

GENENTECH INC  
Form 10-Q  
November 06, 2003

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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(Mark One)

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

For the quarterly period ended September 30, 2003

or

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

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

Commission file number: 1-9813

GENENTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-2347624

(State or other jurisdiction  
of incorporation or organization)

(I.R.S. Employer  
Identification Number)

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

(Address of principal executive offices and Zip Code)

(650) 225-1000

(Registrant's telephone number, including area code)

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

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

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

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock \$0.02 par value	523,198,596 Outstanding at October 30, 2003

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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 and "Special Common Stock" refers to Genentech's callable puttable common stock, par value \$0.02 per share, all of which was redeemed by Roche Holdings, Inc. on June 30, 1999.

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin™ (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis™ (ranibizumab, rhuFab V2) anti-VEGF antibody fragment; Nutropin® (somatropin (rDNA origin) for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen™ (somatropin (rDNA origin) for injection) liquid formulation growth hormone; Nutropin Depot® (somatropin (rDNA origin) for injectable suspension) encapsulated sustained-release growth hormone; Omnitarg™ (pertuzumab); Protropin® (somatrem for injection) growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva™ (efalizumab, formerly Xanelim™) anti-CD11a antibody; and TNKase™ (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of IDEC Pharmaceuticals Corporation; Tarceva™ (erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks and trade names of other companies.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

GENENTECH, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

Three Months  
Ended September 30,

Nine Months  
Ended September 30,

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	2003	2002	2003	2002
<b>Revenues:</b>				
Product sales (including amounts from related parties:				
three months - 2003-\$18,040;	654,948	551,823	\$ 1,897,754	\$ 1,551,899
2002-\$30,192;				
nine months - 2003-\$83,224;				
2002-\$82,858)	\$	\$		
Royalties (including amounts from related party:				
three months - 2003-\$59,912;	116,535	85,082	352,597	252,460
2002-\$37,761;				
nine months - 2003-\$164,376;				
2002-\$97,036)				
Contract revenue (including amounts from related parties:				
three months - 2003-\$31,332;	45,561	13,233	116,078	36,104
2002-\$925;				
nine months - 2003-\$52,035;				
2002-\$9,578)				
<b>Total operating revenues</b>	<b>817,044</b>	<b>650,138</b>	<b>2,366,429</b>	<b>1,840,463</b>
<b>Costs and expenses</b>				
Cost of sales (including amounts for related party:				
three months - 2003-\$20,517;		112,481	353,921	321,792
2002-\$25,161;				
nine months - 2003-\$75,360;				
2002-\$70,045)	115,673			
Research and development (including contract related:				
three months - 2003-\$29,660;		143,659	506,343	438,272
2002-\$2,568;				
nine months - 2003-\$56,112;				
2002-\$15,076)	168,707			
Marketing, general and administrative	209,860	135,553	531,340	376,644
Collaboration profit sharing	119,676	90,048	323,530	246,216
Recurring charges related to redemption	38,586	38,928	115,758	116,784
Special items: litigation-related	(131,617)	12,512	(105,008)	530,512
<b>Total costs and expenses</b>	<b>520,885</b>	<b>533,181</b>	<b>1,725,884</b>	<b>2,030,220</b>
Operating margin (loss)	296,159	116,957	640,545	(189,757)
Other income, net	15,884	15,169	72,456	80,404
Income (loss) before taxes and cumulative effect of accounting change	312,043	132,126	713,001	(109,353)
Income tax provision (benefit)	112,407	42,822	229,549	(80,312)

Income (loss) before cumulative effect of accounting change	199,636	89,304	483,452	(29,041)
Cumulative effect of accounting change, net of tax	(47,655)	-	(47,655)	-
Net income (loss)	<u>\$ 151,981</u>	<u>\$ 89,304</u>	<u>\$ 435,797</u>	<u>\$ (29,041)</u>
Earnings (loss) per share:				
Basic:				
Earnings (loss) before cumulative effect of accounting change	\$ 0.38	\$ 0.17	\$ 0.94	\$ (0.06)
Cumulative effect of accounting change, net of tax	(0.09)	-	(0.09)	-
Net earnings (loss) per share	<u>\$ 0.29</u>	<u>\$ 0.17</u>	<u>\$ 0.85</u>	<u>\$ (0.06)</u>
Diluted:				
Earnings (loss) before cumulative effect of accounting change	\$ 0.38	\$ 0.17	\$ 0.92	\$ (0.06)
Cumulative effect of accounting change, net of tax	(0.09)	-	(0.09)	-
Net earnings (loss) per share	<u>\$ 0.29</u>	<u>\$ 0.17</u>	<u>\$ 0.83</u>	<u>\$ (0.06)</u>
Weighted-average shares used to compute earnings (loss) per share:				
Basic	<u>520,381</u>	<u>516,025</u>	<u>515,070</u>	<u>520,889</u>
Diluted	<u>532,786</u>	<u>519,429</u>	<u>525,825</u>	<u>520,889</u>

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)  
(Unaudited)

Nine Months  
Ended September 30,

2003

2002

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Cash flows from operating activities:		
Net income (loss)	\$ 435,797	\$ (29,041)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Cumulative effect of accounting change, net of tax	47,655	-
Depreciation and amortization	220,926	205,029
Deferred income taxes	(156,918)	(258,708)
Gains on sales of securities available-for-sale and other	(19,304)	(48,889)
Losses on sales of securities available-for-sale	1,507	5,457
Write-down of securities available-for-sale	3,764	33,058
Loss on fixed asset dispositions	8,914	15,920
Changes in assets and liabilities:		
Receivables and other current assets	(73,878)	7,976
Inventories	(47,063)	(37,647)
Investments in trading securities	(26,701)	(110,163)
Accounts payable, other current liabilities and other long-term liabilities	341,676	102,277
Long-term deferred revenue	213,398	10,575
Litigation-related liabilities	42,964	530,512
<b>Net cash provided by operating activities</b>	<b>992,737</b>	<b>426,356</b>
Cash flows from investing activities:		
Purchases of securities available-for-sale	(1,168,001)	(476,851)
Proceeds from sales and maturities of securities available-for-sale	398,045	933,333
Capital expenditures	(211,245)	(244,626)
Change in other assets	(41,308)	22,836
<b>Net cash (used in) provided by investing activities</b>	<b>(1,022,509)</b>	<b>234,692</b>
Cash flows from financing activities:		
Stock issuances	431,606	59,151
Stock repurchases	(195,274)	(609,180)
Repayment of short-term debt	-	(149,692)
<b>Net cash provided by (used in) financing activities</b>	<b>236,332</b>	<b>(699,721)</b>
Net increase (decrease) in cash and cash equivalents	206,560	(38,673)
Cash and cash equivalents at beginning of period	208,130	395,203
Cash and cash equivalents at end of period	\$ 414,690	\$ 356,530

GENENTECH, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2003	December 31, 2002
<b>Assets:</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 414,690	\$ 208,130
Short-term investments	972,533	826,442
Accounts receivable - product sales (net of allowances: 2003-\$20,081; 2002-\$16,827; including amounts from related parties: 2003-\$10,350; 2002-\$18,564)	286,160	242,907
Accounts receivable - royalties (net of allowances: 2003-\$1,833; 2002-\$1,833; including amounts from related party: 2003-\$92,793; 2002-\$60,615)	151,884	116,423
Accounts receivable - other (net of allowances: 2003-\$2,991; 2002-\$3,171; including amounts from related parties: 2003-\$44,920; 2002-\$27,715)	62,707	59,151
Inventories	423,439	393,542
Prepaid expenses and other current assets	282,908	236,189
<b>Total current assets</b>	<b>2,594,321</b>	<b>2,082,784</b>
Long-term marketable securities and other	1,306,143	567,286
Property, plant and equipment (net of accumulated depreciation: 2003-\$865,735; 2002-\$727,612)	1,540,849	1,068,734
Goodwill	1,334,219	1,334,219
Other intangible assets (net of accumulated amortization: 2003-\$1,706,512; 2002-\$1,578,884)	827,109	927,538
Restricted cash	686,600	686,600
Other long-term assets	106,504	110,158
<b>Total assets</b>	<b>\$ 8,395,745</b>	<b>\$ 6,777,319</b>
<b>Liabilities and stockholders' equity:</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 66,479	\$ 51,380

Other accrued liabilities (including amounts due to related parties: 2003-\$20,149; 2002-\$51,116)	719,564	595,280
<b>Total current liabilities</b>	<b>786,043</b>	<b>646,660</b>
Litigation-related liabilities	595,149	552,185
Long-term debt	412,250	-
Deferred revenue	282,931	69,533
Other long-term liabilities	75,326	170,057
<b>Total liabilities</b>	<b>2,151,699</b>	<b>1,438,435</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Preferred stock	-	-
Common stock	10,444	10,256
Additional paid-in capital	7,213,593	6,650,352
Accumulated deficit, since June 30, 1999	(1,279,139)	(1,590,366)
Accumulated other comprehensive income	299,148	268,642
<b>Total stockholders' equity</b>	<b>6,244,046</b>	<b>5,338,884</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 8,395,745</b>	<b>\$ 6,777,319</b>

See Notes to Condensed Consolidated Financial Statements.

GENENTECH, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

We prepared the condensed consolidated financial statements following the requirements of the Securities and Exchange Commission (or SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by accounting principles generally accepted in the United States of America (or GAAP) can be condensed or omitted. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of our financial position and operating results.



Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those for the full year. The information included in this quarterly report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2002.

#### Principles of Consolidation

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

#### Use of Estimates

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

#### Accounts Receivable Allowances

Our accounts receivable includes trade, royalty and other receivables and consists primarily of amounts due to us from our normal business activities. We have significant estimates primarily related to our trade receivables. To determine the collectibility of our trade receivables, we prepare estimates for discounts, rebates and sales returns and allowances based primarily on analysis of existing contractual obligations, historical trends and experience and changes in customer financial conditions.

#### Change in Accounting Principle

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

We adopted FIN 46 on July 1, 2003, and consolidated the entity from which we lease our manufacturing facility located in Vacaville, California as of that date, as we determined that this entity is a VIE, as defined by FIN 46, and that we absorb a majority of its expected losses. Accordingly, we consolidated assets, which consist of the Vacaville manufacturing building and related equipment, which together had a carrying value of \$362.7 million, net of accumulated depreciation on July 1, 2003. Such property and equipment is included in property, plant and equipment in the accompanying condensed consolidated balance sheet at September 30, 2003. On July 1, 2003, we also consolidated the entity's debt of \$412.3 million and noncontrolling interests of \$12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, in the accompanying condensed consolidated

balance sheet at September 30, 2003. We recorded a \$47.6 million charge, net of tax, (or \$0.09 per share) as a cumulative effect of the accounting change on July 1, 2003. Due to our residual value guarantee on the property, the nonrecourse feature of the underlying debt, and certain other provisions of the lease arrangement, we do not allocate any of the entities' depreciation or interest expenses to the noncontrolling interest. We had previously accounted for our involvement with this entity as an operating lease. See also Note 2, "Leases and Contingencies," below for a discussion of all of our leases.

#### Reclassifications

Effective January 1, 2003, we made certain classification changes to our condensed consolidated statements of operations. Comparable amounts in the prior year have been reclassified to conform to the 2003 presentation. These classification changes included:

- a new caption titled "other income, net" (see below for the composition of this new caption),
- a change from the "contract and other" caption to the new "contract revenues" caption (the gains on sales of biotechnology equity securities, which were previously included in "contract and other," are now reflected in the new "other income, net" caption), and
- a change from including write-downs of biotechnology equity securities and changes in the recoverability of our debt securities in "marketing, general and administrative" expenses to including them in the new "other income, net" caption.

The following table summarizes the components of "other income, net" (in thousands):

Other Income, Net	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Gains on sales of biotechnology equity securities and other	\$ 763	\$ 17,930	\$ 20,979	\$ 35,110
Write-downs of biotechnology debt and equity securities	-	(23,607)	(3,764)	(33,058)
Interest income	16,086	20,846	56,206	79,105
Interest expense	(965)	-	(965)	(753)
<b>Total other income, net</b>	<b>\$ 15,884</b>	<b>\$ 15,169</b>	<b>\$ 72,456</b>	<b>\$ 80,404</b>

As part of our strategic alliance efforts, we invest in debt and equity securities of certain biotechnology companies with which we have or have had collaborative agreements. The "other income, net" caption now includes realized gains and losses from the sale of certain of these biotechnology equity securities as well as changes in the recoverability of our debt securities. In addition, "other income, net" includes write-downs for other-than-temporary declines in the fair value of certain of these biotechnology debt and equity securities, interest income and interest expense, net of amounts capitalized in 2002.

Certain other reclassifications of prior year amounts have been made to our condensed consolidated statements of operations and our condensed consolidated balance sheets to conform to the current year presentation.

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## Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (or EITF) of the FASB issued EITF 00-21, "Revenue Arrangements with Multiple Deliverables," which addresses certain aspects of the accounting for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. Under EITF 00-21, revenue arrangements with multiple deliverables should be divided into separate units of accounting if certain criteria are met, including whether the delivered item has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. In addition, the consideration should be allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria should be considered separately for each of the separate units. EITF 00-21 is effective for revenue arrangements entered into beginning July 1, 2003. Our adoption of EITF 00-21 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45 (or FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. Our adoption of FIN 45 did not have a material impact on our results of operations and financial position. See Note 2, "Leases and Contingencies," below for a discussion of our exposure related to our agreement with Serono S.A. and our synthetic leases and the related residual value guarantees.

In December 2002, the FASB issued Statement No. 148 (or FAS 148), "Accounting for Stock-Based Compensation - Transition and Disclosure." FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options. Under APB 25, we do not recognize compensation expense unless the exercise price of our employee stock options is less than the market price of the underlying stock on the date of grant. We grant all of our options at the fair market value of the underlying stock on the date of grant. Consequently, we have not recorded such expense in the periods presented.

We currently grant options under a stock option plan that allows for the granting of non-qualified stock options, incentive stock options and stock purchase rights to employees, directors and consultants of Genentech. Incentive stock options may only be granted to employees under this plan. Generally, non-qualified options and incentive options have a maximum term of 10 years. In general, options vest in increments over four years from the date of grant, although we may grant options with different vesting terms from time to time. No stock purchase rights or incentive stock options have been granted under our current plan to date.

We have an employee stock plan that allows eligible employees to purchase Common Stock at 85% of the lower of the fair market value on the grant date or the fair market value on the first business day of each calendar

quarter. Purchases are limited to 15% of each employee's eligible compensation. All full-time employees of Genentech are eligible to participate in this plan.

The following information regarding net income (loss) and earnings (loss) per share has been determined as if we had accounted for our employee stock options and employee stock plan under the fair value method prescribed by FAS 123. The resulting effect on net income (loss) and earnings (loss) per share pursuant to FAS 123 is not

likely to be representative of the effects in future periods, due to subsequent additional option grants and periods of vesting. The fair value of options was estimated at the date of grant using a Black-Scholes option valuation model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Risk-free interest rate	2.8 %	2.6 %	2.8 %	2.6 %
Dividend yield	0 %	0 %	0 %	0 %
Volatility factors of the expected market price of our Common Stock	45.0 %	43.0 %	44.7 %	43.0 %
Weighted-average expected life of option (years)	5	5	5	5

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not provide a reliable single measure of the fair value of our employee stock options.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net income (loss) - as reported	\$ 151,981	\$ 89,304	\$ 435,797	\$ (29,041)

Deduct: Total stock-based employee compensation

expense determined under the fair value based method for all awards, net of related tax effects	44,096	37,477	123,781	126,418
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Pro forma net income (loss)	\$ 107,885	\$ 51,827	\$ 312,016	\$ (155,459)
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Earnings (loss) per share:

Basic-as reported	\$ 0.29	\$ 0.17	\$ 0.85	\$ (0.06)
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Basic-pro forma	\$ 0.21	\$ 0.10	\$ 0.61	\$ (0.30)
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Diluted-as reported	\$ 0.29	\$ 0.17	\$ 0.83	\$ (0.06)
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Diluted-pro forma	\$ 0.20	\$ 0.10	\$ 0.59	\$ (0.30)
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We are currently evaluating our option valuation methodologies and assumptions in light of evolving accounting standards related to employee stock options.

## Note 2. LEASES AND CONTINGENCIES

### Leases

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance and minimum lease payments. Some of our leases have options to renew. Four of our operating leases are commonly referred to as "synthetic leases." Prior to the issuance of FIN 46, synthetic leases represented a form

of off-balance sheet financing under which they were treated as operating leases for accounting purposes and as financing leases for tax purposes. Under FIN 46, each synthetic lease is evaluated to determine if it qualifies as a VIE and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

Under our synthetic lease structures, an unrelated third-party funds 100% of the costs of the acquisition and/or construction of the property and leases the asset to us, as the lessee, and at least 3% of the third-party funds represent at-risk equity. In addition, under our synthetic lease structures, upon termination or expiration, at our option, we must either purchase the property from the lessor at a predetermined amount that does not constitute a purchase at less than fair market value, sell the real property to a third-party, or renew the lease arrangement. If the property is sold to a third-party at an amount less than the amount financed by the lessor, we have agreed under residual value guarantees to pay the lessor up to an agreed upon percentage of the amount financed by the lessor.

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The most significant of our synthetic leases relates to our manufacturing facility located in Vacaville, California. In November 2001, we completed a synthetic lease transaction for this facility, which had previously been leased to us under a predecessor synthetic lease. This new synthetic lease is structured differently from our other synthetic leases. As the lessee, we lease the property from an unrelated special purpose trust (owner/lessor) under an operating lease agreement for five years ending November 2006. Third-party financing is provided in the form of a 3% at-risk equity participation from investors and 97% debt commitment. Investors' equity contributions were equal to or greater than 3% of the fair value of the property at the lease's inception and are required to remain so for the term of the lease. A bankruptcy-remote, special purpose corporation (or SPC) was formed to fund the debt portion through the issuance of commercial paper notes. The SPC lends the proceeds from the commercial paper to the owner/lessor, who issues promissory notes to the SPC. The SPC loans mature in November 2006. The SPC promissory notes are supported by a credit facility provided by financing institutions and draws are generally available under that credit facility to repay the SPC's commercial paper. The collateral for the SPC loans includes the leased property, and an interest in the residual value guarantee provided by us. The creditors of the SPC do not have recourse to the general credit of Genentech. As the lessee, at any time during the lease term, we have the option to purchase the property at an amount that does not constitute a purchase at less than fair market value.

Under FIN 46, we determined that the entity from which we lease the Vacaville facility qualified as a VIE and that we are the primary beneficiary of this VIE as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46 on July 1, 2003, we consolidated the entity. See Note 1, "Summary of Significant Accounting Policies -- Change in Accounting Principle" section above for information on the impact of our adoption of FIN 46.

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

Under all the synthetic leases, Genentech, as the lessee, is also required to maintain certain pre-defined financial ratios and is limited to the amount of debt it can assume. In addition, no Genentech officer or employee has any financial interest with regard to these synthetic lease arrangements or with any of the special purpose entities used in these arrangements. In the event of a default, the maximum amount payable under the residual value guarantee would equal 100% of the amount financed by the lessor, and our obligation to purchase the leased properties or pay the related residual value guarantees could be accelerated. We believed at the inception of the leases and continue to believe that the occurrence of any event of default that could trigger our purchase obligation is remote.

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Future minimum lease payments under all leases, exclusive of the residual value guarantees, executory costs and sublease income, at December 31, 2002, are as follows (in millions). These minimum lease payments were computed based on interest rates current at that time, which are subject to fluctuations in certain market-based interest rates:

	2003	2004	2005	2006	2007	Thereafter	Total
Vacaville lease <sup>(1)</sup>	\$ 6.0	\$ 6.0	\$ 6.0	\$ 6.0	\$ -	\$ -	\$ 24.0
South San Francisco leases	3.6	3.4	2.8	2.8	1.3	-	13.9
Other operating leases	4.8	3.3	3.1	2.6	2.4	5.2	21.4
Total	<u>\$ 14.4</u>	<u>\$ 12.7</u>	<u>\$ 11.9</u>	<u>\$ 11.4</u>	<u>\$ 3.7</u>	<u>\$ 5.2</u>	<u>\$ 59.3</u>

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

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

	Approximate Initial Fair Value of Leased Property	Lease Expiration	Maximum Residual Value Guarantee
Vacaville Lease	\$ 425.0	11/2006	\$ 371.8
South San Francisco Lease 1	56.6	07/2004	48.1
South San Francisco Lease 2	160.0	06/2007	136.0
South San Francisco Lease 3	25.0	01/2004	21.3
Total	<u>\$ 666.6</u>		<u>\$ 577.2</u>

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

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnifications in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses and expenses to be material. In the case of South San Francisco Lease 1, we have pledged cash collateral of \$56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

#### Contingencies

We entered into an agreement with Serono S.A. to market Raptiva internationally outside the United States and Japan. Development and marketing rights in the United States remain with us and our U.S. collaborator, XOMA (US) LLC, and we retain exclusive marketing rights in Japan. Under the agreement, we and Serono may collaborate on co-developing additional indications of Raptiva and will share certain global development costs. In addition, we have a supply agreement with Serono under which we could have a loss exposure up to a maximum of \$10.0 million.

In the second quarter of 2002, we entered into a manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, to provide Immunex with additional manufacturing capacity for ENBREL® (etanercept) at Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we are responsible for facility modifications needed to manufacture ENBREL, including the internal labor costs and

development production runs. The cost of equipment and outside service costs are reimbursable by Immunex. However, if certain milestones are not met, we are required to reimburse Immunex for up to 45% of the total equipment and outside service costs. Costs associated with development runs are reflected in research and development expense as incurred.

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

We and the City of Hope National Medical Center (or COH) are parties to a 1976 agreement relating to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, Genentech has entered into license agreements with various companies to make, use and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to the COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. The first trial of this suit began on August 28, 2001. On October 24, 2001, the jury hearing the lawsuit announced that it was unable to reach a verdict and on that basis the Court declared a mistrial. COH requested a retrial, and the retrial began on March 20, 2002. On June 10, 2002, the jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, the jury voted to award the COH an additional \$200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and were included in litigation-related liabilities in the condensed consolidated balance sheets at September 30, 2003 and December 31, 2002. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. The appeal process is ongoing. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

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

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



of the university's patent application were first to invent and that their claims are patentable, a new patent would be issued to the university and the Chiron patent would be revoked. On October 24, 2002, the Patent Office redeclared the interference to include, in addition to the above-referenced Chiron patent and university patent application, a number of patents and patent applications owned by either Chiron or Genentech, including Chiron's U.S. Patent No. 4,753,894 that is also at issue in the separate patent infringement lawsuit described below. The interference proceeding is ongoing.

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On March 13, 2001, Chiron filed another patent infringement lawsuit against us in the U.S. District Court in the Eastern District of California, alleging that the manufacture, use, sale and/or offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 4,753,894. Chiron is seeking compensatory damages for the alleged infringement, additional damages, and attorneys' fees and costs. Genentech filed a motion to dismiss this second lawsuit, which was denied. On November 1, 2002, the parties filed a proposed stipulation to stay all proceedings in this lawsuit until (1) the interference involving U.S. Patent No. 4,753,894 is resolved or (2) two years from entry of the proposed stipulation, whichever is sooner. On or about November 13, 2002, the Court entered the stipulation, staying the proceedings as requested by the parties. This lawsuit is separate from and in addition to the Chiron suit mentioned above.

We and Tanox Biosystems, Inc. (or Tanox) are parties to a July 1996 Settlement and Cross-Licensing Agreement relating to the development and manufacture of certain antibody products directed towards immunoglobulin E, including Xolair and Hu-901. On February 20, 2002, Tanox filed an amended demand in an ongoing arbitration proceeding between Genentech and Tanox that is being conducted by the American Arbitration Association in San Francisco. In its amended demand, Tanox has claimed breach of the July 1996 Agreement, conversion, tortious interference, unjust enrichment, and unfair competition by Genentech, and requests injunctive relief as well as monetary damages "many times in excess of \$100,000,000." On March 14, 2002, Genentech denied all of Tanox's claims, and counterclaimed for breach of contract, theft of trade secrets, misappropriation, breach of confidence, interference with contract, and interference with economic expectancies by Tanox. Genentech requested injunctive relief and monetary damages. On October 16, 2002, Tanox announced that in a dispute between it and Novartis, an arbitration panel ruled that Tanox is not entitled to develop independently the Hu-901 antibody product. The Novartis/Tanox panel also ruled that Tanox is entitled to receive certain know-how from Novartis. Tanox contends in its dispute against Genentech that it is entitled to similar information from Genentech. The effect of the October 16 ruling from the Novartis/Tanox arbitration, if any, on Tanox's claims against Genentech cannot be determined since the arbitrators in the Tanox/Genentech proceedings have not yet resolved it. As a general matter, the claims are divided into two categories: (1) compensation for lost rights under agreements with Genentech and Novartis, and (2) additional royalties on future sales. The arbitration began on January 13, 2003 and is ongoing. Tanox closed its case on January 30, 2003 and Genentech closed its case on March 30, 2003. A decision in the arbitration has been delayed and is expected no earlier than December 15, 2003. The outcome of this matter cannot be determined at this time.

On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, City of Hope National Medical Center (or COH), and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 ("the '415 patent") that is co-owned by Genentech and COH and under which MedImmune and other companies have been licensed and are paying royalties to Genentech. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking to have the '415 patent declared invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the '415 patent on sales of its Synagis® antibody product, an injunction to prevent Genentech from enforcing the '415 patent, an award of actual and exemplary damages, and other relief. Genentech intends to vigorously defend itself against all

of the allegations and claims in this lawsuit. An estimate of any potential loss or range of loss cannot be made at this time.

We recorded \$13.4 million in the third quarter and \$40.0 million in the first nine months of 2003, for accrued interest and bond costs related to the COH trial judgment. In the third quarter and first nine months of 2002, we recognized \$12.5 million and \$530.5 million, respectively, of litigation-related special charges. These special charges for the first nine months of 2002 included the COH trial judgment and certain other litigation-related matters. In conjunction with the COH trial judgment, in the second quarter of 2002 we posted a \$600.0 million surety bond and as part of this arrangement, we were required to pledge \$630.0 million in cash and investments to secure the bond. The \$630.0 million cash and investments were classified as restricted cash on our condensed consolidated balance sheets at September 30, 2003 and December 31, 2002. In addition, we accrued \$2.3 million in the third quarter and \$4.7 million in the first nine months of 2003 of royalty expenses related to the COH trial judgment, which were reflected in marketing, general and administrative expenses. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results. These special charges represent our best estimate of the costs for the current resolution of these matters and are included in litigation-related liabilities in the condensed consolidated balance

sheets at September 30, 2003 and December 31, 2002. We developed this estimate in consultation with outside counsel handling our defense in these matters using the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

#### Litigation Settlement

In August 2003, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately \$0.17 in earnings per diluted share for the third quarter of 2003 and was reported as a litigation-related special item in our condensed consolidated statements of operations.

#### Note 3. RELATIONSHIP WITH ROCHE

##### Redemption of Our Special Common Stock

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

##### Exercises of Opt-in Rights

In June 2003, Hoffmann-La Roche, an affiliate of Roche, exercised its option to license from us the rights to market Avastin in all countries outside of the U.S. under its existing licensing and marketing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 75% of all subsequent global development costs related to Avastin. In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, in all countries outside of the U.S. under its existing licensing and marketing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of all subsequent global development costs related to PRO70769. We will receive royalties on all net sales of Avastin and PRO70769 in countries outside of the U.S.

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

We expect from time to time to issue additional shares of common stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that we 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, 2003, Roche's percentage ownership of our common stock was 58.7%.

#### Note 4. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill represents the difference between the purchase price and the fair value of the net assets when accounted for by the purchase method of accounting arising from the Redemption (see Note 3, "Relationship With Roche"). The carrying amount of goodwill at September 30, 2003 and December 31, 2002 was \$1,334.2 million. We performed impairment tests of goodwill on September 30, 2002 and 2003, and found no impairment. We will continue to monitor the carrying value of our goodwill through impairment tests performed at least annually.

The components of our acquisition-related intangible assets arising from the Redemption and push-down accounting (see Note 3, "Relationship With Roche"), patents and other intangible assets at September 30, 2003 and

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December 31, 2002, are as follows (in millions):

	September 30, 2003			December 31, 2002		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Developed product technology	\$ 1,194.1	\$ 749.8	\$ 444.3	\$ 1,194.1	\$ 690.4	\$ 503.7
Core technology	443.5	324.3	119.2	443.5	308.0	135.5
Developed license technology	467.5	416.5	51.0	467.5	394.6	72.9
Tradenames	144.0	62.7	81.3	144.0	55.5	88.5
Key distributor relationships	80.0	69.0	11.0	80.0	58.0	22.0
Patents	110.5	42.5	68.0	100.0	36.2	63.8
Other intangible assets	94.0	41.7	52.3	77.3	36.2	41.1
<b>Total</b>	<b>\$ 2,533.6</b>	<b>\$ 1,706.5</b>	<b>\$ 827.1</b>	<b>\$ 2,506.4</b>	<b>\$ 1,578.9</b>	<b>\$ 927.5</b>

Amortization expense of our other intangible assets was \$42.7 million in the third quarter and \$128.0 million in the first nine months of 2003, and \$42.3 million in the third quarter and \$127.0 million in the first nine months of 2002.

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

For the Year Ending December 31,	Amortization Expense
	\$ 42.9
2003 (remaining three months)	
2004	162.6
2005	139.6
2006	119.7
2007	118.5
2008	116.5
2009-2015	127.3
<b>Total expected future annual amortization</b>	<b>\$ 827.1</b>

Note 5. DERIVATIVE FINANCIAL INSTRUMENTS

We record gains and losses on derivatives related to our equity hedging instruments in "other income, net" in the condensed consolidated statements of operations. We had no such gains or losses in the third quarter and first nine months of 2003 or in the comparable periods of 2002.

At September 30, 2003, net losses on derivative instruments expected to be reclassified from accumulated other comprehensive income to "other income, net" during the next twelve months are \$3.7 million. These net losses are primarily due to the recognition of premiums related to maturing foreign currency exchange options.

#### Derivative Activity in Accumulated Other Comprehensive Income

The following table summarizes activity in other comprehensive income (or OCI) related to derivatives, net of taxes, held during the third quarters and first nine months of 2003 and 2002 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Changes in fair value of derivatives	\$ (1,208)	\$ (4,078)	\$ (170)	\$ 7,034
Losses (gains) reclassified from OCI to income	640	(9)	1,834	(6,445)
Change in unrealized (losses) gains on derivatives	\$ (568)	\$ (4,087)	\$ 1,664	589

#### Note 6. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is comprised of net income (loss) and OCI. OCI includes certain changes in stockholders' equity that are excluded from net income (loss). OCI includes changes in fair value of derivatives designated as and effective as hedges and unrealized gains and losses on our available-for-sale securities. The following table summarizes the components of total comprehensive income, net of taxes, during the third quarters and first nine months of 2003 and 2002 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net income (loss)	\$ 151,981	\$ 89,304	\$ 435,797	\$ (29,041)
Change in unrealized gains (losses) on securities available-for-sale	16,095	20,847	28,842	(52,604)
Change in unrealized (losses) gains on derivatives	(568)	(4,087)	1,664	589
Comprehensive income (loss)	\$ 167,508	\$ 106,064	\$ 466,303	\$ (81,056)

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

	September 30, 2003	December 31, 2002
Unrealized gains on securities available-for-sale	\$ 293,941	\$ 265,099
Unrealized gains on derivatives	5,207	3,543
Accumulated other comprehensive income	\$ 299,148	\$ 268,642

## Note 7. EARNINGS PER SHARE

The following is a reconciliation of the denominator used in basic and diluted earnings (loss) per share (or EPS) computations for the third quarters and first nine months of 2003 and 2002 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
<b>Numerator:</b>				
Net income (loss)	\$ 151,981	\$ 89,304	\$ 435,797	\$ (29,041)
<b>Denominator:</b>				
Weighted-average shares outstanding used for basic earnings (loss) per share	520,381	516,025	515,070	520,889
<b>Effect of dilutive securities:</b>				
Stock options	12,405	3,404	10,755	-
Weighted-average shares and dilutive stock options used for diluted earnings (loss) per share	532,786	519,429	525,825	520,889

Options to purchase 10,654,830 shares of common stock between \$79.70 and \$96.66 per share were outstanding in the third quarter of 2003, and options to purchase 17,230,722 shares of common stock between \$56.50 and \$96.66 per share were outstanding in the first nine months of 2003, but were excluded from the computation of diluted EPS because they were anti-dilutive in both periods. Options to purchase 24,816,592 shares of common stock between \$32.09 and \$95.66 per share were outstanding in the third quarter of 2002, but were excluded from the computation of diluted ESP because they were anti-dilutive. Options to purchase 56,009,923 shares of common stock between \$12.53 and \$95.66 per share were outstanding in the first nine months of 2002, but were excluded from the computation of diluted EPS because such options were anti-dilutive.

## Note 8. INVENTORIES

Our inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in first-out method. If inventory carrying values exceed expected market value due to obsolescence or lack of demand, reserves are recorded for the difference between the cost and the market value. These reserves are determined based on significant estimates.

Inventories at September 30, 2003 and December 31, 2002 are summarized below (in thousands):

	September 30, 2003	December 31, 2002
Raw materials and supplies	\$ 38,477	\$ 30,181
Work in process	353,305	329,819
Finished goods	31,657	33,542
Total	<u>\$ 423,439</u>	<u>\$ 393,542</u>

Work in process includes pre-approval product candidate inventories, net of reserves and advances from collaborator, of \$49.6 million at September 30, 2003 and \$35.9 million at December 31, 2002.

#### Note 9. CAPITAL STOCK

##### Stock Repurchase Program

Under a stock repurchase program approved by our Board of Directors on October 31, 2001, and extended on August 15, 2002, Genentech was authorized to repurchase up to \$1 billion of our common stock through the period ending June 30, 2003. Purchases by Genentech could be made in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech could also engage in transactions in other Genentech securities in conjunction with the repurchase program, including derivative securities. Due to the

extension of the stock repurchase program in August of 2002, Genentech entered into a new 10b5-1 trading plan on November 13, 2002, to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. This plan covered 2.5 million shares. Under the stock repurchase program, we repurchased approximately 5.4 million shares of our common stock at a cost of approximately \$195.3 million in 2003, prior to the program's expiring on June 30, 2003. The program has not been extended and no purchases occurred in the third quarter of 2003. Of those shares repurchased through June 30, 2003, the number of shares repurchased under Genentech's 10b5-1 insider trading plan was approximately 1.5 million. We repurchased approximately 3.8 million shares of our common stock in the third quarter of 2002 at a cost of approximately \$118.0 million and approximately 15.8 million shares of our common stock during the first nine months of 2002 at a cost of approximately \$609.2 million. Of those shares repurchased, the number of shares repurchased under Genentech's prior 10b5-1 insider trading plan was approximately 1.2 million during the third quarter of 2002 and 2.6 million during the first nine months of 2002. Under the stock repurchase program, we repurchased approximately 23.8 million shares of our common stock at a cost of approximately \$893.7 million during the period from November 1, 2001, through June 30, 2003, when the program expired.

The par value method of accounting is used for common stock repurchases. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital with the amounts in excess of the estimated original sales price charged to accumulated deficit.

Note 10. TAXES

Our effective tax rate was 36% in the third quarter and 32% in the first nine months of 2003 as compared to an effective tax rate of 32% in the third quarter and a tax benefit rate of 73% in the first nine months of 2002. The tax benefit for the first nine months of 2002 reflects the tax benefit recognized on the litigation-related special items.

Our effective tax rate increased in the third quarter of 2003 when compared to the second quarter of 2003 primarily as a result of increased pretax income and changes to estimates made earlier in 2003.

INDEPENDENT ACCOUNTANTS' REVIEW REPORT

The Board of Directors and Stockholders of Genentech, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of Genentech, Inc. as of September 30, 2003, and the related condensed consolidated statements of operations for the three-month and nine-month periods ended September 30, 2003 and 2002 and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2003 and 2002. These financial statements are the responsibility of Genentech's management.

We conducted our reviews in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data, and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States, which will be performed for the full year with the objective of expressing an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

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

We have previously audited, in accordance with auditing standards generally accepted in the United States, the consolidated balance sheet of Genentech, Inc. as of December 31, 2002, 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 14, 2003 (except for the note titled Subsequent Event, as to which the date is February 12, 2003), 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, 2002, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ERNST & YOUNG LLP

Palo Alto, California  
October 7, 2003

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

**GENENTECH, INC.  
FINANCIAL REVIEW**

**OVERVIEW**

Genentech is a leading biotechnology company using human genetic information to discover, develop, manufacture and commercialize biotherapeutics for significant unmet medical needs. We manufacture and commercialize in the United States 12 biotechnology products listed below and license several additional products to other companies.

- Herceptin (trastuzumab) anti-HER2 antibody for the treatment of certain patients with metastatic breast cancer whose tumors overexpress the Human Epidermal growth factor Receptor type 2 (or HER2) protein;
- Rituxan (rituximab) anti-CD20 antibody, which we and IDEC Pharmaceuticals Corporation (or IDEC) market 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 (heart attack);
- Activase (alteplase, recombinant) tissue plasminogen activator (or t-PA) for the treatment of acute myocardial infarction (heart attack), acute ischemic stroke (brain attack) within three hours of the onset of symptoms and acute massive pulmonary embolism (blood clots in the lungs);
- Cathflo Activase (alteplase, recombinant) thrombolytic agent for the restoration of function to central venous access devices 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 [somatotropin (rDNA origin) for injection] liquid formulation growth hormone for the same indications as Nutropin;
- Nutropin [somatotropin (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 (manufacture of Protropin has been discontinued but sales are expected to continue through the first half of 2004 or until inventory is depleted);
- Pulmozyme (dornase alfa, recombinant) inhalation solution for the treatment of cystic fibrosis; and
- Xolair (omalizumab) anti-IgE antibody, which we commercialize with Novartis, for the treatment of moderate-to-severe persistent asthma in adults and adolescents. In June 2003, we received U.S. Food and Drug Administration (or FDA) approval to market Xolair. We began shipping Xolair in July 2003.
- Raptiva (efalizumab) anti-CD11a antibody, in co-development with XOMA Ltd., was approved by the FDA on October 27, 2003 for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy. We have not begun shipping Raptiva.

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

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

We receive royalties from third parties on sales of:

- growth hormone products within the U.S. and outside of the U.S.,
- Activase outside of the U.S. and Canada, and
- TNKase outside of the U.S., Canada and Japan.

We also receive worldwide royalties on additional licensed products that are marketed by other companies. Some of our products are sold under different trademarks or trade names when sold outside of the U.S.

#### Redemption of Our Special Common Stock

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche Holdings, Inc. (or Roche) at a price of \$20.63 per share in cash with funds deposited by Roche for that purpose. We refer to this event as the "Redemption." As a result, on that date, Roche's percentage ownership of our outstanding Common Stock increased from 65% to 100%. Consequently, under accounting principles generally accepted in the United States (or GAAP), we were required to use push-down accounting to reflect in our financial statements the

amounts paid for our stock in excess of our net book value. Push-down accounting required us to record \$1,685.7 million of goodwill and \$1,499.0 million of other intangible assets onto our balance sheet on June 30, 1999. See also below in the "Recurring Charges Related to Redemption" section of Results of Operations and Note 3, "Relationship With Roche -- Redemption of Our Special Common Stock," in the Notes to Condensed Consolidated Financial Statements.

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

We expect from time to time to issue additional shares of common stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. The affiliation agreement provides that we will repurchase a sufficient number of shares pursuant to this program such that, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance will be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche as well as for stock splits or stock combinations) divided by 509,194,352 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999 and October 2000. 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, 2003, Roche's percentage ownership of our common stock was 58.7%.

#### Reclassifications

Effective January 1, 2003, we made certain classification changes to our condensed consolidated statements of operations. Comparable amounts in the prior year have been reclassified to conform to the 2003 presentation. These classification changes included:

- a new caption titled "other income, net" (see below in "Results of Operations - Other Income, Net" for the composition of this new caption),
- a change from the "contract and other" caption to the new "contract revenues" caption (the gains on sales of biotechnology equity securities that were previously included in "contract and other" are now reflected in the new "other income, net" caption), and
- a change from including write-downs of biotechnology equity securities and changes in the recoverability of our debt securities in "marketing, general and administrative" expenses to including them in the new "other

income, net" caption.

Certain other reclassifications of prior year amounts have been made to our condensed consolidated statements of operations and our condensed consolidated balance sheets to conform to the current year presentation.

#### Available Information

Our quarterly reports on Form 10-Q, annual reports on Form 10-K and our other filings with the Securities and Exchange Commission, and any amendments to such filings, can be found on our website at <http://www.gene.com> or can be obtained by contacting our Investor Relations Department at (650) 225-1599 or by sending an e-mail message to [investor.relations@gene.com](mailto:investor.relations@gene.com).

#### CRITICAL ACCOUNTING POLICIES

The preparation of our financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The following are critical accounting policies important to our financial condition and results of operations presented in the financial statements and require management to make judgments, assumptions and estimates that are inherently uncertain.

##### *Operating Leases*

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance and minimum lease payments. Some of our leases have options to renew. Four of our operating leases are commonly referred to as "synthetic leases." Prior to the issuance of Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46), "Consolidation of Variable Interest Entities," an interpretation of Accounting Research Bulletin No. 51, synthetic leases represented a form of off-balance sheet financing which allowed us to treat the leases as operating leases for accounting purposes and as financing leases for tax purposes. Under FIN 46, each synthetic lease is evaluated at least quarterly to determine whether the leasing entity qualifies as a variable interest entity (or VIE) and whether Genentech is the primary beneficiary or whether specified assets we lease are essentially siloed in the leasing company. A silo is an asset financed with 95% nonrecourse debt and leased to a lessee under a lease containing a fixed price purchase option. If certain conditions are met, we are required to consolidate the VIE or specified assets of the VIE. We annually assess the properties we lease under synthetic leases to determine if there have been impairments in the fair value of the underlying properties or the use of the properties that would require us to pay amounts under any of the residual value guarantees. See further discussion of FIN 46 and our leases below in "Leases and Contingencies."

##### *Legal Contingencies*

We are currently involved in certain legal proceedings as discussed in Note 2, "Leases and Contingencies" in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. As of September 30, 2003, we have accrued our estimate of the costs for the current resolution of these matters. We developed these estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the outcome of these matters.

*Revenue Recognition*

We recognize revenue related to product sales, royalties and contractual services provided. Our revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

- We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated uncollectible amounts, product returns and discounts.
- We recognize revenue from royalties based on licensees' sales of our products or technologies. Royalties are recognized as earned in accordance with the contract terms when licensees' results can be reliably measured and collectibility is reasonably assured. Royalty estimates are made in advance of amounts collected using historical and forecasted trends.
- Contract revenue for research and development (or R&D) generally includes upfront and continuing licensing fees, manufacturing fees, milestone payments and reimbursements of development costs and post-marketing costs.
  - Nonrefundable upfront fees for which no further performance obligations exist are recognized as revenue on the earlier of when payments are received or collection is assured.
  - Nonrefundable upfront licensing fees and certain guaranteed, time-based payments that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue:
    - ratably over the development period if development risk is significant, or
    - ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.
  - Manufacturing fees are recognized as revenue on a straight-line basis over the longer of the manufacturing obligation or the expected product supply.
  - Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
  - Reimbursements of development and post-marketing costs are recognized as revenue as the related costs are incurred.

R&D expenses include related salaries, benefits and other headcount related expenses, clinical trial and related clinical manufacturing costs, contract and other outside service fees, and facilities and overhead costs. R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. In addition, we fund R&D at other companies and research institutions under agreements that we can generally terminate at will. R&D expenses also include activities such as product registries and investigator sponsored trials. R&D costs, including some upfront fees and milestones paid to collaborators, are expensed as incurred. The timing of upfront fees and milestone payments in the future may cause variability in our future R&D expenses.

#### *Income Taxes*

Income tax expense (benefit) is based on pretax financial accounting income (loss) under the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision (benefit) for income taxes. Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings. We believe that our reserves for these uncertainties are adequate.

#### *Accounts Receivable Allowances*

Our accounts receivable includes trade, royalty and other receivables and consists primarily of amounts due to us from our normal business activities. We have significant estimates primarily related to our trade receivables. To determine the collectibility of our trade receivables, we prepare estimates for discounts, rebates and sales returns and allowances based primarily on analysis of existing contractual obligations, historical trends and experience and changes in customer financial conditions. If actual future results vary, we may need to adjust our estimates, which could have an impact on earnings in the period of the adjustment.

#### *Inventories*

Our inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in first-out method. If inventory carrying values exceed expected market value due to obsolescence or lack of demand, reserves are recorded for the difference between the cost and the market value. These reserves are determined based on management estimates.

Inventories consist of currently marketed products, products manufactured under contract and product candidates awaiting regulatory approval, which are capitalized based on management's judgment of probable near term commercialization. We may be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies.

#### *Marketable Equity Securities and Other*

Marketable equity securities and other debt securities are carried at fair value with unrealized gains and losses on securities classified as "available-for-sale" included in accumulated other comprehensive income in stockholders' equity. If the fair value of a security has declined below its carrying value for each trading day for six consecutive months or if the decline is due to a significant adverse event, the impairment is considered to be other-than-temporary and the security is written down to its estimated fair value. If such security is of a biotechnology company, the write-down is charged to "other income, net." Other-than-temporary declines in fair value of all other short-term or long-term marketable securities are charged against interest income, which is included in "other income, net." Some of the factors we consider in determining whether a significant adverse event has occurred with

an issuer include, among other things, unfavorable clinical trial results and the diminished prospect for new products, a denial of a product approval by a regulatory body, the termination of a major collaborative relationship and the liquidity position and financing activities of the issuer. The determination of whether a decline in fair value is other-than-temporary requires significant judgment, and can have a material impact on our financial results.

#### *Nonmarketable Equity Securities*

Nonmarketable equity securities are carried at cost. We periodically monitor the liquidity position and financing activities of the respective issuers to determine if impairment write-downs are necessary. In the event that impairment write-downs are recorded and subsequently recovered upon the sale of the related security, our financial results will be favorably impacted. We record impairments in "other income, net."

#### *Change in Accounting Principle*

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

We adopted FIN 46 on July 1, 2003, and consolidated the entity from which we lease our manufacturing facility located in Vacaville, California as of that date, as we determined that this entity is a VIE, as defined by FIN 46, and that we absorb a majority of its expected losses. Accordingly, we consolidated assets, which consist of the Vacaville manufacturing building and related equipment, which together have a carrying value of \$362.7 million, net of accumulated depreciation. Such property and equipment is included in property, plant and equipment in the accompanying condensed consolidated balance sheet at September 30, 2003. We also consolidated the entity's debt of \$412.3 million and noncontrolling interests of \$12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, in the accompanying condensed consolidated balance sheet at September 30, 2003. We recorded a \$47.6 million charge, net of tax, (or \$0.09 per share) as a cumulative effect of the accounting change in the third quarter of 2003. We had previously accounted for our involvement with this entity as an operating lease. See also "Leases and Contingencies" below for a discussion of all of our leases.

## RESULTS OF OPERATIONS

*(dollars in millions, except per share amounts)*

Our discussion on results of operations contains forward-looking statements regarding the costs to complete in-process projects and our expectations of higher future revenues. Actual results could differ materially. For a discussion of the risks and uncertainties related to costs to complete in-process projects, see "The Successful Development of Biotherapeutics is Highly Uncertain and Requires Significant Expenditures," "We May Be Unable to Obtain or Maintain Regulatory Approvals for Our Products," "Difficulties or Delays in Product Manufacturing Could Harm Our Business," "Protecting Our Proprietary Rights Is Difficult and Costly," "The Outcome of, and Costs Relating to, Pending Litigation Are Uncertain," and "We May Be Unable to Retain Skilled Personnel and Maintain

Key Relationships" and for our expectations of higher future revenues, see all of the foregoing and "We Face Competition," "Other Factors Could Affect Our Product Sales," "Our Royalty and Contract Revenues Could Decline," "We May Incur Material Product Liability Costs," "Insurance Coverage Is Increasingly More Difficult to Obtain or Maintain," and "Environmental and Other Risks" of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2003	2002	% Change	2003	2002	% Change
Total operating revenues	\$ 817.0	\$ 650.1	26 %	\$ 2,366.4	\$ 1,840.5	29 %

Total operating revenues increased 26% in the third quarter and 29% in the first nine months of 2003 from the comparable periods in 2002. These increases were due to higher product sales, royalty income and contract revenues. These increases are further discussed below.

Product Sales	Three Months Ended September 30,			Nine Months Ended September 30,		
	2003	2002	% Change	2003	2002	% Change
Rituxan	\$ 371.7	\$ 293.9	26 %	\$ 1,076.1	\$ 816.4	32 %
Herceptin	107.7	96.7	11	310.5	278.5	11
Growth Hormone	80.6	77.4	4	238.9	220.4	8
Thrombolytics	46.0	45.6	1	141.1	131.5	7
Pulmozyme	40.4	38.2	6	122.6	105.1	17
Xolair	6.8	-	-	6.8	-	-
Product manufactured under contract	1.7	-	-	1.7	-	-
Total product sales	\$ 654.9	\$ 551.8	19 %	\$ 1,897.7	\$ 1,551.9	22 %

#### Total Product Sales

Total net product sales increased 19% in the third quarter and 22% in the first nine months of 2003 as compared with the prior year periods. The increase was due to higher sales across most products, in particular Rituxan. Increased sales volume accounted for the entire net product sales increase in the third quarter of 2003 and a 16% increase, or \$249.3 million, in the first nine months of 2003. Higher sales prices across the entire product suite accounted for the remainder of the increase in the first nine months of 2003.

#### Rituxan



Net sales of Rituxan increased 26% in the third quarter and 32% in the first nine months of 2003 from the comparable periods in 2002. These increases were primarily driven by higher worldwide sales volumes due to increased use of the product for the treatment of B-cell non-Hodgkin's lymphoma in indolent and aggressive non-Hodgkin's lymphoma (or NHL), as well as chronic lymphocytic leukemia (or CLL), used in both monotherapy and combination therapy settings. The current approved label indication is for relapsed or refractory, low grade or follicular NHL. Additionally, in early 2003, the National Comprehensive Cancer Network (or NCCN) issued guidelines that included the use of Rituxan in the relapsed aggressive NHL setting.

#### Herceptin

Net sales of Herceptin increased 11% in both the third quarter and first nine months of 2003 from the comparable periods in 2002. These increases were primarily driven by higher U.S. sales due to penetration in first-line use in the metastatic breast cancer market and, to a lesser extent, a price increase. These increases were partially offset by an 82% decline in the third quarter and a 62% decline in the first nine months of 2003 in ex-U.S. Herceptin sales from the comparable periods in 2002. In late September 2002, Hoffmann-La Roche received approval from the European Committee for Proprietary Medicinal Products to manufacture Herceptin at its Penzberg, Germany facility. The Penzberg facility is the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Although our ex-U.S. sales of Herceptin to Hoffmann-La Roche have declined from the prior year, we will continue to receive royalties from their ex-U.S. sales of Herceptin.

#### Growth Hormone

Combined net sales of our four growth hormone products, Nutropin Depot, Nutropin AQ, Nutropin, and Protropin, increased 4% in the third quarter and 8% in the first nine months of 2003 from the comparable periods in 2002. These increases were attributable to continued strong demand for the products. The continued strong demand reflects our focus on new patient starts using our Nutropin AQ Pen (which is a delivery system, launched in July 2002, for Nutropin AQ), continued growth in the adult patient market, higher dosing during puberty and an incremental increase in the length of therapy.

#### Thrombolytics

Combined net sales of our three thrombolytic products, Activase, TNKase and Cathflo Activase, increased 1% in the third quarter and 7% in the first nine months of 2003 from the comparable periods in 2002. These increases were primarily due to higher sales of Cathflo Activase for catheter clearance as a result of increased acceptance and use of the product. Additionally, modest increases in Activase usage for acute ischemic stroke are being observed. The total thrombolytic market has been flat compared to last year, reflecting growth in the peripheral markets (including catheter clearance), the increased use of mechanical reperfusion, and early intervention with other preventive therapies in the treatment of heart attacks.

#### Pulmozyme

Net sales of Pulmozyme increased 6% in the third quarter and 17% in the first nine months of 2003 from the comparable periods in 2002. These increases primarily reflect an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and a price increase.

## Xolair

We received FDA approval to market Xolair in June 2003 and began shipping Xolair in July 2003. Xolair achieved total net sales of \$6.8 million in the third quarter of 2003, reflecting initial distribution of product into the supply channel and positive physician adoption rates. Future sales revenue and related expenses are subject to risks and uncertainties, including physician adoption rates and third-party payer reimbursement and coverage decisions.

Royalties and Contract Revenues	Three Months Ended September 30,			Nine Months Ended September 30,		
	2003	2002	% Change	2003	2002	% Change
Royalties	\$ 116.5	\$ 85.1	37 %	\$ 352.6	\$ 252.5	40 %
Contract revenues	45.6	13.2	245	116.1	36.1	222

## Royalties

Royalty income increased 37% in the third quarter and 40% in the first nine months of 2003 from the comparable periods in 2002. These increases were due to higher third-party sales by various licensees, primarily Hoffmann-La Roche on higher international sales volume of our Herceptin and Rituxan products (accounting for \$58.0 million of the increase for the nine month period), coupled with gains on foreign currency exchange rates related to such sales (accounting for \$7.7 million of the increase for the nine month period).

## Contract Revenues

Contract revenues increased in the third quarter and first nine months of 2003 from the comparable periods in 2002. The increases in both periods were primarily due to higher revenues from collaborators related to continued amortization of recent product opt-ins (Avastin, Lucentis and PRO70769, a humanized antibody that binds to CD20), amounts earned on development activities (primarily Avastin, Lucentis, Raptiva and Omnitarg in the third quarter and Raptiva, Avastin, Lucentis, Tarceva and Omnitarg in the first nine months of 2003), and new licensing arrangements. Omnitarg was formerly known as 2C4.

Costs and Expenses	Three Months Ended September 30,			Nine Months Ended September 30,		
	2003	2002	% Change	2003	2002	% Change
Cost of sales	\$ 115.7	\$ 112.5	3 %	\$ 353.9	\$ 321.8	10 %
Research and development	168.7	143.7	17	506.3	438.3	16
Marketing, general and administrative	209.8	135.5	55	531.3	376.6	41
Collaboration profit sharing	119.7	90.0	33	323.6	246.2	31

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Recurring charges related to redemption	38.6	38.9	(1)	115.8	116.8	(1)
Special items: litigation-related	(131.6)	12.5	(1,153)	(105.0)	530.5	(120)
Total costs and expenses	\$ 520.9	\$ 533.1	(2) %	\$ 1,725.9	\$ 2,030.2	(15) %
COS as a % of product sales	18 %	20 %		19 %	21 %	
R&D as a % of operating revenues	21	22		21	24	
MG&A as a % of operating revenues	26	21		22	20	

#### Cost of Sales

Cost of sales (or COS) as a percentage of product sales was 18% in the third quarter and 19% in the first nine months of 2003, a decrease from 20% in the third quarter and 21% in the first nine months of 2002. These decreases were primarily due to a change in product mix and lower production costs for products sold in 2003.

As mentioned above, the Penzberg facility is the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Accordingly, as our ex-U.S. Herceptin sales have declined this year, our cost as a percentage of sales has also declined due to a reduction in the lower gross margins generated by the ex-U.S. Herceptin sales.

#### Research and Development

R&D expenses increased 17% in the third quarter and 16% in the first nine months of 2003 from the comparable periods in 2002. These increases were largely due to higher spending by us and our collaborators on clinical development of products, including Lucentis, Herceptin and Omnitarg, increased Phase IV and investigator sponsored trials and increased headcount and related expenses in support of research activities. We expect increases in R&D expenses over time to be driven mainly by the development of our pipeline products. Our expectations for higher revenues in the future will likely cause R&D as a percentage of operating revenues to decline over time.

The major components of R&D expenses for the three- and nine-month periods ended September 30, 2003 and 2002 were as follows (in millions):

Research and Development	Three Months Ended September 30,			Nine Months Ended September 30,		
	2003	2002	% Change	2003	2002	% Change
Research	\$ 37.0	\$ 32.8	13 %	\$ 104.5	\$ 95.6	9 %
Development	124.7	106.0	18	379.8	318.1	19
In-licensing	7.0	4.9	43	22.0	24.6	(11)
Total	\$ 168.7	\$ 143.7	17 %	\$ 506.3	\$ 438.3	16 %

## Marketing, General and Administrative

Overall marketing, general and administrative (or MG&A) expenses increased 55% in the third quarter of 2003 from the same period in 2002. This increase was due to: (i) a \$34.6 million increase in marketing and promotional programs and headcount growth in support of commercial and pipeline products, including Xolair, Avastin and Raptiva launch activities, (ii) a \$16.8 million increase in corporate functional (of which information resources was the largest increase), headcount related and other expenses, (iii) a \$14.8 million increase related to

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headcount growth and increased commercial training programs in support of all products, and (iv) a \$8.1 million increase in royalty expenses.

MG&A expense increased 41% in the first nine months of 2003 from the comparable period in 2002. This increase was due to: (i) a \$71.6 million increase in marketing and promotional programs and headcount growth in support of commercial and pipeline products, including Xolair, Avastin and Raptiva launch activities, (ii) a \$25.7 million increase in corporate functional (mostly information resources), headcount related and other expenses, partially offset by lower fixed asset disposals, (iii) a \$31.4 million increase related to headcount growth and increased commercial training programs in support of all products, and (iv) a \$26.0 million increase in royalty expenses.

MG&A expenses could trend higher in the near term as we continue to launch Xolair and prepare for the launch of Raptiva later this year and the potential launch of Avastin, dependent on product approval, early next year. However, as we expect revenues to rise, MG&A as a percentage of operating revenues will likely decline over the longer term.

## Collaboration Profit Sharing

Collaboration profit sharing increased 33% in the third quarter and 31% in the first nine months of 2003 from the comparable periods in 2002. These increases were primarily due to increased profit sharing with IDEC Pharmaceuticals Corporation resulting from 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. The charges in the third quarter and first nine months of 2003 were comparable to the third quarter and first nine months of 2002, and were comprised of the amortization of other intangible assets in all periods presented.

## Special Items: Litigation-Related

In August 2003, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately \$0.17 in earnings per diluted share for the third quarter of 2003 and was reported as a litigation-related special item in our condensed consolidated statements of operations. In addition, we recorded \$13.4 million in the third quarter and \$40.0 million in the first nine months of 2003 for accrued interest and bond costs related to the City of Hope (or COH) trial judgment.

In 2002, we recorded a charge of \$518.0 million in the second quarter primarily for the COH trial judgment and certain other litigation-related matters, and we recorded \$12.5 million in the third quarter for accrued interest and associated bond costs related to the COH trial judgment. We expect that we will continue to incur interest charges on the COH trial judgment and service fees on a related \$600.0 million surety bond each quarter through the process of appealing the COH trial results. These special charges represent our best estimate of the costs for the current resolution of these matters and are included in litigation-related liabilities in the condensed consolidated balance sheets at September 30, 2003 and December 31, 2002. We developed this estimate in consultation with outside counsel handling our defense in these matters using the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal. See Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for further information regarding our litigations.

## Other Income, Net

As part of our strategic alliance efforts, we invest in debt and equity securities of certain biotechnology companies with which we have or have had collaborative agreements. "Other income, net" includes realized gains and losses from the sale of certain of these biotechnology equity securities as well as changes in the recoverability of our debt securities. In addition, "other income, net" includes write-downs for other-than-temporary declines in the fair value of certain of these biotechnology debt and equity securities, interest income and interest expense, net of amounts capitalized in 2002.

Other Income, Net	Three Months Ended September 30,			Nine Months Ended September 30,		
	2003	2002	% Change	2003	2002	% Change
Gains on sales of biotechnology equity securities and other	\$ 0.8	\$ 17.9	(96) %	\$ 21.0	\$ 35.1	(40) %
Write-downs of biotechnology debt and equity securities	-	(23.6)	-	(3.7)	(33.0)	(89)
Interest income	16.1	20.8	(23)	56.2	79.1	(29)
Interest expense	(1.0)	-	-	(1.0)	(0.8)	(25)
Total other income, net	\$ 15.9	\$ 15.1	5 %	\$ 72.5	\$ 80.4	(10) %

"Other income, net" increased 5% in the third quarter of 2003 from the comparable period in 2002, primarily because we had no write-downs of our biotechnology securities. This favorable effect was partially offset by lower gains on sales of biotechnology equity securities and changes related to the recoverability of our debt securities. Also partially offsetting the favorable effect was lower interest income resulting from lower investment portfolio yields; the

effect of the lower yields was partially offset by higher cash balances. "Other income, net" decreased 10% in the first nine months of 2003 from the comparable period in 2002, primarily because of lower interest income resulting from lower investment portfolio yields and lower gains on sales of biotechnology equity securities. The decrease was partially offset by the favorable effect of lower write-downs of our biotechnology equity securities; the effect of the lower yields in the first nine months of 2003 was also partially offset by higher cash balances. Although we have had minimal biotechnology marketable equity securities write-downs to-date in 2003, we may determine in future periods, depending on market conditions, that certain of such unhedged securities are impaired and require a write-down to market value.

Income (Loss) Before Taxes, Income Tax Provision (Benefit), Net Income (Loss) and Earnings (Loss) Per Share	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Income (loss) before taxes and cumulative effect of accounting change	\$ 312.0	\$ 132.1	\$ 713.0	\$ (109.3)
Income tax provision (benefit)	112.4	42.8	229.6	(80.3)
Income (loss) before cumulative effect of accounting change	199.6	89.3	483.4	(29.0)
Cumulative effect of accounting change, net of tax	(47.6)	-	(47.6)	-
Net income (loss)	\$ 152.0	\$ 89.3	\$ 435.8	\$ (29.0)
Earnings (loss) per share:				
Basic				
Earnings (loss) before cumulative effect of accounting change	\$ 0.38	\$ 0.17	\$ 0.94	(0.06)
Cumulative effect of accounting change, net of tax	(0.09)	-	(0.09)	-
Net earnings (loss) per share	\$ 0.29	\$ 0.17	\$ 0.85	\$ (0.06)
Diluted				
Earnings (loss) before cumulative effect of accounting change	\$ 0.38	\$ 0.17	\$ 0.92	\$ (0.06)
Cumulative effect of accounting change, net of tax	(0.09)	-	(0.09)	-
Net earnings (loss) per share	\$ 0.29	\$ 0.17	\$ 0.83	\$ (0.06)

### Income Tax Provision (Benefit)

Our effective tax rate was 36% for the third quarter and 32% for the first nine months of 2003 as compared to 32% for the third quarter and a tax benefit rate of 73% for the first nine months of 2002. The tax provisions were \$112.4 million for the third quarter and \$229.6 million for the first nine months of 2003. The tax provision was \$42.8 million for the third quarter and the tax benefit was \$80.3 million for the first nine months of 2002. The tax benefit for the first nine months of 2002 reflects the benefit recognized on the litigation-related special items and a favorable change in the estimates of prior years' items.

We anticipate that our effective tax rate for the entire year 2003 will be lower than that recorded during the third quarter of 2003. Our effective tax rate increased in the third quarter of 2003 when compared to the second quarter of 2003 primarily as a result of increased pretax income and changes to estimates made earlier in 2003. Various factors may have favorable or unfavorable effects on our effective tax rate during the remainder of 2003 and in subsequent years. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings.

### *Change in Accounting Principle*

See the above, "Critical Accounting Policies -- Change in Accounting Principle," section for information on our adoption of FIN 46 and the related cumulative effect of the change in accounting principle.

### Net Income and Earnings Per Share

Net income and diluted earnings per share in the third quarter and first nine months of 2003 increased from the comparable periods in 2002. The increases were primarily due to the changes in year-to-date litigation-related items from charges of \$530.5 million in 2002 to settlement receipts (net of charges) of \$105.0 million in 2003. Also contributing to the increase were higher operating revenues in 2003, driven mostly by higher product sales, offset in part by higher operating expenses in 2003.

### In-Process Research and Development

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

Except as otherwise noted below, there have been no significant changes to the in-process projects since December 31, 2002. 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 \$300.0 million, as compared to \$700.0 million as of the Redemption date. This estimate reflects costs incurred since the Redemption date, discontinued projects, and decreases in the cost to complete estimates for other projects, partially offset by an increase in certain cost estimates related to early stage projects and changes in expected completion dates.

Significant changes to the in-process projects since December 31, 2002 are as follows:

- Xolair (omalizumab) - We announced on June 20, 2003, that the FDA approved Xolair for the treatment of moderate-to-severe persistent asthma in adults and adolescents. We began shipping Xolair in July 2003.

- Herceptin (trastuzumab) - Phase III program studying Herceptin as an adjuvant therapy for breast cancer may take longer to complete than originally anticipated.

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- Lucentis (ranibizumab) - We have initiated two Phase III studies for patients with the wet form of age-related macular degeneration. On June 24, 2003, we announced that Novartis Ophthalmics, the eye health unit of Novartis AG, would receive an exclusive license to develop and market Lucentis outside of North America for indications related to diseases of the eye.
- Raptiva (efalizumab) - We announced on May 12, 2003, in co-development with XOMA Ltd., the decision to terminate Phase II testing of Raptiva in patients with moderate-to-severe rheumatoid arthritis. We and XOMA announced on October 27, 2003, that Raptiva has been approved by the FDA for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy.
- MLN02 antibody - We announced on October 8, 2003, that after a review of the Phase II ulcerative colitis data results, Genentech and Millennium Pharmaceuticals, Inc. have decided not to move forward with a Phase III study at this time. The companies are currently in discussions regarding next steps with the MLN-02 program.
- Avastin (bevacizumab) - We announced on May 19, 2003, that a Phase III study of Avastin plus chemotherapy in previously untreated metastatic colorectal cancer patients met its primary endpoint of improving overall survival. We announced on June 26, 2003 that the FDA has designated Avastin as a Fast Track development program for the treatment of previously untreated first-line metastatic colorectal cancer patients. On September 26, 2003, we completed the filing of a Biologics License Application (or BLA) with the FDA for Avastin as a treatment for first-line metastatic colorectal cancer in combination with chemotherapy.

#### Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (or EITF) of the Financial Accounting Standards Board (or FASB) issued EITF 00-21, "Revenue Arrangements with Multiple Deliverables," which addresses certain aspects of the accounting for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. Under EITF 00-21, revenue arrangements with multiple deliverables should be divided into separate units of accounting if certain criteria are met, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration should be allocated among the separate units based on their fair values, and the applicable revenue recognition criteria should be considered separately for each of the separate units. EITF 00-21 is effective for revenue arrangements entered into beginning July 1, 2003. Our adoption of EITF 00-21 did not have a material impact on our results of operations and financial position.

In November 2002, the FASB issued Interpretation No. 45 (or FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that



information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. Our adoption of FIN 45 did not have a material impact on our results of operations and financial position. See below in "Leases and Contingencies" for a discussion of our exposures related to our agreement with Serono S.A. and our synthetic leases and the related residual value guarantees.

In December 2002, the FASB issued Statement No. 148 (or FAS 148), "Accounting for Stock-Based Compensation - Transition and Disclosure." FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of

accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options. Under APB 25, no compensation expense is recognized unless the exercise price of our employee stock options is less than the market price of the underlying stock on the date of grant. We have not recorded such expenses in the periods presented because we grant options at the fair market value of the underlying stock on the date of grant. See Note 1, "Summary of Significant Accounting Policies" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for the required disclosures under FAS 148.

## FINANCIAL CONDITION

### Liquidity and Capital Resources

(in millions)	September 30, 2003	December 31, 2002
Cash and cash equivalents, short-term investments and long-term marketable securities and other	\$ 2,693.4	\$ 1,601.9
Working capital	1,808.3	1,436.1

We used cash generated from operations, income from investments and proceeds from stock issuances to fund operations, purchase marketable securities, and invest in capital and equity instruments during the first nine months of 2003 and 2002, and to repurchase stock during the first six months of 2003 and first nine months of 2002. Additionally, in the first quarter of 2002 we redeemed our convertible subordinated debentures. See Note 9, "Capital Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for a discussion of our stock repurchase program.

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

type of revenue and the payment terms related to those revenues.

Capital expenditures of \$211.2 million in the first nine months of 2003 decreased from the \$244.6 million in the comparable period of 2002 primarily due to higher spending in 2002 for the purchase of land and the construction of manufacturing facilities. The decrease in spending was partially offset by higher spending in 2003 for the construction of and improvements to office buildings in South San Francisco.

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 future operating cash requirements. In addition, we believe we could access additional funds from the debt and, under certain circumstances, capital markets. See above for a discussion of our leasing arrangements. See "Our Affiliation Agreement With Roche Could Adversely Affect Our Cash Position" section below and Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for factors that could negatively affect our cash position.

## LEASES AND CONTINGENCIES

### Leases

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance and minimum lease payments. Some of our leases have options to renew. Four of our operating leases are commonly referred to as "synthetic leases." Prior to the issuance of FIN 46, synthetic leases represented a form of off-balance sheet financing under which they were treated as operating leases for accounting purposes and as financing leases for tax purposes. Under FIN 46, each synthetic lease is evaluated to determine if it qualifies as a VIE and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

Under our synthetic lease structures, an unrelated third-party funds 100% of the costs of the acquisition and/or construction of the property and leases the asset to us, as the lessee, and at least 3% of the third-party funds represent at-risk equity. In addition, under our synthetic lease structures, upon termination or expiration, at our option, we must either purchase the property from the lessor at a predetermined amount that does not constitute a purchase at less than fair market value, sell the real property to a third-party, or renew the lease arrangement. If the property is sold to a third-party at an amount less than the amount financed by the lessor, we have agreed under residual value guarantees to pay the lessor up to an agreed upon percentage of the amount financed by the lessor.

The most significant of our synthetic leases relates to our manufacturing facility located in Vacaville, California. In November 2001, we completed a synthetic lease transaction for this facility, which had previously been leased to us under a predecessor synthetic lease. This new synthetic lease is structured differently from our other synthetic leases. As the lessee, we lease the property from an unrelated special purpose trust (owner/lessor) under an operating lease agreement for five years ending November 2006. Third-party financing is provided in the form of a 3% at-risk equity participation from investors and 97% debt commitment. Investors' equity contributions were equal to or greater than 3% of the fair value of the property at the lease's inception and are required to remain so for the term of the lease. A bankruptcy-remote, special purpose corporation (or SPC) was formed to fund the debt portion through the issuance of commercial paper notes. The SPC lends the proceeds from the commercial paper to the owner/lessor, who issues promissory notes to the SPC. The SPC loans mature in November 2006. The SPC promissory notes are supported by a credit facility provided by financing institutions and draws are generally available under that credit facility to repay the SPC's commercial paper. The collateral for the SPC loans includes the leased property, and an interest in the residual value guarantee provided by us. The creditors of the SPC do not have recourse to the general credit of Genentech. As the lessee, at any time during the lease term, we have

the option to purchase the property at an amount that does not constitute a purchase at less than fair market value.

Under FIN 46, we determined that the entity from which we lease the Vacaville facility qualified as a VIE and that we are the primary beneficiary of this VIE as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46 on July 1, 2003, we consolidated the entity. See above in the "Critical Accounting Policies -- Change in Accounting Principle" section for further information on our adoption of FIN 46.

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

Under all the synthetic leases, Genentech, as the lessee, is also required to maintain certain pre-defined financial ratios and is limited to the amount of debt it can assume. In addition, no Genentech officer or employee has any financial interest with regard to these synthetic lease arrangements or with any of the special purpose entities used in these arrangements. In the event of a default, the maximum amount payable under the residual value guarantee would equal 100% of the amount financed by the lessor, and our obligation to purchase the leased properties or pay the related residual value guarantees could be accelerated. We believed at the inception of the leases and continue to believe that the occurrence of any event of default that could trigger our purchase obligation is remote.

Future minimum lease payments under all leases, exclusive of the residual value guarantees, executory costs and sublease income, at December 31, 2002, are as follows (in millions). These minimum lease payments were computed based on interest rates current at that time, which are subject to fluctuations in certain market-based interest rates:

	2003	2004	2005	2006	2007	Thereafter	Total
Vacaville lease <sup>(1)</sup>	\$ 6.0	\$ 6.0	\$ 6.0	\$ 6.0	\$ -	\$ -	\$ 24.0
South San Francisco leases	3.6	3.4	2.8	2.8	1.3	-	13.9
Other operating leases	4.8	3.3	3.1	2.6	2.4	5.2	21.4
Total	\$ 14.4	\$ 12.7	\$ 11.9	\$ 11.4	\$ 3.7	\$ 5.2	\$ 59.3

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

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

	Approximate Initial Fair Value of Leased Property	Lease Expiration	Maximum Residual Value Guarantee
Vacaville Lease	\$ 425.0	11/2006	\$ 371.8
South San Francisco Lease 1	56.6	07/2004	48.1
South San Francisco Lease 2	160.0	06/2007	136.0
South San Francisco Lease 3	25.0	01/2004	21.3
Total	<u>\$ 666.6</u>		<u>\$ 577.2</u>

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

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnifications in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses and expenses to be material. In the case of South San Francisco Lease 1, we have pledged cash collateral of \$56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

### *Contingencies*

We entered into an agreement with Serono S.A. to market Raptiva internationally outside the United States and Japan. Development and marketing rights in the United States remain with us and our U.S. collaborator, XOMA (US) LLC, and we retain exclusive marketing rights in Japan. Under the agreement, we and Serono may collaborate on co-developing additional indications of Raptiva and will share certain global development costs. In addition, we have a supply agreement with Serono, under which we could have a loss exposure up to a maximum of \$10.0 million.

In the second quarter of 2002, we entered into a manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, to provide Immunex with additional manufacturing capacity for ENBREL®

(etanercept) at Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we are responsible for facility modifications needed to manufacture ENBREL, including the internal labor costs and development production runs. The cost of equipment and outside service costs are reimbursable by Immunex.

However, if certain milestones are not met, we are required to reimburse Immunex for up to 45% of the total equipment and outside service costs. Costs associated with development runs are reflected in R&D expense as incurred.

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

## RELATED PARTY TRANSACTIONS

We enter into transactions with Roche, Hoffmann-La Roche and its affiliates in the ordinary course of business. The accounting policies we apply to our transactions with Roche and its affiliates are consistent with those used in transactions with independent third-parties. In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under its existing licensing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 75% of all subsequent global development costs related to Avastin. In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of all subsequent global development costs related to PRO70769. We will receive royalties on all net sales of Avastin and PRO70769 in countries outside of the U.S. Contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities after the option exercise date, totaled \$23.9 million in the third quarter and \$33.5 million in the first nine months of 2003 compared to \$1.9 million in the third quarter and \$7.3 million in the first nine months of 2002. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled \$77.9 million in the third quarter and \$247.5 million in the first nine months of 2003, and \$68.0 million in the third quarter and \$179.9 million in the first nine months of 2002.

We understand that Novartis AG (or Novartis) holds approximately 32.7% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, Novartis is deemed to have an indirect beneficial ownership interest under FAS 57 "Related Party Disclosures" of more than 10% of Genentech's voting stock. In June 2003, we entered into an agreement with Novartis Ophthalmics, an affiliate of Novartis AG, under which Novartis Ophthalmics licensed the exclusive right to develop and market Lucentis outside of North America for indications related to diseases of the eye. As part of this agreement, Novartis Ophthalmics agreed to an upfront milestone and R&D reimbursement fee of \$46.6 million and will pay 50% of Genentech's ongoing Phase III and related development expenses. Genentech is not responsible for any portion of the development and commercialization costs incurred by Novartis outside of North America, but we may receive additional payments for Novartis' achievement of certain clinical development and product approval milestones outside of North America. In addition, we will receive royalties on net sales of Lucentis products outside of North America. During 2000, we entered into an arrangement with Novartis, whereby Novartis was required to fund a portion of the cost of our Xolair inventory until the FDA approved the product for marketing. In June 2003, we received FDA approval to market Xolair; in July 2003, \$37.8 million of funding that had been received from Novartis was repaid. Revenue from Novartis related to product sales was not material in the first nine months of 2003. Contract revenue from Novartis, including amounts recognized under new licensing arrangements entered into in 2003 and amounts earned related to commercial and ongoing development activities, was \$7.4 million in the third quarter and \$18.5 million in the first nine months of 2003. In 2002, our revenue related to Novartis was not material.

## STOCK OPTIONS

### Option Program Description

Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our program primarily consists of our amended

and restated 1999 Stock Plan (the "Plan"), a broad-based plan under which stock options are granted to employees, directors and other service providers. Substantially all of our employees participate in our stock option program. In the past, we granted options under our amended and restated 1996 Stock Option/Stock Incentive Plan, our amended and restated 1994 Stock Option Plan and our amended and restated 1990 Stock Option/Stock Incentive Plan. Although we no longer grant options under these plans, exercisable options granted under these plans are still outstanding.

All stock option grants are made at the fair market value of the underlying stock at the date of grant after a review by, and with the approval of, the Compensation Committee of the Board of Directors. See "The Compensation Committee Report" appearing in our 2003 Proxy Statement on file with the Securities and Exchange Commission for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

### General Option Information

#### Summary of Option Activity

(Shares in thousands)

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
December 31, 2001	14,509	46,640	\$ 41.06
Grants	(12,655)	12,655	28.98
Exercises	-	(1,673)	23.43
Cancellations <sup>(1)</sup>	2,195	(2,203)	53.16
Additional shares reserved	-	-	-
December 31, 2002	<u>4,049</u>	<u>55,419</u>	\$ 38.37
Grants	(10,131)	10,131	\$ 80.95
Exercises	-	(13,853)	29.20
Cancellations <sup>(1)</sup>	1,807	(1,807)	45.72
Additional shares reserved	<u>25,000</u>	-	-
September 30, 2003 (Year to date)	<u>20,725</u>	<u>49,890</u>	\$ 49.29

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

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

(Shares in thousands)

As of September 30, 2003	Exercisable		Unexercisable		Total	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
In-the-Money	22,800	\$ 39.91	16,495	\$ 40.04	39,295	\$ 39.97
Out-of-the-Money <sup>(1)</sup>	1,151	\$ 82.79	9,444	\$ 84.02	10,595	\$ 83.88
Total Options Outstanding	23,951		25,939		49,890	

- (1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of Genentech Common Stock, \$80.14, at the close of business on September 30, 2003.

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## Distribution and Dilutive Effect of Options

## Employee and Executive Officer Option Grants

	2003	2002	2001
Net grants during the year as % of outstanding shares	1.62 %	1.98 %	1.64 %
Grants to Named Executive Officers* during the period as % of outstanding shares	0.18 %	0.25 %	0.22 %
Grants to Named Executive Officers during the year as % of total options granted	9.18 %	10.27 %	10.52 %

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

## Equity Compensation Plan Information

Our stockholders have approved all of our equity compensation plans under which options are outstanding.

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

Because our actual results may differ materially from any forward-looking statements made by or on behalf of Genentech, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, royalties, contract revenues, expenses, net income and earnings per share.

#### **The Successful Development of Biotherapeutics Is Highly Uncertain and Requires Significant Expenditures**

Successful development of biotherapeutics is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in 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 (e.g., the trial failed to meet its primary objectives) or to have harmful or problematic side effects.
- Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, extended length of time to achieve study endpoints, additional time requirements for data analysis or Biologics License Application (or BLA) preparation, discussions with the U.S. Food and Drug Administration (or FDA), an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues.
- Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being 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.

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Factors affecting our research and development (or R&D) expenses include, but are not limited to:

- The number of and the outcome of clinical trials currently being conducted by us and/or our collaborators. For example, our R&D expenses may increase based on the number of late-stage clinical trials being conducted by us and/or our collaborators.
- The number of products entering into development from late-stage research. For example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us. In the past, some promising candidates did not yield sufficiently positive preclinical results to meet our stringent



development criteria.

- Hoffmann-La Roche's decisions whether to exercise its options to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
- In-licensing activities, including the timing and amount of related development funding or milestone payments. For example, we may enter into agreements requiring us to pay a significant upfront fee for the purchase of in-process research and development (or IPR&D), which we may record as an R&D expense.
- As part of our strategy, we invest in R&D. R&D as a percentage of revenues can fluctuate with the changes in future levels of revenue. Lower revenues can lead to more limited spending on R&D efforts.
- Future levels of revenue.

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

The biotechnology and pharmaceutical industries are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA's requirements covering R&D, testing, manufacturing, quality control, labeling and promotion of drugs for human use. A biotherapeutic cannot be marketed in the United States until it has been approved by the FDA, and then can only be marketed for the indications and claims approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application (or NDA) or a BLA, are substantial and can require a number of years. In addition, after any of our products receive regulatory approval, they remain subject to ongoing FDA regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and a product recall.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or that we can maintain necessary regulatory approvals for our existing products, and all of the following could have a material adverse effect on our business:

- Significant delays in obtaining or failing to obtain required approvals as described in "The Successful Development of Biotherapeutics is Highly Uncertain" above.
- Loss of, or changes to, previously obtained approvals.
- Failure to comply with existing or future regulatory requirements.
- Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

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

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

We currently produce all of our products at our manufacturing facilities located in South San Francisco, California and Vacaville, California or through various contract-manufacturing arrangements. Problems with any of our or our contractors' manufacturing processes could result in failure to produce adequate product supplies or product defects, which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all.

In addition, any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall of available product inventory. A number of factors could cause interruptions, including equipment malfunctions or failures, damage to a facility due to natural disasters, including earthquakes as our South San Francisco and Vacaville facilities are located in an area where earthquakes could occur, changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA that results in the halting of production of one or more of our products due to regulatory issues, a contract manufacturer going out of business or other similar factors. Because our manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our and our contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share and damage our reputation.

We may also experience insufficient available capacity to manufacture existing or new products which could cause shortfalls of available product inventory and an inability to supply market demand or we may have an excess of available capacity which could lead to an idling of a portion of our manufacturing facilities and incurring idle plant costs, resulting in an increase in our costs of sales.

### 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, such as the matters discussed in Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

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

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

### The Outcome of, and Costs Relating to, Pending Litigation Are Uncertain

Litigation to which we are currently or have been subjected relates to, among other things, our patent and other intellectual property rights, licensing arrangements with other persons, product liability and financing activities. We cannot predict with certainty the eventual outcome of pending litigation, which may include an injunction against the manufacture or sale of a product or potential product or a significant jury verdict or punitive damages award, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in defending these lawsuits.

## 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

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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 could have an effect on the number of shares we are able to grant under our stock option plans. We therefore cannot assure you that we will be able to attract or retain skilled personnel or maintain key relationships.

## We Face Competition

We face competition in 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® 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. In addition, we face potential competition in the catheter clearance market from the reintroduction of Abbott Laboratories' Abbokinase® (urokinase).

Second, in the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. As a result of that competition, we have experienced a loss in market share in the past. Competitors have also received approval to market their existing growth hormone products for additional indications. As a result of this competition, market share of our growth hormone products may decline. In addition, we have certain patents related to the production of growth hormone that have expired and as a consequence those patents no longer exclude others from making growth hormone using the processes claimed by those patents.

Third, in the non-Hodgkin's lymphoma market, Corixa Corporation received FDA approval in June 2003, for Bexxar™ (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan. IDEC Pharmaceuticals Corporation received marketing approval from the FDA and began commercial shipments in late March 2002 for Zevalin™ (ibritumomab tiuxetan), a product that 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.

Upon launch, Raptiva will compete with established therapies for moderate-to-severe psoriasis including oral systemics such as methotrexate and cyclosporin, as well as ultraviolet light therapies. In addition, Raptiva will compete with Biogen's biologic therapy Amevive® (alefacept), approved by the FDA in January 2003 for the treatment of moderate-to-severe psoriasis. Raptiva will also compete with drugs approved for other indications that are used in psoriasis. Additional biologic therapies are expected to enter the psoriasis market in the next several years. ENBREL® (etanercept), marketed by Amgen and Wyeth in the U.S., is already approved for psoriatic arthritis, a

condition associated with psoriasis. Earlier this year, Amgen announced positive phase III trial results using ENBREL for moderate-to-severe plaque psoriasis, and subsequently announced that ENBREL was filed in July 2003 for FDA approval to treat the condition. Other products are known to be in development for the psoriasis market.

#### Other Factors Could Affect Our Product Sales

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

- The timing of FDA approval, if any, of competitive products.
- Our pricing decisions, including a decision to increase or decrease the price of a product, and the pricing decisions of our competitors.

- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Negative data from new clinical studies could cause the utilization and sales of our products to decrease.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products. For example, as described in Note 2, "Leases and Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q, at various times other companies have filed patent infringement lawsuits against us alleging that the manufacture, use and sale of certain of our products infringe their patents.
- The increasing use and development of alternate therapies. For example, the overall size of the market for thrombolytic therapies, such as our Activase product, continues to decline as a result of the increasing use of mechanical reperfusion.
- The rate of market penetration by competing products. For example, we have lost market share to new competitors in the thrombolytic and, in the past, growth hormone markets.

#### Our Royalty and Contract Revenues Could Decline

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

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

- The expiration or termination of existing arrangements with other companies and Hoffmann-La Roche, which may include development and marketing arrangements for our products in the U.S., Europe and other countries outside the United States.
- The timing of non-U.S. approvals, if any, for products licensed to Hoffmann-La Roche and to other licensees.
- Fluctuations in foreign currency exchange rates.
- The initiation of new contractual arrangements with other companies.
- Whether and when contract benchmarks are achieved.
- The failure of or refusal of a licensee to pay royalties.
- The expiration or invalidation of our patents or licensed intellectual property.
- Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

#### We May Incur Material Product Liability Costs

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

#### Insurance Coverage Is Increasingly More Difficult to Obtain or Maintain

While we currently have insurance for our business, property and our products, first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policy may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

#### Environmental and Other Risks

We generally deal with some hazardous materials in connection with our research and manufacturing activities. In the event such hazardous materials are stored, handled or released into the environment in violation of law or any permit, we could be subject to loss of our permits, government fines or penalties and/or other adverse governmental action. The levy of a substantial fine or penalty, the payment of significant environmental remediation costs or the loss of a permit or other authorization to operate or engage in our ordinary course of business could materially adversely affect our business.

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

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

- The overall competitive environment for our products as described in "We Face Competition" above.
- The amount and timing of sales to customers in the United States. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.
- The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the United States and the amount and timing of sales to their respective customers, which directly impacts both our product sales and royalty revenues.
- The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of therapy.
- The extent of product discounts extended to customers.
- The effectiveness and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.
- The rate of adoption and use of our products for approved indications and additional indications. Among other things, the rate of adoption and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
- The potential introduction of new products and additional indications for existing products.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.

- The number and size of any product price increases we may issue.

#### Our Stock Price, Like That of Many Biotechnology Companies, Is Highly Volatile

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. In addition, the market price of our common stock has been and may continue to be volatile.

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

- Announcements of technological innovations or new commercial products by us or our competitors.
- Developments or outcome of litigation, including litigation regarding proprietary and patent rights.
- Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors.
- Regulatory developments or delays concerning our products in the United States and foreign countries.

- Issues concerning the safety of our products or of biotechnology products generally.
- Economic and other external factors or a disaster or crisis.
- Period-to-period fluctuations in our financial results.

#### In Connection with the Redemption of Our Special Common Stock, We Recorded Substantial Goodwill and Other Intangibles, the Amortization or Impairment 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 accounting principles generally accepted in the United States of America (or GAAP) 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 of approximately \$1,685.7 million and other intangible assets of \$1,499.0 million on June 30, 1999. The other intangible assets are being amortized over their estimated useful lives ranging from 5 to 15 years. See Note 4, "Goodwill and Other Intangible Assets" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for further information on these other intangible assets.

Statement of Financial Accounting Standards (or FAS) No. 142, "Goodwill and Other Intangible Assets," which was adopted January 1, 2002, requires 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 did not meet the new criteria under FAS 141, "Business Combinations," for separate recognition of intangible assets have been reclassified into goodwill upon adoption. These intangible assets included our trained and assembled workforce. In addition, the useful lives of recognized intangible assets acquired in transactions completed before July 1, 2001, will be reassessed at each reporting date and the remaining amortization periods adjusted accordingly. At least annually, we will 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. We performed impairment tests of goodwill on September 30, 2002 and 2003, and found no impairment. For more information, see Note 3, "Relationship With Roche -- Redemption of Our Special Common Stock" and Note 4, "Goodwill and Other Intangible Assets" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

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

In the past, our Board of Directors has authorized stock repurchase programs. Generally, under these programs, Genentech could purchase its stock in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech could also engage in transactions in other Genentech securities in conjunction with the repurchase program, including derivative securities.

While the dollar amounts associated with future stock repurchase programs cannot currently be estimated, future stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access additional capital in the financial markets.

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

Our affiliation agreement with Roche provides that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock based on an established Minimum Percentage. For more information on our stock repurchase program, see Note 9, "Capital Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q. See Note 3, "Relationship With Roche -- Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for information regarding the Minimum Percentage.

While the dollar amounts associated with these future stock repurchases cannot currently be estimated, 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 of Our Common Stock by Roche Could Cause the Price of Our Common Stock to Decline

As of September 30, 2003, Roche owned 306,594,352 shares of our common stock or 58.7% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our common stock. Sales of a substantial number of shares of our common stock by Roche in the public market could adversely affect the market price of our common stock.

### Roche Holdings, Inc., Our Controlling Stockholder, May Have Interests That Are Adverse to Other Stockholders

Roche as our majority stockholder, controls the outcome of 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.



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- 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 Ability to Maintain Its Percentage Ownership Interest in Our Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q. For more information on our stock repurchase program, see Note 9, "Capital Stock" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

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

### Our Stockholders May Be Unable to Prevent Transactions That Are Favorable to Roche but Adverse to Us

Our certificate of incorporation includes provisions relating to:

- Competition by Roche with us.
- Offering of corporate opportunities.
- Transactions with interested parties.
- Intercompany agreements.
- Provisions limiting the liability of specified employees.

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

### Potential Conflicts of Interest Could Limit Our Ability to Act on Opportunities That Are Adverse to Roche

Persons who are directors and/or officers of Genentech and who are also directors and/or officers of Roche may decline to take action in a manner that might be favorable to us but adverse to Roche. Two of our directors, Dr. Franz B. Humer and Dr. Jonathan K.C. Knowles, currently serve as officers and employees of Roche Holding Ltd and its affiliates, and Dr. Humer is a director and the Chairman of Roche Holding Ltd.

### We Are Exposed to Market Risk

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

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

The estimated exposures discussed below are intended to measure the maximum amount we could lose from adverse market movements in interest rates, foreign currency exchange rates and equity investment prices, given a

specified confidence level, over a given period of time. Loss is defined in the value at risk estimation as fair market value loss. The exposures to interest rate, foreign currency exchange rate and equity investment price changes are calculated based on proprietary modeling techniques from a Monte Carlo simulation value at risk model using a 21-trading days holding period and a 95% confidence level. The value at risk model assumes non-linear financial returns and generates potential paths various market prices could take and tracks the hypothetical performance of a portfolio under each scenario to approximate its financial return. The value at risk model takes into account correlations and diversification across market factors, including interest rates, foreign currencies and equity prices. Hedge instruments are modeled as positions on the actual underlying securities. No proxies were used. Market volatilities and correlations are based on a one-year historical times-series provided by J.P. Morgan Riskmetrics™ as of December 31, 2002.

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

Our material interest-bearing assets, or interest-bearing portfolio, consisted of cash, cash equivalents, restricted cash, short-term investments, convertible preferred stock investments, nonmarketable debt securities, long-term investments and interest-bearing forward contracts. The balance of our interest-bearing portfolio, including restricted and unrestricted cash, was \$3,053.6 million or 36% of total assets at September 30, 2003. Interest income related to this portfolio was \$56.2 million in the first nine months of 2003. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest-bearing portfolio. To mitigate the impact of fluctuations in U.S. interest rates, for a portion of our portfolio, we may enter into swap transactions that involve the receipt of fixed rate interest and the payment of floating rate interest without the exchange of the underlying principal.

Based on our overall interest rate exposure at December 31, 2002, including derivative and other interest rate sensitive instruments, a near-term change in interest rates, within a 95% confidence level based on historical interest rate movements could result in a potential loss in fair value of our interest rate sensitive instruments of \$14.1 million.

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

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

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

Based on our overall currency rate exposure at December 31, 2002, including derivative and other foreign currency sensitive instruments, a near-term change in currency rates within a 95% confidence level based on historical currency rate movements would not materially affect the fair value of our foreign currency sensitive instruments.

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

As part of our strategic alliance efforts, we invest in equity instruments of biotechnology companies. Our biotechnology equity investment portfolio totaled \$326.4 million or 4% of total assets at September 30, 2003. These investments are subject to fluctuations from market value changes in stock prices. For example, in 2002, we recorded charges related to the write-down of certain equity security investments that had other than temporary impairments.

To mitigate the risk of market value fluctuation, certain equity securities are hedged with zero-cost collars and forward contracts. A zero-cost collar is a purchased put option and a written call option in which the cost of the purchased put and the proceeds of the written call offset each other; therefore, there is no initial cost or cash outflow for these instruments at the time of purchase. The purchased put protects us from a decline in the market value of the security below a certain minimum level (the put "strike" level), while the call effectively limits our potential to benefit from an increase in the market value of the security above a certain maximum level (the call "strike" level). A forward contract is a derivative instrument where we lock-in the termination price we receive from the sale of stock based on a pre-determined spot price. The forward contract protects us from a decline in the market value of the security below the spot price and limits our potential benefit from an increase in the market value of the security above the spot price. Throughout the life of the contract, we receive interest income based on the notional amount and a floating-rate index. In addition, as part of our strategic alliance efforts, we hold convertible preferred stock, including dividend-bearing convertible preferred stock, and have made interest-bearing loans that are convertible into the equity securities of the debtor or repaid in cash. Depending on market conditions, we may determine that in 2003 certain of our other unhedged equity security investments are impaired, which would result in additional write-downs of those equity security investments.

Based on our overall exposure to fluctuations from market value changes in marketable equity prices at December 31, 2002, a near-term change in equity prices within a 95% confidence level based on historic volatilities could result in a potential loss in fair value of our equity securities portfolio of \$23.0 million.

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

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

#### The Company's Effective Tax Rate May Vary Significantly

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include but are not limited to changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings.

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

In January 2003, the Financial Accounting Standards Board (or FASB) issued Interpretation No. 46 (or FIN 46), "Consolidation of Variable Interest Entities," an interpretation of Accounting Research Bulletin No. 51. FIN 46 requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE's expected losses, receives a majority of the entity's expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003. However, the FASB deferred the effective date for VIEs created before February 1, 2003 to the period ended December 31, 2003 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. See the "Change in Accounting Principle" above and Note 2, "Leases and Contingencies" in the Notes

to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for a discussion of our synthetic leases and the impact of our adoption of FIN 46.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options. Under APB 25, no compensation expense is recognized unless the exercise price of our employee stock options is less than the market price of the underlying stock on the date of grant. We have not recorded such expenses in the periods presented because we grant options at the fair market value of the underlying stock on the date of grant. See Note 1, "Summary of Significant Accounting Policies" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for the required disclosures under FAS 148.

There may be potential new accounting pronouncements or regulatory rulings, which may have an impact on our future financial position and results of operations. In particular, there are a number of rule changes and proposed legislative initiatives following the recent corporate bankruptcies and failures which could result in changes in accounting rules, including the accounting for employee stock options as an expense. These and other potential changes could materially impact our assets and liabilities, and the expenses we report under generally accepted accounting principles, and could adversely affect our operating results or financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2003 have not changed significantly from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2002 on file with the Securities and Exchange Commission. See Note 5, "Derivative Financial Instruments," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 and the "Forward-Looking Information and Cautionary Factors That May Affect Future Results -- We Are Exposed to Market Risk" section of Item 2 of this Form 10-Q for additional discussions of our market risks.

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* The Company's principal executive and financial officers reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rule 13a-15 and 15(d)-15) as of the end of the period covered by this Form 10-Q. Based on that evaluation, the Company's principal executive and financial officers concluded that the Company's disclosure controls and procedures are effective in timely providing them with material information relating to the Company, as required to be disclosed in the reports the Company files under the Exchange Act.

(b) *Changes in internal control over financial reporting.* There was no change in our internal control over financial reporting that occurred during the period covered by this Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

In the arbitration proceeding between Genentech and Tanox, a decision in the arbitration has been delayed and is expected no earlier than December 15, 2003.

See also Item 3 of our report on Form 10-K for the period ended December 31, 2002 and Part II, Item 1 of each of our reports on Form 10-Q for the periods ended March 31, 2003 and June 30, 2003.

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

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

- (i) 15.1 Letter regarding Unaudited Interim Financial Information.
- (ii) 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- (iii) 31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- (iv) 32.1 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K.

On July 9, 2003, we filed a Report on Form 8-K under Item 5 - Other Events, reporting the issuance of a press release, announcing our earnings for the quarter ended June 30, 2003.

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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: November 3, 2003

/s/ARTHUR D. LEVINSON

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

Date: November 3, 2003

/s/LOUIS J. LAVIGNE, JR.

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

Date: November 3, 2003

/s/JOHN M. WHITING

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