actelion Ltd; Xolair, trademark, (Omalizumab) anti-Ige antibody is a trademark of Novartis AG; Veletri, trademark, (Tezosentan) is a trademark of Actelion Ltd. This report also includes trademarks, service marks and trade names of other companies.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	Three Months Ended September 30,		Ni Ended
	2001	2000	200
		(Restated)	
Revenues:			
Product sales (including amounts from related parties: three months - 2001-$16,550; 2000-$15,794; nine months - 2001-$54,852; 2000-$57,560)	$448,700	$334,173	$1,250
Royalties (including amounts from related parties: three months - 2001-$18,462; 2000-$11,242; nine months - 2001-$59,882; 2000-$33,068)	66,051	51,818	193
Contract and other (including amounts from related parties: three months - 2001-$913; 2000-$417; nine months - 2001-$3,598; 2000-$2,478)	8,941	35,637	68
Interest	32,473	25,712	99
Total revenues	556,165	447,340	1,612
Costs and expenses:			
Cost of sales (including amounts from related parties: three months - 2001-$13,831; 2000-$13,412; nine months - 2001-$45,883; 2000-$48,740)	96,030	91,356	256
Research and development (including contract related: three months - 2001-$1,457; 2000-$2,686; nine months - 2001-$7,172; 2000-$13,357)	128,195	113,636	387
Marketing, general and administrative	109,365	94,087	345
Collaboration profit sharing	65,796	37,639	170
Recurring charges related to redemption	79,404	97,780	242
Interest	1,719	1,175	4
Total costs and expenses	480,509	435,673	1,406

Income (loss) before taxes and cumulative effect of accounting change	75,656	11,667	205
Income tax provision (benefit)	32,915	5,907	92
Income (loss) before cumulative effect of accounting change	42,741	5,760	113
Cumulative effect of accounting change, net of tax	-	-	(5
Net income (loss)	$ 42,741	$ 5,760	$ 108
Earnings (loss) per share:			
Basic: Earnings (loss) before cumulative effect of accounting change	$ 0.08	$ 0.01	$
Cumulative effect of accounting change, net of tax	-	-	(
Net earnings (loss) per share	$ 0.08	$ 0.01	$
Diluted: Earnings (loss) before cumulative effect of accounting change	$ 0.08	$ 0.01	$
Cumulative effect of accounting change, net of tax	-	-	(
Net earnings (loss) per share	$ 0.08	$ 0.01	$
Weighted average shares used to compute earnings (loss) per share:			
Basic	527,328	522,928	526
Diluted	533,670	541,483	534

See Notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2001	2000
		(Restated)
Cash flows from operating activities:		
Net income (loss)	$ 108,140	$ (89,516)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	318,895	358,325
Deferred income taxes	20,834	(150,828)
Gain on sales of securities available-for-sale	(27,494)	(84,046)
Loss on sales of securities available-for-sale	1,989	2,570

Write-down of securities available-for-sale	22,180	-
Loss on property and equipment dispositions	1,006	129
Changes in assets and liabilities:		
Investments in trading securities	(83,840)	(13,884)
Receivables and other current assets	(40,715)	(35,893)
Inventories, including inventory write-up effect in 2000	(71,531)	37,412
Accounts payable, other current liabilities and other long-term liabilities	68,302	40,447
Net cash provided by operating activities	317,766	64,716
Cash flows from investing activities:		
Purchases of securities available-for-sale	(1,022,169)	(453,077)
Proceeds from sales of securities available-for-sale	696,500	389,165
Purchases of non-marketable equity securities	(10,830)	(4,855)
Capital expenditures	(118,753)	(78,999)
Change in other assets	311	(20,935)
Transfer to restricted cash included in other assets	(61,417)	-
Net cash used in investing activities	(516,358)	(168,701)
Cash flows from financing activities:		
Stock issuances	73,771	150,388
Stock repurchases	(34,034)	-
Net cash provided by financing activities	39,737	150,388
Net (decrease) increase in cash and cash equivalents	(158,855)	46,403
Cash and cash equivalents at beginning of period	551,384	337,682
Cash and cash equivalents at end of period	$ 392,529	$ 384,085

See Notes to Condensed Consolidated Financial Statements.

CONDENSED CONSOLIDATED BALANCE SHEETS
(thousands)

	September 30, 2001 (unaudited)	December 31, 2000(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 392,529	$ 551,384
Short-term investments	1,107,914	642,475
Accounts receivable, net (including amounts		

from related party: 2001-$49,550; 2000-$36,299)	309,054	261,682
Inventories	340,069	265,830
Deferred tax assets	42,379	40,619
Prepaid expenses and other current assets	38,540	26,821
Total current assets	2,230,485	1,788,811
Long-term marketable securities	1,022,419	1,265,515
Property, plant and equipment (net of accumulated depreciation: 2001-$669,202; 2000-$604,332)	797,146	752,892
Goodwill (net of accumulated amortization: 2001-$958,458; 2000-$843,494)	1,340,814	1,455,778
Other intangible assets (net of accumulated amortization: 2001-$1,414,289; 2000-$1,282,090)	1,154,469	1,280,359
Other long-term assets	320,300	168,458
Total assets	$ 6,865,633	$ 6,711,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 149,692	$ -
Accounts payable	24,304	34,503
Other accrued liabilities (including amounts to related party: 2001-$6,989; 2000-$12,265)	469,793	414,178
Total current liabilities	643,789	448,681
Long-term debt	-	149,692
Deferred tax liabilities	344,062	349,848
Other long-term liabilities	69,935	89,389
Total liabilities	1,057,786	1,037,610
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	10,544	10,510
Additional paid-in capital	6,741,038	6,651,428
Accumulated deficit, since June 30, 1999	(1,235,011)	(1,319,353)
Accumulated other comprehensive income	291,276	331,618
Total stockholders' equity	5,807,847	5,674,203
Total liabilities and stockholders' equity	$ 6,865,633	$ 6,711,813

(1) Amounts obtained from audited financial statements.

See Notes to Condensed Consolidated Financial Statements.

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 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- and nine-month periods ended September 30, 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 the commercialization and development of future products.

Other Assets: Under certain lease agreements, we may be required from time to time to set aside cash as collateral. At September 30, 2001, other assets included $118.0 million of restricted cash related to such lease agreements.

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.

Changes in Accounting Principles

Securities and Exchange Commission's Staff Accounting Bulletin No. 101 (SAB 101): We adopted the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 on revenue recognition 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 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 three- and nine-months ended September 30, 2000 were restated to reflect the effects of the accounting change. For the quarter ended September 30, 2000, the impact of the change in accounting principle was to increase net income by $1.3 million (net of tax) of the related deferred revenue recognized as revenue during the quarter (less than $0.01 per share). For the nine months ended September 30, 2000, the impact of the change in accounting principle was to

increase net loss by $53.9 million, or ($0.10) per share, comprised of the $57.8 million cumulative effect of the change (net of tax) as described above ($0.11 per share), net of $3.9 million of the related deferred revenue (net of tax) that was recognized as revenue during the nine months ended September 30, 2000 ($0.01 per share). For the three- and nine-month periods ended September 30, 2001, we recognized $2.3 million (net of tax) and $10.5 million (net of tax) respectively, 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 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 $5.0 million, net of tax, 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 a 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 is 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. No collars were outstanding at September 30, 2001.

In the nine months ended September 30, 2001, we recognized a net gain of $10.0 million related to the change in the time value of certain hedging

instruments. In the third quarter of 2001, we had no such gains or losses. We record gains in contract and other revenues, and losses 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 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 as of December 31, 2000 and September 30, 2001. Our interest-rate swap agreements effectively convert a portion of our short-term investments in our interest bearing portfolio to a fixed-rate basis over the next two 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 September 30, 2001.

During the quarter ended September 30, 2001 and the first nine months of 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 September 30, 2001, we expect to reclassify $1.6 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.

Derivative Activity in Accumulated Other Comprehensive Income

The following table summarizes activity in other comprehensive income related to derivatives, net of taxes, held by us during the third quarter and first nine months of 2001 (in thousands):

	Three Months Ended September 30, 2001	Nine Months Ended September 30, 2001
Cumulative effect of adopting FAS 133	$ -	$ 5,020
Changes in fair value of derivatives	1,648	6,535
Gains reclassified from other comprehensive income	(433)	(2,172)
Accumulated derivative gains	$1,215	$ 9,383

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% of our common stock on that date. The Redemption was reflected as a purchase of a business which under U.S. 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 $15.8 million in cost of sales in the third quarter of 2000 and $90.4 million in the first nine months of 2000 related to the inventory adjustment.

- 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. 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. 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 and $95.3 million during the third quarter of 2001

and 2000, respectively, and $238.2 million and $285.8 million in the first nine months of 2001 and 2000, respectively.

- 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 $2.5 million in the third quarter of 2000 and $4.2 million and $8.6 million in the first nine months of 2001 and 2000, respectively.

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 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. On September 30, 2001, Roche's percentage ownership of our common stock was 58.15%, which was 2.06% below the Minimum Percentage. Genentech and Roche are in discussion concerning the matter.

Note 4. Comprehensive Income

Comprehensive income is comprised of net income (loss) 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 and its components for the three- and nine-month periods ended September 30, 2001 and 2000 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
		(Restated)		(Restated)
Net income (loss)	$ 42,741	$ 5,760	$108,140	$(89,516)
Changes in unrealized (loss) gain on securities available-for-sale, net of tax	(40,782)	103,328	(49,725)	167,139
Changes in fair value of derivative instruments, net of tax	1,215	-	9,383	-
Comprehensive income	$ 3,174	$109,088	$ 67,798	$ 77,623

The components of accumulated other comprehensive income, net of related taxes, are as follows (in thousands):

	September 30, 2001	December 31, 2000
Unrealized gains on securities available-for-sale	$281,893	$331,618
Unrealized gains on derivatives instruments	9,383	-
Accumulated other comprehensive income	$291,276	$331,618

Note 5. Earnings (Loss) Per Share

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings (loss) per share (EPS) computations for the three-

and nine-month periods ended September 30, 2001 and September 30, 2000 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000 (Restated)	2001	2000 (Restated)
Numerator:				
Net income (loss) - numerator for basic and diluted earnings (loss) per share:	$ 42,741	$ 5,760	$108,140	$(89,516)
Denominator:				
Denominator for basic earnings (loss) per share - weighted-average shares	527,328	522,928	526,709	521,097
Effect of dilutive securities:				
Stock options	6,342	18,555	8,074	-
Denominator for diluted earnings (loss) per share - adjusted weighted-average shares and assumed conversions	533,670	541,483	534,783	521,097

Options to purchase 9,971,552 shares of common stock between $44.06 and $95.66 per share were outstanding in the third quarter of 2001, and options to purchase 9,736,102 shares of common stock between $50.55 and $95.66 per share were outstanding in the first nine months of 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 antibody products, one of our thrombolytic products, as well as 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. The trial of this suit began on April 17, 2001.

On May 4, 2001 the jury hearing the lawsuit unanimously found that Herceptin and Rituxan do not infringe the patents and therefore that Genentech is not required to pay royalties to Glaxo. The jury also unanimously found that all of the patent claims that Glaxo asserted against Genentech were invalid. On May 31, 2001, Glaxo filed a notice of appeal of the jury's verdict with the U.S. Court of Appeals for the Federal Circuit. No date has been set for the argument of the appeal. Proceedings in connection with Genentech's claim against Glaxo for inequitable conduct and other related issues are still pending before the district court.

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 has been rescheduled to begin on June 17, 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. On January 4, 2001, we filed a motion to dismiss the case for lack of subject matter jurisdiction. The judge denied the motion on February 1, 2001. Jury selection for the trial began on August 28, 2001, and the trial is currently ongoing. City of Hope is seeking compensatory damages in the amount of approximately $445.0 million (including interest) and special damages.

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 on 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 filed a motion to dismiss this second lawsuit, which was denied. The judge

has scheduled the trial of this suit to begin in March 2003. This lawsuit is separate from and in addition to the Chiron suit mentioned above.

We and Pharmacia AB (formerly Pharmacia & Upjohn AB) are parties to a 1978 agreement relating to Genentech's development of recombinant human growth hormone products, under which Pharmacia is obligated to pay Genentech 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. The ICC has not yet given a decision on that claim.

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. On May 2, 2001, Genzyme 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. On May 3, 2001, we filed our answer to Genzyme's complaint. The court has consolidated this lawsuit and the declaratory judgement lawsuit suit referred to above for further proceedings. The trial of this consolidated lawsuit is scheduled to begin on January 21, 2003.

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

In anticipation of the launch of Xolair, we have built approximately $34.3 million of Xolair inventory, net of amounts paid by collaborators and inventory reserves. Due to the launch delay of Xolair, we will continually assess the recoverability of our Xolair inventory based on an expected U.S. Food and Drug Administration approval date and sales.

Inventories are summarized below (in thousands):

	September 30, 2001	December 31, 2000
Raw materials and supplies	$ 25,279	$ 17,621
Work in process	296,224	233,121
Finished goods	18,566	15,088
Total	$340,069	$265,830

Note 8. Capital Stock

In August 2001, we repurchased 800,000 shares of our common stock at an average price of approximately $42.50 per share.

Note 9. New Accounting Pronouncement

In July 2001, the Financial Accounting Standards Board, or FASB, issued two statements as a result of its deliberations on the business combinations project, Statement of Financial Accounting Standards No. 141, or FAS 141, on Business Combinations and FAS 142 on Goodwill and Other Intangible Assets. FAS 141 will be effective for any business combinations initiated after June 30, 2001 and also includes the criteria for the recognition of intangible assets separately from goodwill. FAS 142 will be effective for fiscal years beginning after December 15, 2001 and will require that goodwill not be amortized, but rather be subject to an impairment test at least annually. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that do not meet the new criteria for separate recognition of intangible assets will be subsumed into goodwill upon adoption. In addition, the useful lives of recognized intangible assets acquired in transactions completed before July 1, 2001 will be reassessed and the remaining amortization periods adjusted accordingly.

The adoption of FAS 141 and 142 is not expected to have a significant impact on our financial position at transition. We expect that the elimination of goodwill amortization related to push-down accounting would have a positive impact on reported net income in 2002 of at least $150.0 million.

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 September 30, 2001, and the related condensed consolidated statements of operations for the three-month and nine-month periods ended September 30, 2001 and 2000 and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 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

Palo Alto, California
October 8, 2001

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

GENENTECH, INC.
FINANCIAL REVIEW

Overview

Genentech, Inc. is a leading biotechnology company using human genetic information to discover, develop, manufacture and market human pharmaceuticals that address significant unmet medical needs. Fifteen of the approved products of biotechnology stem from or are based on our science. We manufacture and market ten 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;

- Cathflo Activase (alteplase, recombinant) tissue plasminogen activator, or t-PA, approved for the restoration of function to central venous access devises that have become occluded due to a blood clot;

- 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 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 on sales of tenecteplase outside of the United States (excluding Japan and Canada). 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 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 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. On September 30, 2001,

Roche's percentage ownership of our common stock was 58.15%, which was 2.06% below the Minimum Percentage. Genentech and Roche are in discussion concerning the matter.

RESULTS OF OPERATIONS
(dollars in millions, except per share amounts)

REVENUES	Three Months Ended September 30, 2001	2000 (Restated)	% Change	Nine Months Ended September 30, 2001	2000 (Restated)	% Change
Revenues	$556.1	$447.3	24%	$1,612.1	$1,251.0	29%

Revenues increased 24% in the third quarter and 29% in the first nine months of 2001 from the comparable periods in 2000 primarily as a result of higher product sales, royalty income and interest income. These increases were partially offset by lower contract and other revenues. These revenue changes are further discussed below.

PRODUCT SALES	Three Months Ended September 30, 2001	2000	% Change	Nine Months Ended September 30, 2001	2000	% Change
Herceptin	$ 83.9	$ 72.6	16%	$ 244.0	$208.0	17%
Rituxan	212.8	117.9	80	572.6	305.8	87
Activase/TNKase/Cathflo	48.6	50.7	(4)	152.3	155.0	(2)
Growth Hormone	67.7	61.1	11	185.7	166.1	12
Pulmozyme	32.8	30.0	9	90.9	89.1	2
Actimmune	2.9	1.9	53	5.4	2.8	93
Total product sales	$448.7	$334.2	34%	$1,250.9	$926.8	35%

Total product sales increased 34% in the third quarter and 35% in the first nine months of 2001 from the comparable periods in 2000 primarily as a result of higher sales from our bio-oncology products, Rituxan and Herceptin, and higher sales from our Growth Hormone products.

Herceptin: Net sales of Herceptin increased 16% in the third quarter and 17% in the first nine months of 2001 from the comparable periods in 2000. An increase in penetration into the metastatic breast cancer market has contributed to a positive sales trend.

Rituxan: Net sales of Rituxan increased 80% in the third quarter and 87% in the first nine months of 2001 from the comparable periods 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/Cathflo: Combined net sales of our three cardiovascular products, Activase, TNKase and Cathflo Activase, decreased 4% in the third quarter of 2001 and were slightly lower in the first nine months of 2001 compared to the same periods last year. These decreases reflect the continued decline in the overall size of the thrombolytic therapy market due to increasing use of mechanical reperfusion and competition from Centocor, Inc.'s Retavase, registered trademark, (reteplase). Cathflo Activase received U.S. Food and Drug Administration, or FDA, approval in early September 2001 and was launched in late September 2001. TNKase received 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 11% in the third quarter and 12% in the first nine months of 2001 from the comparable periods in 2000. This net sales growth primarily reflects an increase in market penetration and the effects of a price increase for these products.

Pulmozyme: Net sales of Pulmozyme increased 9% in the third quarter of 2001 and were slightly higher in the first nine months of 2001 compared to the same periods last year. These increases primarily reflect fluctuations in distributor ordering patterns.

ROYALTIES, CONTRACT AND OTHER, AND INTEREST INCOME	Three Months Ended September 30, 2001	2000 (Restated)	% Change	Nine Months Ended September 30, 2001	2000 (Restated)	% Change
Royalties	$ 66.0	$ 51.8	27%	$193.1	$148.8	30%
Contract and other	8.9	35.6	(75)	68.3	106.0	(36)
Interest income	32.5	25.7	26	99.8	69.4	44

Royalties: Royalty income increased 27% in the third quarter and 30% in the first nine months of 2001 from the comparable periods in 2000. These increases were primarily due to higher third-party sales from Roche and various licensees, offset in part by lower sales from several licensees including one that has been addressing manufacturing issues which has temporarily impacted their ability to produce product for sales.

Contract and Other Revenues: Contract and other revenues decreased 75% in the third quarter and 36% in the first nine months of 2001 from the comparable periods in 2000. The decrease in the third quarter was primarily due to lower gains from the sale of biotechnology equity securities. The decrease in the first nine months of 2001 was attributable to lower gains from the sale of biotechnology equity securities partially offset by higher contract revenues and the recognition of $10.0 million in gains related to the change in the time value of certain hedging instruments in the first quarter of 2001. (See Note 1, "Statement of Accounting Presentation and Significant Accounting Policies," of the Notes to Condensed Consolidated Financial Statements for more information on our derivative and hedging activities.) The increase in contract revenues in the first nine months of 2001 was primarily due to the recognition of revenues from third-party collaborators that were previously deferred under the Securities and Exchange Commission's Staff Accounting Bulletin No. 101. (See the "Changes in Accounting Principles" section of Note 1, "Statement of Accounting Presentation and Significant Accounting Policies," of the Notes to Condensed Consolidated Financial Statements.)

Interest Income: Interest income increased 26% in the third quarter and 44% in the first nine months of 2001 from the comparable periods in 2000. The increase in the third quarter of 2001 was due to a higher portfolio balance, offset in part by a lower portfolio yield. The increase in the first nine months of 2001 was primarily due to a higher portfolio balance.

	Three Months Ended September 30,			Nine Months Ended September 30,	
COSTS AND EXPENSES	2001	2000	% Change	2001	2000
Cost of sales	$ 96.0	$ 91.4	5%	$ 256.0	$ 295.1
Research and development	128.2	113.6	13	388.0	340.6
Marketing, general and administrative	109.4	94.1	16	345.1	264.0
Collaboration profit sharing	65.8	37.6	75	170.1	86.9
Recurring charges related to redemption	79.4	97.8	(19)	242.4	294.4
Interest expense	1.7	1.2	42	4.5	3.7
Total costs and expenses	$480.5	$435.7	10%	$1,406.1	$1,284.7

Cost of Sales: Cost of sales in the third quarter of 2001 increased to $96.0 million compared to $91.4 million in the third quarter of 2000 and decreased to $256.0 million in the first nine months of 2001 compared to $295.1 million in the first nine months of 2000. Cost of sales as a percent of product sales decreased to 21% in the third quarter of 2001 from 27% in the prior year. Cost of sales as a percent of product sales decreased to 20% in the first nine months of 2001 from 32% in the prior year. The decrease in the ratios 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 was sold by December 31, 2000.

Research and Development: Research and development, or R&D, expenses increased 13% in the third quarter and 14% in the first nine months of 2001 from the comparable periods in 2000. The increase in the third quarter of 2001 was largely due to higher expenses related to late-stage clinical trials and increased in-licensing expenses. The increase in the first nine months of 2001 was primarily due to higher expenses related to late-stage clinical trials and costs related to the termination of a collaboration agreement. R&D expenses included $19.0 million in the first nine months of 2001 and $15.0 million in the comparable period of 2000 of upfront payments 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 16% in the third quarter and 31% in the first nine months of 2001 from the comparable periods in 2000. The increase in the third quarter of 2001 was primarily due to increased royalty expenses associated with higher sales by licensees, higher marketing and selling expenses primarily in support of the continued growth of our bio-oncology products and commercial development of pipeline products and higher corporate expenses. The increase in the first nine months of 2001 was driven by higher marketing and selling expenses in support of commercial development of pipeline products and the continued growth of our bio-oncology products, the write-down of certain biotechnology investments, higher royalty expenses and higher legal and other corporate expenses.

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 the commercialization and development of future products. Collaboration profit sharing expenses increased to $65.8 million in the third quarter of 2001 from $37.6 million in the third quarter of 2000. Collaboration profit sharing expenses increased to $170.1 million in the first nine months of 2001 from $86.9 million in the first nine months of 2000. These increases were primarily due to increased Rituxan profit sharing with IDEC due to higher Rituxan sales.

Recurring Charges Related to Redemption: We began recording recurring charges related to the Redemption and push-down accounting in the third quarter of 1999. These charges include the amortization of intangibles and goodwill, and compensation expense 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. Recurring charges related to the Redemption decreased to $79.4 million in the third quarter of 2001 compared to $97.8 million in the same period of 2000 and decreased to $242.4 million in the first nine months of 2001 compared to $294.4 million in the same period of 2000. These decreases were primarily due to lower amortization of intangibles and deferred compensation expense. The deferred compensation was fully amortized at June 30, 2001. (See Note 2, "Redemption of Our Special Common Stock," of the Notes to Condensed Consolidated Financial Statements.)

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 September 30,			Nine Months Ended September 30,		
	2001	2000	% Change	2001	2000	% C
		(Restated)			(Restated)	
Income (loss) before taxes and cumulative effect of accounting change	$75.6	$ 11.7	546%	$206.0	$(33.7)	
Income tax provision (benefit)	32.9	5.9	458	92.2	(2.0)	4,
Income (loss) before cumulative effect of accounting change	42.7	5.8	636	113.8	(31.7)	
Cumulative effect of accounting change, net of tax	-	-	-	(5.6)	(57.8)	

Changes in Accounting Principles: 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 $5.0 million, net of tax, 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 September 30, 2000, the impact of the change in accounting principle was to increase net income by $1.3 million (net of tax) of the related deferred revenue recognized as revenue during the quarter ended September 30, 2000 (less than $0.01 per share). For the nine months ended September 30, 2000, the impact of the change in accounting principle was to increase net loss by $53.9 million, or ($0.10) per share, comprised of the $57.8 million cumulative effect of the change (net of tax) as described above ($0.11 per share), net of $3.9 million of the related deferred revenue (net of tax) that was recognized as revenue during the nine months ended September 30, 2000 ($0.01 per share). For the three-

and nine-month periods ended September 30, 2001, we recognized $2.3 million (net of tax) and $10.5 million (net of tax) respectively, 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 $32.9 million for the third quarter of 2001 increased over the tax provision of $5.9 million for the third quarter of 2000. The tax provision of $92.2 million for the first nine months of 2001 increased over the tax benefit of $2.0 million for the first nine months of 2000 primarily due to increased pretax income and decreased charges related to the Redemption.

Our effective tax rates were approximately 44% for the third quarter and 45% for the first nine months of 2001 and 50% for the third quarter and 6% for the first nine months of 2000, which reflect the non-deductibility of goodwill amortization.

The effective tax rate of 32% in the third quarter and first nine months 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 third quarter and first nine months of 2000 primarily due to decreased R&D tax credits.

	Three Months Ended September 30,			Nine Months Ended September 30,	
NET INCOME (LOSS)	2001	2000	% Change	2001	2000
		(Restated)			(Restated
Net income (loss)	$ 42.7	$ 5.8	636%	$108.2	$(89.5)
Earnings (loss) per share:					
Basic: Earnings (loss) before cumulative effect of accounting change	$ 0.08	$ 0.01	700%	$ 0.22	$(0.06)
Cumulative effect of accounting change, net of tax	-	-	-	(0.01)	(0.11)
Net earnings (loss) per share	$ 0.08	$ 0.01	700%	$ 0.21	$(0.17)
Diluted: Earnings (loss) before cumulative effect of accounting change	$ 0.08	$ 0.01	700%	$ 0.21	$(0.06)
Cumulative effect of accounting change, net of tax	-	-	-	(0.01)	(0.11)
Net earnings (loss) per share	$ 0.08	$ 0.01	700%	$ 0.20	$(0.17)

Net Income (Loss): Net income of $42.7 million, or $0.08 per diluted share in the third quarter of 2001 and net income of $108.2 million, or $0.20 per diluted share in the first nine months of 2001, primarily reflect an increase in product sales, royalties and interest income and a decrease in recurring charges related to redemption and costs related to the sale of inventory written up at the Redemption. These favorable variances were offset in part by increased MG&A, collaboration profit sharing and R&D expenses and a decrease in contract and other revenues.

In-Process Research and Development: At June 30, 1999, the Redemption date, we determined that the acquired in-process technology was not technologically feasible and that the in-process technology had no future alternative uses. As a result, $500.5 million of in-process research and development, or IPR&D,

related to Roche's 1990 through 1997 purchases of our common stock was

charged to additional paid-in capital, and $752.5 million of IPR&D related to the Redemption was charged to operations at June 30, 1999.

Except as otherwise noted below, there have been no significant changes to the 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 $650.0 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 significant changes that occurred during the first nine months of 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 for this indication.
- Activase t-PA for intravenous catheter clearance - project received FDA approval in September 2001.
- Anti-IgE antibody for asthma and seasonal allergic rhinitis - FDA complete response letter received. We plan to submit the data requested by the FDA in late 2002 or in early 2003.

LIQUIDITY AND CAPITAL RESOURCES	September 30, 2001	December 31, 2000
Cash and cash equivalents, short-term investments and long-term marketable securities	$2,522.9	$2,459.4
Working capital	1,586.7	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 and stock repurchases.

Cash and cash equivalents, short-term investments and long-term marketable securities at September 30, 2001 increased from December 31, 2000 by $63.5 million. Working capital increased by $246.6 million in the third quarter of 2001 from December 31, 2000.

Capital expenditures totaled $118.8 million in the first nine months of 2001 compared to $79.0 million in the comparable period of 2000. The increase in

2001 compared to 2000 was primarily due to an increase in machinery and equipment and 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, 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 - Future Stock Repurchases 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 the first nine months of 2001 and 2000 primarily due to competition from Centocor's Retavase and 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 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, sales of Pulmozyme to Hoffmann-La Roche decreased in the third quarter and the first nine months of 2001 compared to the same periods last year.

  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 Rituxan increased in the last quarter of 2000 and the first nine months 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-Hodgkin's 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.

  For example, in April 2001, we announced that a Phase III clinical trial of Veletri - 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.

  For example, in October 2001, the FDA requested inclusion of an additional pharmacokinetics study in the potential BLA submission for Xanelim which will result in the filing date occurring later than originally estimated.

- Failure to receive the necessary regulatory approvals or delay in receiving such approvals.

  For example, in July 2001, we received a Complete Response letter from the FDA for the license application for Xolair that was filed with the FDA in 2000. The letter requests additional preclinical and clinical data, as well as pharmacokinetic information. With the requirement of additional

data, FDA approval of Xolair has been delayed beyond 2001. It is also anticipated that the initial proposed label claim will likely be for only adult allergic asthma. The exact timing of resubmission to the FDA will be dependent on the scope of the discussions with the FDA but is expected to occur in 2002 or early 2003. In anticipation of the launch of Xolair, we have built approximately $34.3 million of Xolair inventory, net of amounts paid by collaborators and inventory reserves. Due to the launch delay of Xolair, we will continually assess the recoverability of our Xolair inventory based on an expected FDA approval date and sales.

- Manufacturing costs or other factors that make the product uneconomical.

- The proprietary rights of others and their competing products and technologies that may prevent the product from being 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 third quarter and first nine months 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 Veletri 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, Tarceva, 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

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

- Require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock based on an established Minimum Percentage. For information regarding Minimum Percentage, see Note 3, "Relationship with Roche -- Roche's Right to Maintain Its Percentage Ownership Interest in Our Stock" in the Notes to Condensed Consolidated Financial Statements.

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.

- Provisions limiting the liability of specified employees.

Our certificate of incorporation provides that any person purchasing or acquiring an interest in shares of our capital stock shall be deemed to have consented to the provisions in the certificate of incorporation relating to competition with Roche, conflicts of interest with Roche, the offer of corporate opportunities to Roche and intercompany agreements with Roche. This deemed consent 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

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 mechanical reperfusion 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. 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 a revised Biologics License Application, or BLA, for Bexxar, trademark, (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan, and the FDA's Oncologic Drugs Advisory Committee has recommended approval of IDEC's BLA for Zevalin, trademark, (ibritumomab 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.

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 Nordisk A/S, 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 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.

- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.

For example, as described in Note 6, "Legal Proceedings," in the Notes to Condensed Consolidated Financial Statements of Part I, several companies have filed patent infringement lawsuits against us alleging that the manufacture, use and sale of certain of our products infringe their patents.

- The increasing use and development of alternate therapies.

  For example, the overall size of the market for thrombolytic therapies, such as our Activase product, continues to decline as a result of the increasing use of mechanical reperfusion.

- The rate of market penetration by competing products.

  For example, 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 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.

Effective for fiscal years beginning after December 15, 2001, the adoption of the Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards No. 142, or FAS 142, will require that

goodwill not be amortized, but rather be subject to an impairment test at least annually. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001, that do not meet the new criteria for separate recognition of intangible assets will be subsumed into goodwill upon adoption. In addition, the useful lives of recognized intangible assets acquired in transactions completed before July 1, 2001, will be reassessed and the remaining amortization periods adjusted accordingly. We will continuously evaluate whether events and circumstances have occurred that indicate the remaining balance of goodwill and other intangible assets may not be recoverable. If our evaluation of the assets results in a 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. For more information regarding FAS 142, see "New Accounting Pronouncement Could Impact Our Financial Position and Results of Operations" below.

Our Royalty and Contract Revenues Could Decline

Royalty and contract revenues in future periods could vary significantly. Major factors affecting these revenues include, but are not limited to:

- Hoffmann-La Roche's decisions whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.

- Variations in Hoffmann-La Roche's sales and other licensees' sales of licensed products.

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

  For example, in the second quarter of 2001, we reacquired from Schwarz Pharma AG the exclusive development and marketing rights for Nutropin AQ and Nutropin Depot in Europe and other countries outside the United States, Canada, China and Japan.

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

  For example, we expect the approval of Herceptin outside the United States, which occurred in the 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.

- Whether and when contract benchmarks are achieved.

- The failure of or refusal of a licensee to pay royalties.

- The expiration or invalidation of patents or licensed intellectual property.

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

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. Our current patent litigation matters are discussed in Note 6, " Legal Proceedings," in the Notes to Condensed Consolidated Financial Statements of Part I. 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.

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.

We May Incur Material Litigation Costs

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

  For example, see "The Successful Development of Pharmaceutical Products is Highly Uncertain" above for a description of the delay in receipt of FDA approval for Xolair.

- 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.

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

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 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 July 2001, we passed a full inspection by the FDA Team Biologics confirming that Genentech is in a full state of manufacturing compliance.

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 a utility such as 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.

Future Stock Repurchases Could Adversely Affect Our Cash Position

We have reviewed the practices of other companies in our and related industries with respect to the use of share repurchases to offset the dilution of stock options and employee stock purchase plan purchases. Based upon an ongoing review of such factors as current interest rates, current market conditions, our current share price and also the share repurchase provisions of our affiliation agreement with Roche, we may repurchase shares of our common stock on the open market from time to time.

While the dollar amounts associated with these future stock repurchases cannot currently be estimated, these stock repurchases could have a material adverse effect on our cash position, credit rating and ability to access capital in the financial markets, and could limit our ability to use our capital stock as consideration for acquisitions.

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. For example, our common 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 $38.65 per share in July 2001.

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.

- Developments concerning proprietary rights, including patents.

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

- Regulatory developments concerning our products in the United States and foreign countries.

- Issues concerning the safety of our products or of biotechnology products generally.

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

- Period-to-period fluctuations in financial results.

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 based on an established Minimum Percentage. For information regarding Minimum Percentage, see Note 3, "Relationship with Roche -- Roche's Right to Maintain Its Percentage Ownership Interest in Our Stock" in the Notes to Condensed Consolidated Financial Statements.

While the dollar amounts associated with these future stock repurchases cannot currently be estimated, these 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.

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

As of September 30, 2001, Roche owned 306,594,352 shares of our common stock or approximately 58.15% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our common stock. Sales of a substantial number of shares of our common stock by Roche in the public market could adversely affect the market price of our common stock.

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 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 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 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.

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

In July 2001, the Financial Accounting Standards Board, or FASB, issued two statements as a result of its deliberations on the business combinations project, Statement of Financial Accounting Standards No. 141, or FAS 141, on Business Combinations and FAS 142 on Goodwill and Other Intangible Assets. FAS 141 will be effective for any business combinations initiated after June 30, 2001 and also includes the criteria for the recognition of intangible assets separately from goodwill. FAS 142 will be effective for fiscal years beginning after December 15, 2001 and will require that goodwill not be amortized, but rather be subject to an impairment test at least annually. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that do not meet the new criteria for separate recognition of intangible assets will be subsumed into goodwill upon adoption. In addition, the useful lives of recognized intangible assets acquired in transactions completed before July 1, 2001 will be reassessed and the remaining amortization periods adjusted accordingly.

The adoption of FAS 141 and 142 is not expected to have a significant impact on our financial position at transition. We expect that the elimination of goodwill amortization related to push-down accounting would have a positive impact on reported net income in 2002 of at least $150.0 million.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2001 have not changed significantly from those discussed in Item 7A of our Form 10-K for the period ended December 31, 2000 on file with the Securities and Exchange Commission. See also the

"Derivative and Hedging Activities" section of Note 1, "Statement of Accounting Presentation and Significant Accounting Policies" of Item 1 and the "Forward-Looking Information and Cautionary Factors That May Affect Future Results--We Are Exposed to Market Risk" section of Item 2 of this Form 10-Q for additional discussions of our market risks.

GENENTECH, INC.
PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In connection with the patent infringement lawsuit filed against us by GlaxoSmithKline plc on May 28, 1999, the jury hearing the lawsuit unanimously found that Herceptin and Rituxan do not infringe the Glaxo patents and therefore that Genentech is not required to pay royalties to Glaxo. The jury also unanimously found that all of the patent claims that Glaxo asserted against Genentech were invalid. On May 31, 2001, Glaxo filed a notice of appeal of the jury's verdict with the U.S. Court of Appeals for the Federal Circuit. No date has been set for the argument of the appeal. Proceedings in connection with Genentech's claim against Glaxo for inequitable conduct and other related issues are still pending before the district court.

In connection with the declaratory judgement lawsuit filed by Genentech against Genzyme Corporation on March 13, 2001, and the patent infringement lawsuit filed by Genzyme against us on April 6, 2001, Genzyme filed its answer to our complaint on May 2, 2001 and Genentech filed its answer to Genzyme's complaint on May 3, 2001. The court has consolidated these two lawsuits for further proceedings. The trial date of this consolidated suit is scheduled to begin January 21, 2003.

In connection with the breach of contract lawsuit filed against us by City of Hope Medical Center on August 13, 1999, jury selection for the trial began on August 28, 2001, and the trial is currently ongoing. City of Hope is seeking compensatory damages in the amount of approximately $445.0 million (including interest) and special damages.

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

See also Item 1 of our reports on Form 10-Q for the periods ended March 31, 2001 and June 30, 2001.

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

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

15.1 Letter regarding Unaudited Interim Financial Information.

(b) Reports on Form 8-K

There were no reports on Form 8-K filed during the quarter ended September 30, 2001.

GENENTECH, INC.
SIGNATURES

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

GENENTECH, INC.

Date: October 12, 2001

/s/ARTHUR D. LEVINSON
Arthur D. Levinson, Ph.D.
Chairman and Chief Executive Officer

Date: October 12, 2001

/s/LOUIS J. LAVIGNE, JR.
Louis J. Lavigne, Jr.
Executive Vice President and Chief Financial Officer

Date: October 12, 2001

/s/JOHN M. WHITING
John M. Whiting
Vice President, Controller and Chief Accounting Officer