

GENENTECH INC  
Form 10-Q  
May 02, 2006

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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 March 31, 2006**

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**

(State or other jurisdiction of incorporation or  
organization)

**94-2347624**

(I.R.S. Employer Identification Number)

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

(Address of principal executive offices and Zip Code)

**(650) 225-1000**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

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

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock \$0.02 par value	1,053,627,146 Outstanding at April 26, 2006

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In this report, “Genentech,” “we,” “us” and “our” refer to Genentech, Inc.; “Common Stock” refers to Genentech’s Common Stock, par value \$0.02 per share, “Special Common Stock” refers to Genentech’s callable puttable Common Stock, par value \$0.02 per share, all of which was redeemed by Roche Holdings, Inc. (or “Roche”) on June 30, 1999.

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin® (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis™ (ranibizumab, rhuFab V2) anti-VEGF antibody fragment; Nutropin® (somatropin (rDNA origin) for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen® (somatropin (rDNA origin) for injection) liquid

formulation growth hormone; Nutropin Depot® (somatropin (rDNA origin) for injectable suspension) encapsulated sustained-release growth hormone; Omnitarg™ (pertuzumab) HER dimerization inhibitor; Protropin® (somatrem for injection) growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva® (efalizumab) anti-CD11a antibody; and TNKase® (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva® (erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks and trade names of other companies.

**PART I—FINANCIAL INFORMATION****Item 1. Financial Statements**

**GENENTECH, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF INCOME**  
*(In millions, except per share amounts)*  
*(Unaudited)*

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Revenues</b>		
Product sales (including amounts from related parties: 2006-\$59; 2005-\$54)	\$ 1,644	\$ 1,186
Royalties (including amounts from a related party: 2006-\$167; 2005-\$104)	286	232
Contract revenue (including amounts from related parties: 2006-\$28; 2005-\$26)	56	44
<b>Total operating revenues</b>	<b>1,986</b>	<b>1,462</b>
<b>Costs and expenses</b>		
Cost of sales (including amounts for related parties: 2006 and 2005-\$50)	262	256
Research and development (including amounts for related parties: 2006-\$53; 2005-\$44) (including contract related: 2006-\$36; 2005-\$27)	374	243
Marketing, general and administrative	441	310
Collaboration profit sharing (including amounts for a related party: 2006-\$43; 2005-\$24)	226	176
Recurring charges related to redemption	26	35
Special items: litigation-related	13	11
<b>Total costs and expenses</b>	<b>1,342</b>	<b>1,031</b>
Operating income	644	431
Other income (expense):		
Interest and other income, net	53	18
Interest expense	(19)	(3)
Total other income, net	34	15
Income before taxes	678	446
Income tax provision	257	162
<b>Net income</b>	<b>\$ 421</b>	<b>\$ 284</b>
<b>Earnings per share</b>		
Basic	\$ 0.40	\$ 0.27
Diluted	\$ 0.39	\$ 0.27
Shares used to compute basic earnings per share	1,054	1,047
Shares used to compute diluted earnings per share	1,075	1,067



**GENENTECH, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(In millions)*  
*(Unaudited)*

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 421	\$ 284
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	96	88
Employee stock-based compensation	74	-
Deferred income taxes	(50)	(21)
Deferred revenue	10	(9)
Litigation-related liabilities	13	13
Tax benefit from employee stock options	-	51
Excess tax benefit from stock-based compensation arrangements	(49)	-
Gain on sales of securities available-for-sale and other	(3)	(1)
Write-down of securities available-for-sale and other	-	4
Changes in assets and liabilities:		
Receivables and other current assets	(96)	(103)
Inventories	(86)	25
Investments in trading securities	(7)	(1)
Accounts payable, other accrued liabilities, and other long-term liabilities	139	55
<b>Net cash provided by operating activities</b>	<b>462</b>	<b>385</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(454)	(72)
Proceeds from sales and maturities of securities available-for-sale	193	162
Capital expenditures	(253)	(144)
Change in other assets	(13)	(8)
<b>Net cash used in investing activities</b>	<b>(527)</b>	<b>(62)</b>
<b>Cash flows from financing activities</b>		
Stock issuances under employee stock plans	89	106
Stock repurchases	(227)	(156)
Excess tax benefit from stock-based compensation arrangements	49	-
<b>Net cash used in financing activities</b>	<b>(89)</b>	<b>(50)</b>
Net (decrease) increase in cash and cash equivalents	(154)	273
Cash and cash equivalents at beginning of period	1,225	270
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,071</b>	<b>\$ 543</b>
<b>Supplemental cash flow data</b>		
Non-cash investing and financing activities		
Capitalization of construction in progress related to financing lease transaction	\$ 27	\$ 44

Exchange of note receivable for a prepaid royalty and other long-term asset	-	29
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*See Notes to Condensed Consolidated Financial Statements.*



**GENENTECH, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(In millions)*  
*(Unaudited)*

	March 31, 2006	December 31, 2005
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 1,071	\$ 1,225
Short-term investments	1,213	1,140
Accounts receivable—product sales (net of allowances: 2006-\$93; 2005-\$83; including amounts from related parties: 2006-\$24; 2005-\$4)	615	554
Accounts receivable—royalties (including amounts from related party: 2006-\$199; 2005-\$173)	332	297
Accounts receivable—other (net of allowances: 2006-\$1; 2005-\$1; including amounts from related parties: 2006-\$129; 2005-\$132)	187	199
Inventories	804	703
Prepaid expenses and other current assets	311	268
Total current assets	4,533	4,386
Long-term marketable debt and equity securities	1,658	1,449
Property, plant and equipment, net	3,565	3,349
Goodwill	1,315	1,315
Other intangible assets	548	574
Restricted cash and investments	735	735
Other long-term assets	358	339
<b>Total assets</b>	<b>\$ 12,712</b>	<b>\$ 12,147</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable (including amounts to related parties: 2006-\$3; 2005-\$1)	\$ 328	\$ 339
Deferred revenue	45	44
Taxes payable	318	62
Other accrued liabilities (including amounts to related parties: 2006-\$148; 2005-\$132)	1,059	1,215
Total current liabilities	1,750	1,660
Long-term debt	2,103	2,083
Deferred revenue	229	220
Litigation-related and other long-term liabilities	736	714
Total liabilities	4,818	4,677
Commitments and contingencies		
Stockholders' equity		
Common stock	21	21
Additional paid-in capital	9,468	9,263
Accumulated other comprehensive income	255	253
Accumulated deficit, since June 30, 1999	(1,850)	(2,067)

Total stockholders' equity		7,894		7,470
<b>Total liabilities and stockholders' equity</b>	<b>\$</b>	<b>12,712</b>	<b>\$</b>	<b>12,147</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 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. 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, 2005. 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 expected for the full year or any future period.

***Principles of Consolidation***

The Condensed Consolidated Financial Statements include the accounts of Genentech and all wholly owned subsidiaries. Material intercompany accounts and transactions have been eliminated.

***Use of Estimates and Reclassifications***

The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in our Condensed Consolidated Financial Statements and accompanying notes. Actual results could differ materially from those estimates.

Certain reclassifications of prior period amounts have been made to our Condensed Consolidated Financial Statements to conform to the current period presentation.

***Earnings Per Share***

Basic earnings per share (or “EPS”) are computed based on the weighted-average number of shares of our Common Stock outstanding. Diluted EPS are computed based on the weighted-average number of shares of our Common Stock and other dilutive securities.

The following is a reconciliation of the numerators and denominators of the basic and diluted EPS computations (*in millions*):

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Numerator:</b>		
Net income	\$ 421	\$ 284

**Denominator:**

Weighted-average shares outstanding used to compute basic EPS	1,054	1,047
Effect of dilutive stock options	21	20
Weighted-average shares outstanding and dilutive securities used to compute diluted EPS	1,075	1,067

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Employee stock options to purchase approximately 19 million shares of our Common Stock were outstanding in the first quarter of 2006. These employee stock options were excluded from the computation of diluted EPS because the effect would have been anti-dilutive.

### ***Comprehensive Income***

Comprehensive income is comprised of net income and other comprehensive income (or “OCI”). OCI includes certain changes in stockholders’ equity that are excluded from net income. Specifically, we include in OCI changes in the estimated fair value of derivatives designated as effective cash flow hedges and unrealized gains and losses on our available-for-sale securities.

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

	<b>March 31, 2006</b>		<b>December 31, 2005</b>	
Net unrealized gains on securities available-for-sale	\$	233	\$	230
Net unrealized gains on cash flow hedges		22		23
Accumulated other comprehensive income	\$	255	\$	253

The activity in comprehensive income, net of income taxes, was as follows (*in millions*):

	<b>Three Months Ended March 31, 2006</b>		<b>2005</b>	
Net income	\$	421	\$	284
Change in unrealized gains (losses) on securities available-for-sale		3		(77)
Change in unrealized gains (losses) on derivatives		(1)		13
Comprehensive income	\$	423	\$	220

### ***Derivative Financial Instruments***

At March 31, 2006, estimated net gains on cash flow hedge derivative instruments, consisting of foreign currency exchange options and marketable equity security collars, expected to be reclassified from accumulated OCI to “other income, net” during the next twelve months are \$23 million.

### **Note 2. Employee Stock-Based Compensation**

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), “Share-Based Payment” (or “FAS 123R”), which supersedes our previous accounting under APB Opinion No. 25, “Accounting for Stock Issued to Employees” (or “APB 25”). FAS 123R requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options and stock issued under our employee stock plans. FAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our Condensed Consolidated Statements of Income. Also, certain of these costs are capitalized into inventory on our Condensed Consolidated Balance Sheets, and generally will be recognized as an expense when the related products are sold. We adopted FAS 123R using the modified prospective transition method, which requires that compensation expense be recognized in the financial statements for all awards granted after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method does

not require restatement of prior periods to reflect the impact of FAS 123R.

In November 2005, the Financial Accounting Standards Board (or “FASB”) issued FSP No. 123R-3, “Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards.” We have adopted the simplified method to calculate the beginning balance of the additional paid-in-capital (or “APIC”) pool of the excess

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tax benefit, and to determine the subsequent impact on the APIC pool and Condensed Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that were outstanding upon our adoption of FAS 123R.

Prior to the adoption of FAS 123R, we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under FAS No. 123, "Accounting for Stock-Based Compensation" (or "FAS 123"). Under the intrinsic value method, no employee stock-based compensation expense had been recognized in our Condensed Consolidated Statements of Income for any period prior to our adoption of FAS 123R on January 1, 2006, as the exercise price of the stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

### ***Employee Stock Plans***

We currently have an employee stock purchase plan, adopted in 1991 and amended thereafter (or "the 1991 Plan"). The 1991 Plan allows eligible employees to purchase Common Stock at 85% of the lower of the fair market value of the Common Stock on the grant date or the fair market value on the purchase date. The offering period under the 1991 Plan is currently 15 months, and the purchase price is established during each new offering period. Purchases are limited to 15% of each employee's eligible compensation and subject to certain Internal Revenue Service restrictions. All of our full-time employees are eligible to participate in the 1991 Plan. Of the 52,400,000 shares of Common Stock reserved for issuance under the 1991 Plan, 45,640,634 shares have been issued as of March 31, 2006.

We currently grant options under a stock option plan adopted in 1999 and amended thereafter (or "the 1999 Plan"), that allows for the granting of non-qualified stock options, incentive stock options and stock purchase rights to our employees, directors and consultants. 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, and 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. When an employee over the age of 65 retires, the number of options that would have vested in the 12 month period following the retirement date, if the retiree had remained an employee, automatically becomes fully vested. The expiration date of the exercisable options remains the original expiration date at the time the options were granted. Upon employee termination, unexercised options will expire at the end of three months. No stock purchase rights or incentive stock options have been granted under the 1999 Plan to date.

### ***Adoption of FAS 123R***

Employee stock-based compensation expense recognized in the first quarter of 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Employee stock-based compensation expense recognized under FAS 123 was as follows (*in millions, except for per share data*):

	<b>Three Months Ended March 31, 2006</b>
Research and development	\$ 33
Marketing, general and administrative	41
Total employee stock-based compensation expense	74
Tax benefit related to employee stock-based compensation expense	(27)

Net effect on net income	\$	47
Effect on earnings per share:		
Basic	\$	0.04
Diluted	\$	0.04

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As of March 31, 2006, total compensation cost related to nonvested stock options not yet recognized was \$734 million, which is expected to be allocated to expense and production costs over a weighted-average period of 27 months.

The carrying value of inventory on our Condensed Consolidated Balance Sheet as of March 31, 2006 includes employee stock-based compensation costs of \$16 million. Substantially all of the products sold in the first quarter of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs. In future periods, when product manufactured after the adoption of FAS 123R is sold or written off, or reserves are required for obsolescence or lack of demand, we will recognize employee stock-based compensation expense in cost of sales.

The following pro forma net income and EPS were determined as if we had accounted for employee stock-based compensation for our employee stock plans under the fair value method prescribed by FAS 123 in prior periods and had capitalized certain costs into inventory manufactured in those prior periods, with the resulting impact on cost of sales for the quarter ended March 31, 2006 when previously manufactured products were sold. *(In millions, except for per share data):*

	<b>Three Months Ended March 31, 2006</b>
Net income as reported	\$ 421
Deduct: Total employee stock-based compensation expense includable in cost of sales, net of related tax effects	(8)
Pro forma net income	\$ 413
Earnings per share:	
Basic-as reported	\$ 0.40
Basic-pro forma	\$ 0.39
Diluted-as reported	\$ 0.39
Diluted-pro forma	\$ 0.38

***Pro Forma Information for Period Prior to Adoption of FAS 123R***

The following pro forma net income and EPS were determined as if we had accounted for employee stock-based compensation for our employee stock plans under the fair value method prescribed by FAS 123. *(In millions, except for per share data):*

	<b>Three Months Ended March 31, 2005</b>
Net income as reported	\$ 284
Deduct: Total employee stock-based compensation expense determined under the fair value based method for all awards, net of related tax effects	(40)
Pro forma net income	\$ 244
Earnings per share:	
Basic-as reported	\$ 0.27
Basic-pro forma	\$ 0.23
Diluted-as reported	\$ 0.27
Diluted-pro forma	\$ 0.22



**Valuation Assumptions**

The employee stock-based compensation expense recognized under FAS 123R and presented in the pro forma disclosure required under FAS 123 was determined using the Black-Scholes option valuation model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted-average assumptions used are as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Risk-free interest rate	4.6%	4.0%
Dividend yield	0.0%	0.0%
Expected volatility	29.0%	32.0%
Expected term (years)	4.2	4.2

Due to the redemption of our Special Common Stock in June 1999 by Roche, there is limited historical information available to support our estimate of certain assumptions required to value our employee stock options and the stock issued under our employee stock purchase plan. In developing our estimate of expected term, we have determined that our historical stock option exercise experience is a relevant indicator of future exercise patterns. We also take into account other available information, including industry averages. We primarily base our determination of expected volatility through our assessment of the implied volatility of our Common Stock. Implied volatility is the volatility assumption inherent in the market prices of a company's traded options.

**Stock Option Activity**

The following is a summary of option activity for the first quarter of 2006 (*shares in millions*):

	<b>Shares Available for Grant</b>	<b>Options Outstanding</b>	
		<b>Number of Shares</b>	<b>Weighted- Average Exercise Price</b>
<b>December 31, 2005</b>	84	83	\$ 46.64
Grants	(1)	1	88.10
Exercises	-	(2)	30.38
Cancellations	1	(1)	57.63
<b>March 31, 2006</b>	84	81	\$ 47.43

The intrinsic value of options exercised during the first quarters of 2006 and 2005 was \$125 million and \$117 million, respectively. The estimated fair value of shares vested during the first quarters of 2006 and 2005 was \$90 million and \$40 million, respectively. The weighted-average estimated fair value of stock options granted during the three months ended March 31, 2006 and 2005 was \$27.34 and \$15.95, respectively, based on the assumptions in the Black-Scholes valuation model discussed above.

The following table summarizes outstanding and exercisable options at March 31, 2006 (*in millions, except exercise price data*):

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number of Shares Outstanding	Weighted-Average Contractual Life (in years)	Weighted-Average Exercise Price	Number of Shares Outstanding	Weighted-Average Contractual Life (in years)	Weighted-Average Exercise Price
\$6.27 - \$8.89	0.5	5.61	\$ 7.71	0.5	5.61	\$ 7.71
\$10.00 - \$14.35	13.7	5.68	\$ 13.73	11.2	5.51	\$ 13.61
\$15.04 - \$22.39	9.0	5.09	\$ 20.82	8.7	5.04	\$ 20.91
\$22.88 - \$33.00	0.3	5.07	\$ 27.53	0.3	5.07	\$ 27.53
\$35.63 - \$53.23	36.9	7.53	\$ 46.79	18.0	6.93	\$ 44.71
\$53.95 - \$75.90	1.5	8.53	\$ 59.26	0.5	8.34	\$ 56.09
\$81.15 - \$98.80	18.9	9.49	\$ 86.12	-	9.54	\$ 86.04
	80.8			39.2		

At March 31, 2006, the aggregate intrinsic value of the outstanding options was \$3,032 million and the aggregate intrinsic value of the exercisable options was \$2,136 million.

### ***Stock Repurchase Program***

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2006 (see also Note 7, "Subsequent Event" for a discussion of the April 2006 extension), we are authorized to repurchase up to 100 million shares of our Common Stock for an aggregate amount of up to \$6.0 billion through June 30, 2007. During the first quarter of 2006, we repurchased approximately 3 million shares at an aggregate cost of \$227 million. Since the program's inception, we have repurchased approximately 52 million shares at a total price of \$3.6 billion. We intend to use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock plans and also to maintain Roche's minimum percentage ownership interest in our stock.

### **Note 3. Condensed Consolidated Financial Statement Detail**

#### ***Inventories***

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

	March 31, 2006	December 31, 2005
Raw materials and supplies	\$ 89	\$ 79
Work in process	463	438
Finished goods	252	186
Total	\$ 804	\$ 703

Included in work in process are approximately \$47 million at March 31, 2006 and \$31 million at December 31, 2005 for pre-approval inventories of Lucentis, in anticipation of the product launch, and for a qualification campaign at a contract manufacturing facility. During the first quarter of 2006, approximately \$16 million in employee stock-based compensation costs were capitalized in inventory pursuant to FAS 123R.



#### Note 4. Contingencies

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

On October 4, 2004, we received a subpoena from the United States (or “U.S.”) Department of Justice, requesting documents related to the promotion of Rituxan, a prescription treatment now approved for three indications: (1) the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin’s lymphoma, (2) the first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma in combination with CHOP or other anthracycline-based chemotherapy regimens (approved on February 10, 2006), and (3) for use in combination with methotrexate to reduce signs and symptoms in adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies (approved on February 28, 2006). We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. The government has called and is expected to call former and current Genentech employees to appear before a grand jury in connection with this investigation. The outcome of this matter cannot be determined at this time.

On July 29, 2005, a former Genentech employee, whose employment ended in April 2005, filed a qui tam complaint under seal in the United States District Court for the District of Maine against Genentech and Biogen Idec, alleging violations of the False Claims Act and retaliatory discharge of employment. On December 20, 2005, the United States District Court filed notice of its election to decline intervention in the lawsuit. The complaint was subsequently unsealed and we were served on January 5, 2006. The outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (or “COH”) are parties to a 1976 agreement relating to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the “Riggs/Itakura Patents.” Since that time, we have 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. On June 10, 2002, a jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, a 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 are included in the accompanying Condensed Consolidated Balance Sheets in “litigation-related and other long-term liabilities” at March 31, 2006 and December 31, 2005. We filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. On October 21, 2004, the California Court of Appeal affirmed the verdict and damages awards in all respects. On November 22, 2004, the California Court of Appeal modified its opinion without changing the verdict and denied Genentech’s request for rehearing. On November 24, 2004, we filed a petition seeking review by the California Supreme Court. On February 2, 2005, the California Supreme Court granted that petition. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court’s review of the matter, however, it may take longer than one year to further resolve the matter.

We recorded \$13 million of accrued interest and bond costs related to the COH trial judgment for the three months ended March 31, 2006 and 2005. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of \$735 million at March 31, 2006 and December 31, 2005 to secure the bond. These amounts are reflected in “restricted cash and investments” in the accompanying Condensed Consolidated Balance Sheets. 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.

On April 11, 2003, MedImmune, Inc. (or “MedImmune”) filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 (or “the ‘415 patent” or “Cabilly patent”) that we co-own with COH and under which MedImmune and other companies have been licensed and are paying royalties to us. The lawsuit includes claims for

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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 us from enforcing the '415 patent, an award of actual and exemplary damages, and other relief. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in our favor on all of MedImmune's antitrust and unfair competition claims. On April 23, 2004, the District Court granted our motion to dismiss all remaining claims in the case. On October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. MedImmune filed a petition for certiorari with the United States Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune's petition on February 21, 2006 and the briefing on the merits of this case before the Supreme Court is ongoing. The outcome of this matter cannot be determined at this time.

On May 13, 2005, a request was filed by a third party for reexamination of the '415 or Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent Office ordered reexamination of the '415 patent. On September 13, 2005, the Patent Office issued an initial "non-final" Office action rejecting the claims of the '415 patent. We filed our response to the Office action on November 25, 2005. The Patent Office has not yet acted on this response. On December 23, 2005, a second request for reexamination of the '415 patent was filed by another third party. On January 23, 2006, the Patent office granted the reexamination request.

Because the two above-described reexamination proceedings are ongoing, the final outcome of these matters cannot be determined at this time. The '415 patent, which expires in 2018, relates to methods we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. We have licensed the '415 patent to other companies and derive significant royalties from those licenses. The claims of the '415 patent remain valid and enforceable throughout the reexamination process.

## **Note 5. Relationship with Roche and Related Party Transactions**

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

We 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 with respect to any issuance of Common Stock by Genentech in the future, we will repurchase a sufficient number of shares so that immediately after such issuance the percentage of Genentech Common Stock owned by Roche will be no lower than 2% below the "Minimum Percentage" (as defined below), provided however, as long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, 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 Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by Roche since the July 1999 offering (adjusted for dispositions of shares of Genentech Common Stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704, the number of shares of Genentech Common Stock outstanding at the time of the July 1999 offering, as adjusted for stock splits. We have repurchased shares of our Common Stock since 2001. 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. The Minimum Percentage at March 31, 2006 was 57.7% and, under the terms of the affiliation agreement, Roche's ownership percentage is to be no lower than 55.7%. At March 31, 2006, Roche's ownership percentage was 55.7%.

### **Related Party Transactions**



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

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### ***Hoffmann-La Roche***

Under our existing arrangements with Hoffmann-La Roche, including our licensing and marketing agreements, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$18 million and \$16 million in the first quarters of 2006 and 2005, respectively. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled \$224 million and \$155 million in the first quarters of 2006 and 2005, respectively. Cost of sales (or “COS”) included amounts related to Hoffmann-La Roche of \$49 million and \$47 million in the first quarters of 2006 and 2005, respectively. Our reported research and development (or “R&D”) expenses in each of the first quarters of 2006 and 2005 included \$43 million and \$34 million, respectively, related to development activities undertaken on projects on which we collaborate with Hoffmann-La Roche.

### ***Novartis***

Based on information available to us at the time of filing this Form 10-Q, we believe the Novartis Group holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, the Novartis Group is deemed to have an indirect beneficial ownership interest under FAS 57 “Related Party Disclosures” of more than 10% of our voting stock.

We have an agreement with Novartis Ophthalmics (now merged into Novartis AG) under which Novartis Ophthalmics has the exclusive right to develop and market Lucentis outside of the U.S. and Canada for indications related to diseases or disorders of the eye. As part of this agreement, the parties share the cost of certain of our ongoing Phase III and related development expenses.

We, along with Novartis Pharma AG (a wholly owned subsidiary of Novartis AG) and Tanox, Inc., are co-developing Xolair in the U.S. We and Novartis are co-promoting Xolair in the U.S. and we both make certain joint and individual payments to Tanox; Genentech’s joint and individual payments are in the form of royalties. We record all sales and cost of sales in the U.S. and Novartis markets the product and records all sales and cost of sales in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. We are currently supplying the product and receive cost plus a mark-up similar to other supply arrangements. On January 20, 2006, Novartis received FDA approval to manufacture bulk supply of Xolair at their Huningue production facility in France. Future production costs of Xolair may initially be higher than those currently reflected in our COS as a result of the production shift from us to Novartis until production economies of scale can be achieved by Novartis.

Contract revenue from Novartis related to manufacturing, commercial and ongoing development activities was \$10 million in the first quarters of 2006 and 2005. Revenue from Novartis related to product sales and COS was not material in the first quarters of 2006 and 2005. Our reported R&D expenses in each of the first quarters of 2006 and 2005 included approximately \$10 million related to development activities undertaken on products on which we collaborate with Novartis. Collaboration profit sharing payments from us to Novartis were \$43 million and \$24 million in the first quarters of 2006 and 2005, respectively.

### **Note 6. Income Taxes**

The effective income tax rate was 38% in the first quarter of 2006, as compared to 36% in the first quarter of 2005. The increase in the income tax rate primarily reflects higher income before taxes and the December 31, 2005 expiration of provisions in federal tax law for the R&D tax credit. Currently there are bills in Congress to extend the R&D tax credit retroactively to January 1, 2006. If such legislation is passed, then at that time we will record a tax benefit for R&D tax credits.



**Note 7. Subsequent Event**

***Stock Repurchase Program***

On April 19, 2006, our Board of Directors authorized the extension of our current stock repurchase program for the repurchase of up to an additional \$2 billion of our common stock for a total of \$6 billion through June 30, 2007. Our Board of Directors also amended the current repurchase program by increasing the maximum number of shares that can be repurchased from 80 million to 100 million shares.

Under our stock repurchase program we repurchased approximately 664,000 shares of our common stock, at a cost of approximately \$53 million during the period from April 1 through April 25, 2006.

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**Report of Independent Registered Public Accounting Firm**

*The Board of Directors and Stockholders of Genentech, Inc.*

We have reviewed the condensed consolidated balance sheet of Genentech, Inc. as of March 31, 2006, and the related condensed consolidated statements of income and cash flows for the three-month periods ended March 31, 2006 and 2005. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

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

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Genentech, Inc. as of December 31, 2005, and the related consolidated statements of income, stockholders' equity, and cash flows for the year then ended not presented herein, and in our report dated February 10, 2006, 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, 2005, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
April 7, 2006,  
except for Note 7, as to which the date is  
April 25, 2006

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

### GENENTECH, INC. FINANCIAL REVIEW

#### Overview

##### *The Company*

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. We commercialize multiple biotechnology products, and also receive royalties from companies that are licensed to market products based on our technology.

##### *Major Developments in the First Quarter of 2006*

In the first quarter of 2006, our total operating revenues were \$1,986 million, an increase of 36% from \$1,462 million in the first quarter of 2005. Our net income was \$421 million, an increase of 48% from \$284 million in the first quarter of 2005. Net income in the first quarter of 2006 includes the effect of stock-based compensation expense related to employee stock options and employee stock purchases under Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" (or "FAS 123R"), which decreased our net income by \$47 million after taxes.

Significant milestones during the first quarter of 2006 were as follows:

*We received the following U.S. Food and Drug Administration (or "FDA") approvals:*

- Rituxan - for use in first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma (or "DLBCL"); and
- Rituxan - to treat patients with active rheumatoid arthritis (or "RA") who have had an inadequate response to tumor necrosis factor antagonist therapy.

*We submitted the following FDA filings:*

- a Supplemental Biologics License Application (or "sBLA") for use of Herceptin to treat early-stage, HER2-positive breast cancer;
- with Biogen Idec, an sBLA for use of Rituxan to treat indolent front-line non-Hodgkin's lymphoma (or "NHL"); and
- on April 11, 2006, an sBLA for use of Avastin in first-line treatment of advanced, non-squamous, non-small cell lung cancer.

On February 28, 2006, the FDA accepted our Biologics License Application (or "BLA") for the use of Lucentis in the treatment of neovascular wet age-related macular degeneration with an action date of June 30, 2006.

In January 2006, the FDA approved the production of Xolair bulk drug substance at Novartis' production facility in Huningue, France. In addition, in February 2006, we acquired a second facility in Oceanside, California from Biogen Idec. The facility was purchased for \$29 million and includes approximately 5,500 liters of capacity to be used for

clinical bulk manufacturing of new molecular entities.

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On January 1, 2006, we adopted FAS 123R, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors, including employee stock options and employee stock purchases, based on estimated fair values. Employee stock-based compensation expense recognized under FAS 123R for the three months ended March 31, 2006 was \$74 million, or approximately \$0.04 per diluted share. For the full year 2006, we expect employee stock-based compensation expense to be in the range of \$0.15 to \$0.17 per diluted share. See also Note 2, "Employee Stock-Based Compensation" in the Condensed Consolidated Financial Statements of Part 1, Item 1 of this Form 10-Q for further information.

### *Our Strategy*

Our business objectives for the years 2006 through 2010 are reflected in our revised Horizon 2010 strategy and goals summarized below and on our website at <http://www.gene.com>.

- To bring at least 20 new molecules into clinical development.
- To bring at least 15 major new products or indications onto the market.
- To become the number one U.S. oncology company in sales.
- To achieve compound annual non-GAAP earnings per share<sup>(1)</sup> growth of 25 percent.
- To achieve cumulative free cash flow<sup>(2)</sup> of \$12 billion.

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Non-GAAP financial goals are included because our management uses non-GAAP financial measures to monitor and evaluate Genentech's operating results and trends on an ongoing basis and to facilitate internal comparison to historical operating results. Excluding the effects of charges related to employee stock-based compensation expense, Roche's redemption of our special common stock, litigation, and changes in accounting principles from our operating results provides users of our financial statements an important insight into our operating results and related trends that affect our business. In addition, our management uses non-GAAP financial information and measures internally for operating, budgeting and financial planning purposes, including the establishment of corporate, functional, departmental and individual performance goals.

- (1) The non-GAAP EPS goal for 2006 through 2010 excludes the after-tax effect of the following items: employee stock-based compensation expense associated with our adoption of FAS 123R, recurring charges related to the redemption of our special common stock by Roche, litigation-related special charges for accrued interest and associated bond costs on the City of Hope judgment and other potential special charges related to existing or future litigation or its resolution, and changes in accounting principles, all of which may be significant. GAAP EPS for 2006 through 2010 will include the items described above.
- (2) Our free cash flow measure is defined as cash from ongoing operations less gross capital expenditures. Cash from ongoing operations is derived from the "net cash provided by operating activities" line in our consolidated statements of cash flows, but this number may be adjusted for items that would allow the measure to better reflect our operational performance. These adjustments include, for example, cash receipts or payments related to litigation settlements, investments in trading securities and other potential items, any of which may be significant.



***Economic and Industry-wide Factors***

Our goals and objectives are challenged by economic and industry-wide factors that affect our business. Some of the most important factors are discussed below:

- Successful development of biotherapeutics is highly difficult and uncertain. Our long-term business growth depends upon our ability to commercialize important new therapeutics to treat unmet medical needs such as cancer. Since the underlying biology of these diseases is not completely understood, it is very challenging to discover and develop safe and effective treatments, and the majority of potential new therapeutics fail to generate the safety and efficacy data required to obtain regulatory approval. In addition, we face tremendous competition in the diseases of interest to us. Our business requires significant investments in research and development (or “R&D”) over many years, often for products that fail during the R&D process. In addition, after our products receive FDA approval, they remain subject to ongoing FDA regulation, including changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisement to physicians, and/or product recalls.

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- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection on one or more products could result in lost sales to competing products and may negatively affect our sales, royalty revenues and operating results. We are often involved in disputes over contracts and intellectual property and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.
  - Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. The manufacture of a biotherapeutic requires developing and maintaining a process to reliably manufacture and formulate the product at an appropriate scale, obtaining regulatory approval to manufacture the product, and is subject to changes in regulatory requirements or standards that may require modifications to the manufacturing process or FDA action (see “Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively affect our financial performance” of “Risk Factors” in Part II, Item 1A of this Form 10-Q).
- The Medicare Prescription Drug Improvement and Modernization Act (or “Medicare Act”) was enacted into law in December 2003 and on November 3, 2004, the 2005 Physician Fee Schedule and Hospital Outpatient Prospective Payment System Final Rules were announced. As Centers for Medicare and Medicaid Services (or “CMS”) is our single largest payer, the new rules continue to represent an important area of focus. To date, we have not seen any detectable effects of the new rules on our product sales, and we anticipate minimal effects on our revenues in 2006. On November 2, 2005, CMS released its Final Rule with comment on the Medicare Part B Competitive Acquisition Program (or “CAP”). The CAP option, which the CMS expects to begin in July 2006, required under the Medicare Act, will be available to physicians providing services under Part B of Medicare. Under the CAP, physicians could choose to either obtain drugs directly from qualified CAP vendors, or continue to purchase drugs directly and be reimbursed by CMS at the Average Selling Price + 6% rate. Although CMS is still finalizing details of the program, we anticipate that the impact of the program on our sales will be minimal.
- Our ability to attract and retain highly qualified and talented people in all areas of the company, and our ability to maintain our unique culture, will be critical to our success over the long-term. In the first quarter of 2006 we grew to over 10,000 employees. We are working diligently across the company to make sure that we successfully hire, train and integrate new employees into the Genentech culture and environment.

## Marketed Products

We commercialize in the United States (or “U.S.”) the biotechnology products listed below.

*Avastin* (bevacizumab) is an anti-VEGF humanized antibody approved for use in combination with intravenous 5-fluorouracil based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum.

*Rituxan* (rituximab) is an anti-CD20 antibody which we commercialize with Biogen Idec Inc. It is approved for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin’s lymphoma, including retreatment and bulky disease, and on February 10, 2006, it was approved for use in first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma (or “DLBCL”) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens. On February 28, 2006 Rituxan was approved for use in combination with methotrexate for reducing signs and symptoms in adult patients with moderately-to-severely active rheumatoid arthritis (or “RA”) who have had an inadequate response to one or more tumor necrosis factor (or “TNF”) antagonist therapies.

*Herceptin* (trastuzumab) is a humanized anti-HER2 antibody approved for the treatment of certain patients with metastatic breast cancer. Herceptin is approved for use as a first-line therapy in combination with paclitaxel and as a

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single agent in second- and third-line therapy for patients with metastatic breast cancer who have tumors that overexpress the human epidermal growth factor receptor 2 (or “HER2”) protein.

*Tarceva* (erlotinib), which we commercialize with OSI Pharmaceuticals, Inc., is a small-molecule tyrosine kinase inhibitor of the HER1/epidermal growth factor receptor (or “EGFR”) signaling pathway. *Tarceva* is approved for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (or “NSCLC”) after failure of at least one prior chemotherapy regimen. It is also approved, in combination with gemcitabine chemotherapy, for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

*Xolair* (omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis AG (or “Novartis”). *Xolair* is approved for the treatment of moderate-to-severe persistent allergic asthma in adults and adolescents 12 years and older.

*Raptiva* (efalizumab) is a humanized anti-CD11a antibody approved for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy.

*Nutropin* (somatropin [rDNA origin] for injection) and *Nutropin AQ* are growth hormone products approved for the treatment of growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency prior to kidney transplantation, short stature associated with Turner syndrome and long-term treatment of idiopathic short stature.

*Activase* (alteplase, recombinant) is a tissue plasminogen activator (or “t-PA”) approved for the treatment of acute myocardial infarction (heart attack), acute ischemic stroke (blood clots in the brain) within three hours of the onset of symptoms and acute massive pulmonary embolism (blood clots in the lungs).

*TNKase* (tenecteplase) is a modified form of t-PA approved for the treatment of acute myocardial infarction (heart attack).

*Cathflo Activase* (alteplase, recombinant) is a t-PA approved in adult and pediatric patients for the restoration of function to central venous access devices that have become occluded due to a blood clot.

*Pulmozyme* (dornase alfa, recombinant) is an inhalation solution of deoxyribonuclease (rhDNase) I, approved for the treatment of cystic fibrosis.

### **Licensed Products**

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

- Herceptin, Pulmozyme, and Avastin outside of the U.S.,
- Rituxan outside of the U.S., excluding Japan, and
- Nutropin products, Activase and TNKase in Canada.

### **Available Information**

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

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;

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- our policies related to corporate governance, including Genentech's Principles of Corporate Governance, Good Operating Principles (Genentech's code of ethics applying to Genentech's directors, officers and employees) as well as Genentech's Code of Ethics applying to our CEO, CFO and senior financial officials and;
- the charter of the Audit Committee of our Board of Directors.

### **Critical Accounting Policies and the Use of Estimates**

The accompanying discussion and analysis of our financial condition and results of operations are based upon our Condensed Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States (or "GAAP"). The preparation of these Condensed Consolidated Financial Statements requires management to make estimates, assumptions and judgments that affect the reported amounts in our Condensed Consolidated Financial Statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and we have established internal controls related to the preparation of these estimates. Actual results and the timing of the results could differ materially from these estimates.

We believe the following policies to be critical to understanding our financial condition, results of operations, and our expectations for 2006 because these policies require management to make significant estimates, assumptions and judgments about matters that are inherently uncertain.

#### ***Legal Contingencies***

We are currently, or have been, involved in certain legal proceedings as discussed in Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. Included in "litigation-related and other long-term liabilities" in the accompanying Condensed Consolidated Balance Sheet at March 31, 2006 is \$689 million, which represents our estimate of the costs for the current resolution of these matters. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters different than previously estimated could have a material effect on our financial position or our results of operations in any one quarter.

#### ***Product Sales Allowances***

Revenues from product sales, which are principally generated in the U.S., are recorded net of allowances for rebates, wholesaler chargebacks, prompt pay sales discounts, product returns, wholesaler incentives, and bad debts, all of which are established at the time of sale. In order to prepare our Condensed Consolidated Financial Statements, we are required to make estimates regarding the amounts earned or to be claimed on the related product sales.

Rebate reserves and accruals represent our estimated obligations to wholesalers and third parties (clinics, hospitals and pharmacies), respectively. These reserves and accruals result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth. As a result, the calculation for these rebates requires an estimate of the customer's buying patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period. If our estimate of a customer's buying patterns is incorrect, we may need to adjust our estimates in future periods. In the first quarter of 2006, the majority of these reserves and accruals relate to our non-oncology products.

To date, we have not recorded any adjustments to our estimates of product sales allowances that were material to our Condensed Consolidated Financial Statements. However, it is possible that we may need to adjust our estimates in future periods. As of March 31, 2006, our Condensed Consolidated Balance Sheet reflected product sales allowance reserves and accruals totaling approximately \$134 million and for the three months ended March 31, 2006, our net

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product sales were approximately \$1,644 million.

### ***Royalties***

For substantially all of our agreements with licensees, we estimate royalty revenue and royalty receivables in the periods these royalties are earned, in advance of collection. Our estimate of royalty revenue and receivables in those instances is based upon communication with some licensees, historical information and forecasted sales trends. Differences between actual revenues and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. Historically, such adjustments have not been material to our condensed consolidated financial condition or results of operations.

### ***Income Taxes***

Income tax expense is based on income before taxes and is computed using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. Various internal and external factors may have favorable or unfavorable effects on our future effective income 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, changes in estimates of prior years' items, past and future levels of R&D spending, and changes in overall levels of income before taxes.

### ***Inventories***

Inventories consist of currently marketed products, products manufactured under contract, product candidates awaiting regulatory approval, currently marketed products manufactured at facilities awaiting regulatory approval, which are capitalized based on management's judgment of probable near term commercialization, and include employee stock-based compensation costs capitalized under FAS 123R. The valuation of inventory requires us to estimate the value of inventory that may become obsolete prior to use or that may fail to be released. The determination of obsolete inventory requires us to estimate the future demands for our products, and in the case of pre-approval inventories, an estimate of the regulatory approval date for the product. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies or new information that suggests that the inventory will not be saleable. In the event that a pre-approval product candidate receives regulatory approval, subsequent sales of previously reserved inventory may result in increased gross margins.

### ***Employee Stock-Based Compensation—Adoption of FAS 123R***

Beginning January 1, 2006, we account for employee stock-based compensation in accordance with FAS 123R. Under the provisions of FAS 123R, we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Due to the redemption of our Special Common Stock in June 1999 (or "Redemption") by Roche Holdings, Inc. (or "Roche"), there is limited historical information available to support our estimate of certain assumptions required to value our stock options. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value employee stock-based awards granted in future periods.



Further, FAS 123R requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. Accordingly, in the first quarter of 2006, we recognized employee stock-based compensation as part of our operating expenses with an allocation of \$33 million to R&D, \$41 million to marketing, general and administrative (or "MG&A"), and we recognized a related tax benefit of \$27 million. In addition, we capitalized \$16 million of

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employee stock-based compensation costs in inventory as a cost of production during the first quarter of 2006. We adopted FAS 123R on a modified prospective basis. Substantially all of the products sold in the first quarter of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs; therefore, we did not record any employee stock-based compensation expense as a component of cost of sales in the first quarter of 2006. In future periods, when product manufactured after the adoption of FAS 123R is sold or written off, or reserves are required for obsolescence or lack of demand, we will recognize employee stock-based compensation expense in cost of sales. The allocation of employee stock-based compensation costs to each operating expense line and to inventory are estimated based on specific employee headcount information at each grant date and revised, if necessary, in future periods if actual employee headcount information differs materially from those estimates. As a result, the amount of employee stock-based compensation costs we record in future periods in each operating expense line and capitalize in inventory may differ significantly from what we have recorded in the current period. As of March 31, 2006, total compensation cost related to nonvested stock options not yet recognized was \$734 million, which is expected to be allocated to expense and production costs over a weighted-average period of 27 months.

There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized under FAS 123R during the three months ended March 31, 2005.

**Results of Operations***(In millions)*

	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2006</b>	<b>2005</b>	
Product sales	\$ 1,644	\$ 1,186	39%
Royalties	286	232	23
Contract revenue	56	44	27
Total operating revenues	1,986	1,462	36
Cost of sales	262	256	2
Research and development	374	243	54
Marketing, general and administrative	441	310	42
Collaboration profit sharing	226	176	28
Recurring charges related to redemption	26	35	(26)
Special items: litigation-related	13	11	18
Total costs and expenses	1,342	1,031	30
Operating income	644	431	49
Other income (expense):			
Interest and other income, net	53	18	194
Interest expense	(19)	(3)	533
Total other income, net	34	15	127
Income before taxes	678	446	52
Income tax provision	257	162	59
Net income	\$ 421	\$ 284	48
Earnings per share:			
Basic	\$ 0.40	\$ 0.27	48
Diluted	\$ 0.39	\$ 0.27	44
Pretax operating margin	32%	29%	
Cost of sales as a % of product sales	16	22	
Research and development as a % of operating revenues	19	17	
Marketing, general and administrative as a % of operating revenues	22	21	
Net income as a % of operating revenues	21	19	

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

***Total Operating Revenues***

Total operating revenues increased 36% in the first quarter of 2006 from the comparable period in 2005. These increases were primarily due to higher product sales and royalty income, and are further discussed below.



**Total Product Sales***(In millions)*

	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2006</b>	<b>2005</b>	
Net U.S. Product Sales			
Rituxan	\$ 477	\$ 440	8%
Avastin	398	203	96
Herceptin	290	130	123
Tarceva	93	48	94
Xolair	95	65	46
Raptiva	21	17	24
Nutropin products	87	90	(3)
Thrombolytics	59	50	18
Pulmozyme	49	44	11
Total U.S. product sales	\$ 1,569	\$ 1,087	44
Net product sales to collaborators	75	99	(24)
Total product sales	\$ 1,644	\$ 1,186	39

Total product sales increased 39% to \$1,644 million in the first quarter of 2006 from the comparable period in 2005. Total U.S. product sales increased 44% to \$1,569 million in the first quarter of 2006 from the comparable period in 2005. The increase in U.S. product sales was due to higher sales across most products, in particular higher sales of our oncology products. Increased U.S. sales volume accounted for 88%, or \$429 million, of the increase in U.S. net product sales in the first quarter of 2006, and 92%, or \$346 million, in the first quarter of 2005. Changes in net U.S. sales prices across the portfolio accounted for most of the remaining increase in net U.S. product sales in the first quarter of 2006.

*Avastin*

Net U.S. sales of Avastin increased 96% to \$398 million in the first quarter of 2006 from the comparable period in 2005. The increase in sales was primarily a result of increased use of Avastin in first-line metastatic colorectal cancer (or "mCRC") in combination with 5FU-based chemotherapies (our approved indication) and in first-line non small cell lung cancer (or "NSCLC") (an unapproved use). In first-line mCRC patients, we estimate that Avastin penetration was over 70% during the first quarter of 2006 compared to penetration of 61% during the first quarter of 2005. Duration of treatment among patients in the first-line mCRC setting who completed Avastin therapy increased modestly relative to the first quarter of 2005, but was comparable to the fourth quarter of 2005. Due to competing products entering the market in the first quarter of 2006, we have seen a slight decline in the adoption of Avastin in renal cell carcinoma, an unapproved use of Avastin. Net U.S. sales in the first quarter of 2006 include a \$3 million reimbursement for a shipment that was destroyed while in transit to a wholesaler in the first quarter of 2005. There were no price increases in the first quarter of 2006 or in 2005.

While there has been increased uptake in the first-line mCRC setting, opportunities remain to continue to appropriately identify eligible patients. We also anticipate growth in 2006 from use in potential new (but currently unapproved) indications, including relapsed mCRC, metastatic first-line NSCLC and metastatic first-line breast cancers.

In December 2005, we submitted an sBLA to the FDA for Avastin in relapsed mCRC, and priority review has been granted with an action date of June 20, 2006.

On April 11, 2006, we submitted an sBLA to the FDA for Avastin in combination with platinum-based chemotherapy for first-line treatment of advanced, non-squamous, NSCLC.

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### *Rituxan*

Net U.S. sales of Rituxan increased 8% to \$477 million in the first quarter of 2006 from the comparable period in 2005. Net U.S. sales in the first quarter of 2005 included \$10 million for a reorder to replace a shipment that was destroyed while in transit to a wholesaler. The sales growth resulted from increased use of Rituxan in NHL and chronic lymphocytic leukemia (or "CLL"), including areas of unapproved use. We estimate that Rituxan's overall adoption rate in combined markets of NHL and CLL, including areas of unapproved use, was 82% at the end of the first quarter of 2006 compared to 77% at the end of the first quarter of 2005. Also contributing to the increase in product sales were price increases that were effective on July 6, 2005 and October 5, 2005. U.S. Rituxan sales in the first quarter of 2006 decreased 1% from \$484 million in the fourth quarter of 2005 and the overall adoption rate remained flat at 82% as compared to the fourth quarter of 2005. Rituxan for the treatment of adult patients with moderately-to-severely active RA was launched in the first quarter of 2006. There are significant hurdles to reliably measuring the portion of Rituxan sales attributable to RA, and we do not expect to be able to precisely attribute revenues to the RA indication (or any other non-oncology indication) in the foreseeable future.

On March 30, 2006, we and Biogen Idec submitted an sBLA to the FDA for the use of Rituxan as first-line treatment of previously-untreated patients with low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine, prednisone) or CHOP chemotherapy or following CVP chemotherapy in those patients who achieved a response of stable disease or better.

### *Herceptin*

Net U.S. sales of Herceptin increased 123% to \$290 million in the first quarter of 2006 from the comparable period in 2005. The sales growth resulted from increased treatment of first-line HER2-positive metastatic breast cancer and increased cumulative treatment duration relative to the comparable period in 2005, as well as increased use of Herceptin in adjuvant breast cancer (an unapproved use). We believe that continued Herceptin sales growth will primarily occur in the adjuvant setting. Also contributing to the increase in product sales, to a lesser extent, was a price increase effective on February 24, 2005. Net U.S. sales in the first quarter of 2006 include a \$2 million reimbursement for a shipment that was destroyed while in transit to a wholesaler in the first quarter of 2005.

On February 15, 2006, we submitted an sBLA with the FDA for use of Herceptin to treat early-stage HER2-positive breast cancer, and priority review was granted with an action date of August 17, 2006.

### *Tarceva*

Net U.S. sales of Tarceva increased 94% to \$93 million in the first quarter of 2006 from \$48 million in the first quarter of 2005, driven by growth in penetration in second-line NSCLC and first-line pancreatic cancer. In the first quarter of 2006, we estimate that Tarceva's penetration averaged 34% in second-line NSCLC and 40% in first-line pancreatic cancer. Also affecting our product sales were price increases that were effective on April 5, 2005 and November 9, 2005. Future sales growth in NSCLC will depend on further gains in penetration against chemotherapy within second-line NSCLC.

### *Xolair*

Net U.S. sales of Xolair increased 46% to \$95 million in the first quarter of 2006 from the comparable period in 2005. The sales growth was primarily driven by an increase in our patient and prescriber base and, to a lesser extent, a price increase that was effective on July 21, 2005.

### *Raptiva*

Net U.S. sales of Raptiva increased 24% to \$21 million in the first quarter of 2006 from the comparable period in 2005. Contributing to the increase in product sales were price increases that were effective on April 21, 2005 and November 17, 2005.



### *Nutropin Products*

Combined net U.S. sales of our Nutropin products decreased 3% to \$87 million in the first quarter of 2006 from the comparable period in 2005. Nutropin sales have decreased due to declining market share of new patients and loss of managed care product placement due to price discounting. The decrease in sales volume was partially offset by a price increase that was effective on March 3, 2005.

### *Thrombolytics*

Combined net U.S. sales of our three thrombolytics products, Activase, Cathflo Activase, and TNKase, increased 18% to \$59 million in the first quarter of 2006 from the comparable period in 2005. The increase was due to growth in Cathflo Activase sales in the catheter clearance market and increased Activase sales in the acute ischemic stroke market. Also contributing to the increase in product sales were price increases effective on January 11, 2005. Aggressive price discounting by competitors affected our acute myocardial infarction business in some hospitals.

### *Pulmozyme*

Net U.S. sales of Pulmozyme increased 11% to \$49 million in the first quarter of 2006 from the comparable period in 2005. The increase primarily reflects a price increase effective on April 26, 2005 and, to a lesser extent, a greater focus on aggressive treatment of cystic fibrosis early in the course of the disease.

### *Product Distribution—Changes in Commercial Terms*

We recently renegotiated our distribution agreements with a number of our major wholesalers which will result in a number of changes in commercial terms effective July 1, 2006, most notably resulting in the reduction of certain allowances provided to the wholesalers on certain products. Further, our commercial shipping terms with all our domestic customers and the resulting point at which we recognize products sales revenue for all of our products will change from the time at which we ship the product to the time at which our products arrives at a designated receiving location. We do not expect the 2006 annual net effect of these changes to be material to our results of operations.

### *Sales to Collaborators*

Product sales to collaborators, the majority of which were for non-U.S. markets, decreased 24% to \$75 million in the first quarter of 2006 from the comparable period in 2005. The decrease primarily reflects the discontinuation of our Enbrel® sales to Amgen due to the cancellation of our manufacturing obligation in the second quarter of 2005. This decrease was partially offset by an increase in sales of Avastin to Hoffman-La Roche.

For the full year 2006, given Roche's higher supply needs, we expect sales to collaborators to increase by approximately 30% over the \$326 million in 2005.

### *Royalties*

Royalty revenues increased 23% to \$286 million in the first quarter of 2006 from the comparable period in 2005. The increase was due to higher sales by Hoffmann-La Roche primarily of our Herceptin, Avastin and Rituxan products. Of the overall royalties received, royalties from Hoffmann-La Roche represented approximately 58% in the first quarter of 2006. Royalties from other licensees include royalty revenue on our patents including our Cabilly patents noted below. For the full year 2006, we expect royalties to increase by approximately 30% compared to \$935 million in 2005 based on higher sales forecasts from our licensees, in particular Roche.

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 and No. 4,816,567 (the “Cabilly patents”), under which we receive royalty revenue on sales of products that are covered by one or more of the Cabilly patents. The ‘567 patent expired in March 2006, while the ‘415 patent expires in December 2018. The licensed products for which we receive the most significant Cabilly royalties are Humira®, Remicade®, Synagis® and ERBITUX®. Cabilly royalties impact three lines on our Condensed Consolidated Statement of Income:

(i) We record gross royalties we receive from Cabilly patent licensees as royalty revenue;

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(ii) On royalties we receive from Cabilly licensees, we in turn pay City of Hope National Medical Center (or “COH”) a percentage of our royalty income and these payments to COH are recorded with our MG&A expenses as royalty expense; (iii) We pay royalty expenses directly to COH on sales of our products that are covered by the Cabilly patents and these payments to COH are recorded in cost of sales (or “COS”). The overall net after-tax contribution from revenues and expenses related to the Cabilly patents was approximately \$19 million in the first quarter of 2006, or approximately \$0.02 per diluted share. We expect our full year 2006 Cabilly related net income after taxes to be approximately \$0.06 per diluted share. See also Note 4, “Contingencies” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on our Cabilly patent reexamination.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase simple foreign currency put option contracts (or “options”) and forwards to hedge these foreign currency cash flows. The terms of these options and forwards are generally one to five years. See also Note 1, “Summary of Significant Accounting Policies—Derivative Financial Instruments” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

### ***Contract Revenues***

Contract revenues increased 27% to \$56 million in the first quarter of 2006 from the comparable period in 2005. The increase was primarily due to higher contract revenues from Hoffman-La Roche and our other collaborators, driven by higher reimbursements related to R&D development efforts on Avastin, Rituxan and second generation anti-CD20. See “Related Party Transactions” below for more information on contract revenue from Hoffmann-La Roche.

Contract revenues vary each quarter and are dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones and opt-in payments received, and new contract arrangements. For the full year 2006, we expect contract revenues to be relatively flat as compared to \$210 million in 2005.

### ***Cost of Sales***

COS as a percentage of product sales was 16% in the first quarter of 2006 compared to 22% in the first quarter of 2005. This decrease is primarily due to the discontinuation of our lower margin Enbrel® sales to Amgen and higher sales volume of our higher margin products (primarily oncology products).

For the full year 2006, we expect COS to be approximately 16% of net product sales, compared to 18% in 2005. We expect continued quarter-to-quarter variability based on product volume and mix changes, and there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing, or inventory related issues.

### ***Research and Development***

R&D expenses increased 54% to \$374 million in the first quarter of 2006 over the comparable period in 2005. The higher level of expenses reflect increased activity across our entire product portfolio, including increased spending on late-stage clinical trials (notably Avastin and Rituxan Immunology) and early stage projects, higher research expenses due to increased headcount and headcount related expenses and higher clinical manufacturing expenses at our Oceanside manufacturing facility. Also contributing to the increase were post-marketing studies on new and existing indications for Avastin, Rituxan and Tarceva. In addition, R&D expenses for the first quarter of 2006 included \$33 million of employee stock-based compensation expense related to FAS 123R.

R&D as a percentage of operating revenues was 19% in the first quarter of 2006 as compared to 17% in the first quarter of 2005. We expect R&D absolute dollar spending in 2006 to continue to increase over 2005 levels as we

continue to invest in our late stage pipeline and continue to add new programs in the early stage pipeline.

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

<b>Research and Development</b>	<b>Three Months Ended March 31,</b>			<b>% Change</b>
	<b>2006</b>		<b>2005</b>	
Product development (including post marketing)	\$ 283	\$	178	59%
Research	74		53	40
In-licensing	17		12	42
Total R&D	\$ 374	\$	243	54

### ***Marketing, General and Administrative***

MG&A expenses increased 42% to \$441 million in the first quarter of 2006 from the comparable period in 2005. The increase was primarily due to: (i) an increase of \$67 million in commercial activities in support of pre-launch activities related to Avastin in lung and breast cancer indications, Rituxan Immunology, Lucentis and Herceptin (adjuvant setting); (ii) \$41 million of employee stock-based compensation expense related to FAS 123R; and (iii) an increase of \$23 million in general corporate expenses to support our continued growth and higher legal costs.

MG&A as a percentage of operating revenues was 22% in the first quarter of 2006 as compared to 21% for the comparable period in 2005. MG&A absolute dollar spending is expected to increase during the remainder of 2006 primarily driven by marketing and sales costs in support of anticipated product launches.

### ***Collaboration Profit Sharing***

Collaboration profit sharing expenses increased 28% to \$226 million in the first quarter of 2006 from the comparable period in 2005 due to higher sales of Tarceva, Xolair and Rituxan and the related profit sharing expenses. For the full year 2006, our collaboration profit sharing expenses are expected to grow in proportion to our Rituxan, Xolair and Tarceva sales growth.

### ***Recurring Charges Related to Redemption***

We record recurring charges related to the June 1999 redemption of our Special Common Stock and push-down accounting (see discussion below in “Relationship with Roche—Redemption of Our Special Common Stock”). These charges were \$26 million in the first quarter of 2006 and \$35 million in the first quarter of 2005, and were comprised of the amortization of Redemption-related other intangible assets in the periods presented.

### ***Special Items: Litigation-Related***

We recorded \$13 million of accrued interest and bond costs related to the COH trial judgment in each of the first quarters of 2006 and 2005. 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. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court’s review of the matter; however, we expect that it may take longer than one year to resolve this matter. Also included in this line is an amount received during the first quarter of 2005 for a litigation settlement. See Note 4, “Contingencies,” in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding our litigation.

### ***Operating Income***

Operating income was \$644 million in the first quarter of 2006, a 49% increase from the first quarter of 2005. Our operating income as a percentage of operating revenues (or “pretax operating margin”) was 32% in the first quarter of 2006 and 29% in the first quarter of 2005.

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**Other Income, Net**

<b>Other Income, Net</b>	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2006</b>	<b>2005</b>	
	<i>(In millions)</i>		
Gains on sales of biotechnology equity securities and other	\$ 3	\$ 1	200%
Write-downs of biotechnology debt, equity securities and other	-	(4)	(100)
Interest income	49	21	133
Interest expense	(19)	(3)	533
Other miscellaneous income	1	-	-
Total other income, net	\$ 34	\$ 15	127

The components of other income, net have changed primarily due to the effects of our debt issuance in July 2005. Investment income increased as a result of the higher average cash balances maintained and interest expense increased due to the debt service costs incurred in the first quarter of 2006.

We expect interest income, net of interest expense, in 2006 to be 30% higher than 2005 levels, subject to changes in interest rates. Also, in the second quarter of 2006, we will recognize a gain of approximately \$30 million from Amgen's acquisition of Abgenix, Inc, which closed on April 3, 2006.

**Income Tax Provision**

The effective income tax rate was 38% in the first quarter of 2006, as compared to 36% in the first quarter of 2005. The increase in the income tax rate primarily reflects higher income before taxes and the December 31, 2005 expiration of provisions in federal tax law for the R&D tax credit. Currently there are bills in Congress to extend the R&D tax credit retroactively to January 1, 2006. If such legislation is passed, then at that time we will record a tax benefit for R&D tax credits.

We anticipate that our annual 2006 effective income tax rate will be fractionally above 37%, assuming the R&D tax credit is extended retroactive to January 1, 2006. Various factors may have favorable or unfavorable effects on our effective tax rate during the remainder of 2006 and in subsequent years. These factors include, but are not limited to, changing interpretations of existing tax laws, changes in tax laws and rates, past and future levels of R&D spending, and changes of estimates of prior years' items, and changes in overall levels of income before taxes, all of which may result in periodic revisions to our effective tax rate.

**Liquidity and Capital Resources**

<b>Liquidity and Capital Resources</b>	<b>March 31, 2006</b>	<b>December 31, 2005</b>
	<i>(In millions)</i>	
Unrestricted cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	\$ 3,942	\$ 3,814
Net receivable - equity hedge instruments	66	73
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	\$ 4,008	\$ 3,887
Working capital	\$ 2,783	\$ 2,726

Current ratio	2.6:1	2.6:1
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Unrestricted cash, cash equivalents, short-term investments and long-term marketable securities, including the fair value of the equity hedge instruments, were approximately \$4.0 billion at March 31, 2006, an increase of approximately \$121 million from December 31, 2005. This increase primarily reflects cash generated from operations, partially offset by cash used for capital expenditures and repurchases of our common stock. To mitigate the risk of market value fluctuation, certain of our biotechnology marketable equity securities are hedged with zero-cost collars and forward contracts, which are carried at fair value. See Note 1, "Summary of Significant Accounting

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Policies—Comprehensive Income,” in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding activity in our marketable investment portfolio and derivative instruments.

See “Our affiliation agreement with Roche could limit our ability to make acquisitions” below in the “Forward-Looking Information and Cautionary Factors” section and Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for factors that could negatively affect our cash position.

### ***Cash Provided by Operating Activities***

Cash provided by operating activities is primarily driven by increases in our net income. However, operating cash flows differ from net income as a result of non-cash charges or differences in the timing of cash flows and earnings recognition. Significant components of cash provided by operating activities are as follows:

Our “accounts receivable—product sales” was \$615 million at March 31, 2006, an increase of \$61 million from December 31, 2005. The increase is primarily due to higher product sales of Herceptin, Avastin and Tarceva. The average collection period of our “accounts receivable—product sales” as measured in days sales outstanding (or “DSO”) was 34 days for the first quarter 2006, compared to 52 days in the first quarter of 2005. The decline in DSO from the first quarter of 2005 reflects the termination of the extended payment term incentive program in the first quarter of 2005.

Our inventory balance was \$804 million at March 31, 2006, an increase of \$101 million from December 31, 2005. The increase is primarily due to bulk campaign production of our Avastin and Herceptin products. Inventory also increased in the first quarter of 2006 due to non-cash employee stock-based compensation costs of \$16 million that were capitalized in inventory pursuant to our adoption of FAS 123R.

### ***Cash Used in Investing Activities***

Cash used in investing activities primarily relate to purchases, sales and maturities of investments and capital expenditures. Capital expenditures were \$253 million during the first quarter of 2006 compared to \$144 million during the first quarter of 2005. Capital expenditures in the first quarter of 2006 included ongoing construction of our second manufacturing facility in Vacaville, California, ongoing start-up and validation costs at our manufacturing facility in Oceanside, California, the purchase of a second facility in Oceanside, purchase of equipment and information systems, and ongoing expenditures to support our corporate infrastructure needs.

We currently anticipate that our capital expenditures for the full year 2006 will be approximately \$1.5 billion, primarily driven by manufacturing expansion due to ongoing construction of our second manufacturing facility in Vacaville, start-up and validation of our Oceanside manufacturing facilities, and for projects related to existing facilities, increases in office space, and land purchases.

### ***Cash Used in Financing Activities***

Cash used in financing activities is primarily related to activity under our employee stock plans and our stock repurchase program. We used cash for stock repurchases of \$227 million during the first quarter of 2006 and \$156 million during the first quarter of 2005 pursuant to our stock repurchase program approved by our Board of Directors. We also received \$89 million during the first quarter of 2006 and \$106 million during the first quarter of 2005 related to stock option exercises and stock issuances under our employee stock plans.

Prior to our adoption of FAS 123R, the tax benefit from stock option exercises was reported as operating cash flows. FAS 123R requires excess tax benefits be reported as a financing cash inflow rather than as a reduction of taxes paid. At March 31, 2006, the excess tax benefit from stock-based compensation arrangements was \$49 million.

During 2006, our total cash, unrestricted cash equivalents, short-term investments and marketable securities are expected to decline modestly relative to the level at December 31, 2005 due to cash requirements for capital

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expenditures, share repurchases under our stock repurchase program, and other uses of working capital. We believe our existing unrestricted funds, together with funds provided by operations and our debt issuance in July 2005 will be sufficient to meet our foreseeable future operating cash requirements. See “Our affiliation agreement with Roche Holdings, Inc. could adversely affect our cash position” below in Part II, Item 1A “Risk Factors” of this Form 10-Q for factors that could negatively affect our cash position.

On April 19, 2006, the Board of Directors approved an extension of our stock repurchase program for the repurchase of up to an additional \$2.0 billion of our common stock for a total of \$6.0 billion through June 30, 2007. The Board also amended the current repurchase program by increasing the maximum number of shares that can be repurchased from 80 million to 100 million shares. Under this stock repurchase program, purchases may be made in the open market or in privately negotiated transactions from time to time at management’s discretion. Genentech also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. Genentech intends to use the repurchased stock to offset dilution caused by the issuance of shares in connection with Genentech’s employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to make prudent investments of our cash resources; (ii) to allow for an effective mechanism to provide stock for our employee stock plans; and (iii) to address provisions of our affiliation agreement with Roche relating to maintaining Roche’s minimum ownership percentage. See below in “Relationship with Roche” for more information on Roche’s minimum ownership percentage. We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately 2 million shares and will run through June 30, 2006.

Our shares repurchased during the first quarter of 2006 were as follows (*shares in millions*):

	<b>Total Number of Shares Purchased in 2006</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
January 1-31, 2006	0.9	\$ 88.37		
February 1-28, 2006	0.7	85.31		
March 1-31, 2006	1.0	84.24		
Total	2.6	\$ 85.95	52	48

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.

### Off-Balance Sheet Arrangements

We have certain contractual arrangements that create potential risk for Genentech and are not recognized in our Condensed Consolidated Balance Sheets. Discussed below are those off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operation, liquidity, capital expenditures or capital resources.

### Leases

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to our South San Francisco campus. For accounting purposes, due to the nature of our involvement with the construction of the buildings, we are considered to be the owner of the assets during the construction period through the lease commencement date, even though the funds to construct the building shell and some infrastructure costs are paid by the lessor. In the first quarter of 2006, we capitalized \$27 million of construction costs in property, plant and equipment, for a project-to-date capitalized total of \$121 million. We have also recognized a corresponding amount as a construction financing obligation in "long-term debt" in the accompanying Condensed Consolidated Balance Sheets. We expect at the time of completion of the project, if all the buildings and infrastructure were completed by

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the lessor, our construction asset and related obligation may be as much as \$365 million, excluding costs related to leasehold improvements. Our aggregate lease payments as contemplated by the Master Lease Agreement through 2020 will be approximately \$544 million.

### ***Contractual Obligations***

During the first quarter of 2006, we believe there have been no significant changes in our payments due under contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005.

### **Contingencies**

We are party to various legal proceedings, including patent infringement litigation and licensing and contract disputes, and other matters. See Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information.

### **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") at a price of \$10.31 per share in cash with funds deposited by Roche for that purpose. We refer to this event as the "Redemption." As a result, on that date, Roche's percentage ownership of our outstanding Common Stock increased from 65% to 100%. Consequently, under GAAP, we were required to use push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value. Push-down accounting required us to record \$1,686 million of goodwill and \$1,499 million of other intangible assets on our balance sheet on June 30, 1999. Refer to Note 3, "Condensed Consolidated Financial Statement Detail—Other Intangible Assets," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information about these intangible assets.

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

We 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 with respect to any issuance of Common Stock by Genentech in the future, we will repurchase a sufficient number of shares so that immediately after such issuance the percentage of Genentech Common Stock owned by Roche will be no lower than 2% below the "Minimum Percentage" (as defined below), provided however, as long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, 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 Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by Roche since the July 1999 offering (to be adjusted for dispositions of shares of Genentech Common Stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704, the number of shares of Genentech Common Stock outstanding at the time of the July 1999 offering, as adjusted for stock splits. We have repurchased shares of our Common Stock since 2001 (see discussion above in Liquidity and Capital Resources). 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. The Minimum Percentage at March 31, 2006 was 57.7% and, under the terms of the affiliation agreement, Roche's ownership percentage is to be no lower than 55.7%. At March 31, 2006, Roche's ownership percentage was 55.7%.

### **Related Party Transactions**

We enter into transactions with our related parties, Roche and other Roche affiliates (including Hoffmann-La Roche) and Novartis, under existing agreements in the ordinary course of business. The accounting policies we apply to our transactions with our related parties are consistent with those applied in transactions with independent third-parties and all related party agreements are negotiated on an arm's-length basis.

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### ***Hoffmann-La Roche***

Under our existing arrangements with Hoffmann-La Roche, including our licensing and marketing agreement, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$18 million in the first quarter of 2006 and \$16 million in the first quarter of 2005. All other revenues from Hoffmann-La Roche and their affiliates, principally royalties and product sales, were \$224 million in the first quarter of 2006 and \$155 million in the first quarter of 2005. COS included amounts related to Hoffmann-La Roche of \$49 million in the first quarter of 2006 and \$47 million in the first quarter of 2005. Our reported R&D expenses in each of the first quarters of 2006 and 2005 included \$43 million and \$34 million, respectively, related to development activities undertaken on projects on which we collaborate with Hoffmann-La Roche.

### ***Novartis***

Based on information available to us at the time of filing this Form 10-Q, we believe the Novartis Group holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, the Novartis Group is deemed to have an indirect beneficial ownership interest under FAS 57 "Related Party Disclosures" of more than 10% of our voting stock.

We have an agreement with Novartis Ophthalmics (now merged into Novartis AG) under which Novartis Ophthalmics has the exclusive right to develop and market Lucentis outside of the U.S. and Canada for indications related to diseases or disorders of the eye. As part of this agreement, the parties share the cost of certain of our ongoing Phase III and related development expenses.

We, along with Novartis Pharma AG (a wholly owned subsidiary of Novartis AG) and Tanox, Inc., are co-developing Xolair in the U.S. We and Novartis are co-promoting Xolair in the U.S. and we both make certain joint and individual payments to Tanox; Genentech's joint and individual payments are in the form of royalties. We record all sales and cost of sales in the U.S. and Novartis markets the product and records all sales and cost of sales in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. We are currently supplying the product and receive cost plus a mark-up similar to other supply arrangements. On January 20, 2006, Novartis received FDA approval to manufacture bulk supply of Xolair at their Huningue production facility in France. Future production costs of Xolair may initially be higher than those currently reflected in our COS as a result of the production shift from us to Novartis until production economies of scale can be achieved by Novartis.

Contract revenue from Novartis related to manufacturing, commercial and ongoing development activities was \$10 million in the first quarters of 2006 and 2005. Revenue from Novartis related to product sales and COS was not material in the first quarters of 2006 and 2005. Our reported R&D expenses in each of the first quarters of 2006 and 2005 included approximately \$10 million related to development activities undertaken on products on which we collaborate with Novartis. Collaboration profit sharing payments from us to Novartis were \$43 million in the first quarter of 2006 and \$24 million in the first quarter of 2005.

### **Stock Options**

#### ***Option Program Description***

Our employee 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. In addition, our stockholders approved, in April 2004, our 2004 Equity Incentive Plan under which

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stock options, restricted stock, stock appreciation rights and performance shares and units may be granted to our employees, directors and consultants in the future.

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors. See “The Compensation Committee Report” appearing in our 2006 Proxy Statement 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 millions)

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted-Average Exercise Price
<b>December 31, 2004</b>	102	94	\$ 32.32
Grants	(20)	20	84.01
Exercises	-	(29)	25.88
Cancellations	2	(2)	42.16
<b>December 31, 2005</b>	84	83	\$ 46.64
Grants	(1)	1	88.10
Exercises	-	(2)	30.38
Cancellations	1	(1)	57.63
<b>March 31, 2006 (Year to date)</b>	84	81	\$ 47.43

#### *In-the-Money and Out-of-the-Money Option Information* (Shares in millions)

	Exercisable		Unexercisable		Total	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
<b>As of March 31, 2006</b>						
In-the-Money	39	\$ 30.06	24	\$ 46.60	63	\$ 36.28
Out-of-the-Money <sup>(1)</sup>	-	-	18	86.33	18	86.33
<b>Total Options Outstanding</b>	<b>39</b>		<b>42</b>		<b>81</b>	

(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, \$84.51, at the close of business on March 31, 2006.

### *Dilutive Effect of Options*

Net grants, as a percentage of outstanding shares, were 0.02% for the three months ended March 31, 2006, 1.70% for the year ended December 31, 2005 and 1.83% for the year ended December 31, 2004.

### *Equity Compensation Plan Information*

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

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This report contains forward-looking statements regarding our horizon 2010 strategy of bringing 20 new molecules into clinical development, 15 major new products or indications onto the market, becoming the number one U.S. oncology company in sales, achieving compound annual non-GAAP earnings per share growth of 25 percent, and achieving cumulative free cash flow of \$12 billion; growth from the use in potential new but unapproved uses of Avastin; Herceptin sales growth; Cabilly related net income; royalty and contract revenues; cost of sales as a

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percentage of net product sales; research and development and marketing, general and administrative spending; sales to collaborators; interest income; annual effective income tax rate; capital expenditures and construction costs; collaboration profit sharing expenses; the level of our cash, unrestricted cash equivalents, short-term investments and marketable securities, our ability to meet our foreseeable operating cash requirements; our level of contractual obligations; the effects of the Medicare Prescription Drug Improvement and Modernization Act on our revenues; the effect of product distribution changes on our results of operations; and employee stock-based compensation expense.

These forward-looking statements involve risks and uncertainties, and the cautionary statements set forth below and those contained in “Risk Factors” identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. Such factors include, but are not limited to, unexpected safety, efficacy or manufacturing issues, additional time requirements for data analysis, BLA preparation and decision making, FDA actions or delays, failure to obtain FDA approval, competition, pricing, the ability to supply product and meet demand for our products, product withdrawals and new product approvals and launches, our ability to protect our proprietary rights, unanticipated expenses such as litigation or legal settlement expenses or equity securities write-downs, fluctuations in royalties and contract revenues, increased costs of sales, research and development and management, general and administrative expenses, fluctuations in tax and interest rates, increased capital expenditures including greater than expected construction and validation costs, our indebtedness and ability to pay our indebtedness, actions by Roche that are adverse to our interests, decreases in third party reimbursement rates, reaction to and acceptance by distributors of changes to our distribution strategy, and the number of options granted to employees, Genentech’s stock price and certain valuation assumptions concerning Genentech stock. We disclaim and do not undertake any obligation to update or revise any forward-looking statement in this Form 10-Q.

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

Our market risks at March 31, 2006 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2005 on file with the Securities and Exchange Commission. See also Note 1, “Summary of Significant Accounting Policies—Derivative Financial Instruments” section in the Notes to Condensed Consolidated Financial Statements in Part I of this Form 10-Q.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures:* The Company’s principal executive and financial officers reviewed and evaluated the Company’s disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) 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.

*Changes in Internal Controls over Financial Reporting:* There were no changes in the Company’s internal control over financial reporting that occurred during the Company’s last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

See Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q.

See also Item 3 of our report on Form 10-K for the year ended December 31, 2005.

### Item 1A. Risk Factors

This Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of Genentech, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, royalties, contract revenues, expenses, net income and earnings per share.

#### **The successful development of biotherapeutics is highly uncertain and requires significant expenditures**

Successful development of biotherapeutics is highly uncertain. Products that appear promising in research or early phases of development may be delayed or fail to reach later stages of development or the market for several reasons including:

- Preclinical tests may show the product to be toxic or lack efficacy in animal models.
- Clinical trial results may show the product to be less effective than desired 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 Biologic Licensing 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, efficacy or manufacturing issues.
- Difficulties formulating the product, scaling the manufacturing process or in getting approval for manufacturing.
  - Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being developed or commercialized.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. If our large-scale clinical trials are not successful, we will not recover our substantial investments in the product.

Factors affecting our research and development (or “R&D”) productivity and the amount of our 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.
  - Decisions by F. Hoffmann-La Roche (or “Hoffmann-La Roche”) 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 R&D, which we may record as an R&D expense.
  - Participation in a number of collaborative research arrangements. On many of these collaborations, our share of expenses recorded in our financial statements is subject to volatility based on our collaborators’ spending activities as well as the mix and timing of activities between the parties.
  - Charges incurred in connection with expanding our product manufacturing capabilities, as described in “Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively affect our financial performance” below.
- Future levels of revenue.

### **We may be unable to obtain or maintain regulatory approvals for our products**

We 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 (or “U.S.”) until it has been approved by the FDA, and then can only be marketed for the indications approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application or a BLA, are substantial and can require a number of years. In addition, even if 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/or a product recall.

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

- Significant delays in obtaining or failing to obtain required approvals as described in “The successful development of biotherapeutics is highly uncertain and requires significant expenditures” above.
- Loss of, or changes to, previously obtained approvals, including those resulting from post-approval safety or efficacy issues.

- 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.

In addition, 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 or require us to make significant expenditures to obtain or maintain such approvals.

**Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively affect our financial performance**

Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated for this purpose. It can take longer than five years to design, construct, validate, and license a new biotechnology manufacturing facility. We currently produce our products at our manufacturing facilities located in South San Francisco, California; Vacaville, California; Porriño, Spain; and increasingly, 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 could result in product defects which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all. In addition, we may need to record period charges associated with manufacturing or inventory failures or other production-related costs or incur costs to secure additional sources of capacity. Furthermore, there are inherent uncertainties associated with forecasting future demand, especially for newly introduced products of ours or of those for whom we produce products, and as a consequence we may have inadequate capacity to meet our own actual demands and/or the actual demands of those for whom we produce product.

In order to maintain adequate supply to keep up with growing demand for our products, we must successfully implement a number of manufacturing capacity enhancement projects on schedule, utilize nearly 100 percent of our production capacity in the next several years and maintain a state of regulatory compliance at all production sites. If we, or any of our contract manufacturers, for any reason fail to obtain licensure for our capacity enhancement projects on schedule, fail to operate at or near full capacity utilization, fail to maintain a state of regulatory compliance, or if actual demand significantly exceeds our internal forecasts, we may be unable to maintain an adequate supply of our products to meet all demand. Key capacity enhancement projects, which we must successfully implement, include the following: (i) licensure of Wyeth Pharmaceuticals contract manufacturing facility at Andover, Massachusetts to produce Herceptin bulk drug substance by the end of 2006; (ii) licensure of additional capacity at our Porriño, Spain facility in 2006 to produce Avastin bulk drug substance; (iii) licensure of yield improvement processes for Rituxan and Avastin by the end of 2006; (iv) licensure of our Oceanside, California manufacturing facility during the first half of 2007; and (v) construction, qualification and licensure of our new plant in Vacaville, California in the second half of 2009.

If we experience a significant malfunction in our filling facility, we could experience a shortfall or stock out of one or more products, which, if it were to continue for a significant period of time, could result in a material adverse effect on our product sales and our business.

Furthermore, certain of our raw materials and supplies required for the production of our principal products or products we make for others are available only through sole source suppliers (the only recognized supplier available to us) or single source suppliers (the only approved supplier for us among other sources), and we may not be able to obtain such raw materials without significant delay or at all. If such sole source or single source suppliers were to limit or terminate production or otherwise fail to supply these materials for any reason, such failures could also have a material adverse impact on our products sales and our business.

Any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall or stock-out of



available product inventory, any of which could have a material adverse impact on our business. A number of factors could cause prolonged interruptions, including:

- the inability of a supplier to provide raw materials used for manufacture of our products; equipment obsolescence, malfunctions or failures;

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- product contamination problems;
- damage to a facility, including our warehouses and distribution facilities, due to natural disasters, including, but not limited to, earthquakes as our South San Francisco, Oceanside and Vacaville facilities are located in areas where earthquakes could occur;
- changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes;
- action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products we make for others due to regulatory issues;
  - a contract manufacturer going out of business or failing to produce product as contractually required;
- other similar factors.

Because our manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our or our contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share, damage our reputation and could result in a material adverse effect on our product sales, financial condition and results of operations.

### **We face competition**

We face competition from pharmaceutical companies, pharmaceutical divisions of chemical companies, and biotechnology companies.

The introduction of new competitive products or follow-on biologics or new information about existing products may result in lost market share for us, reduced utilization of our products, and/or lower prices, even for products protected by patents.

*Avastin*: Avastin competes with Erbitux® (Imclone/Bristol-Myers Squibb), which is an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer patients. While Erbitux® and Avastin are approved for use in different settings (Avastin in front-line and Erbitux® in relapsed patients), physicians use both products across all lines of therapy. In December 2005, the FDA approved Nexavar® (sorafenib Bayer Corporation/Onyx Pharmaceuticals, Inc.) for the treatment of patients with advanced renal cell carcinoma (or "RCC"), or kidney cancer (unapproved uses of Avastin). In January 2006, the FDA approved Sutent® (sunitinib malate, Pfizer, Inc.) for use in advanced RCC and Gleevec-refractory / intolerant gastrointestinal stromal tumor (unapproved uses of Avastin). Avastin could face competition from products in development that currently do not have regulatory approval, including panitumumab and AMG 706 (Amgen). Amgen has announced that it expects panitumumab to be approved for refractory metastatic colorectal cancer in late 2006, and that it will initiate head-to-head clinical trials between AMG 706 and Avastin this year. Additionally, there are more than 30 potential molecules which target VEGF inhibition, and over 130 companies that are developing molecules which, if approved, may compete with Avastin.

*Rituxan*: Rituxan's competitors include Bexxar® (GlaxoSmithKline) and Zevalin® (Biogen Idec), both of which are radioimmunotherapies indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma (or "NHL"). While indicated for the treatment of NHL, both products currently represent limited competition for Rituxan. Other competitors include Campath® (Berlex, Inc.), which is indicated for B-cell chronic lymphocytic leukemia (an unapproved use of Rituxan), and Velcade® (Millennium

Pharmaceuticals, Inc.) which is indicated for multiple myeloma (an unapproved use of Rituxan).

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Rituxan's current biologic competitors in rheumatoid arthritis include Enbrel® (Amgen/Wyeth), Humira® (Abbott), Remicade® (Johnson & Johnson), Orenicia® (Bristol-Myers Squibb), and Kineret® (Amgen). These products are indicated for a broader RA patient population than Rituxan.

*Herceptin:* Herceptin could face competition in the future from experimental drugs and products in development that do not currently have regulatory approval for any use outside of clinical trials, including Tykerb® (lapatinib ditosylate), which is being developed by GlaxoSmithKline. On April 3, 2006, GlaxoSmithKline announced that it halted enrollment in its Phase III clinical trial to evaluate its drug Tykerb® because of positive results in treating HER2 positive metastatic breast cancer in women whose disease had progressed following treatment with Herceptin and other cancer therapies. GSK said it will file for regulatory approval of Tykerb® in the second half of this year.

*Tarceva:* Tarceva competes with the chemotherapeutic products Taxotere® (Sanofi-Aventis) and Alimta® (Eli Lilly and Company), both of which are indicated for the treatment of relapsed NSCLC. Although not FDA approved for use in pancreatic cancer, Xeloda® (Roche) and 5-FU represent competitors in this market. Tarceva could also face competition in the future from products in late-phase development that currently do not have regulatory approval for use in NSCLC or pancreatic cancer. Examples of potential competitors in Phase III NSCLC trials are Erbitux® (Bristol-Myers Squibb), Xyotax® (Cell Therapeutics Inc.), Telcyta® (Telik, Inc.), Nexavar® (sorafenib, Bayer/Onyx) and Zactima® (Astra Zeneca). Examples of potential competitors in Phase III pancreatic cancer trials, in addition to Xeloda® (Roche), are Erbitux® (Bristol-Myers Squibb) Eloxatin® (oxaliplatin, Sanofi-Aventis) and Avastin.

*Xolair:* While Xolair has no direct competitors, it faces competition from other asthma therapies, including inhaled corticosteroids, long-acting beta agonists, combination products such as fixed dose inhaled corticosteroids/long-acting beta agonists and leukotriene inhibitors, as well as oral corticosteroids.

*Raptiva:* Raptiva competes with established therapies for moderate-to-severe psoriasis including oral systemics such as methotrexate and cyclosporin, as well as ultraviolet light therapies. In addition, Raptiva competes with FDA approved biologic agents Amevive® (Biogen Idec) and Enbrel® (Amgen). Raptiva also competes with the unapproved biologic agents Remicade® (Centocor, Inc.) and Humira® (Abbott Laboratories), both of which are currently used in the psoriasis market. In October 2005, Centocor filed with the FDA for approval of Remicade® for the treatment of psoriasis.

*Nutropin:* In the growth hormone market, we face competition from other companies currently selling growth hormone products. Nutropin's current competitors are Genotropin® (Pfizer), Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly and Company), Tev-Tropin® (Teva Pharmaceutical Industries Ltd.), and Saizen® (Serono, Inc.). As a result of multiple competitors, we have experienced, and may continue to experience, a loss of new patient share and increased competition for managed care product placement based on pricing; which may require that we discount our product in the future.

*Thrombolytics:* We face competition in our acute myocardial infarction market with sales of TNKase and Activase affected by the adoption by physicians of mechanical reperfusion strategies. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. TNKase and Activase for acute myocardial infarction also face competition from aggressive price discounting on Retavase® (reteplase), marketed by ESP Pharma, Inc. (a wholly owned subsidiary of PDL BioPharma, Inc.). Cathflo Activase may face competition in the catheter clearance market from Nuvelo's Alfimeprase®, currently in ongoing Phase III clinical trials.

*Pulmozyme:* Pulmozyme faces competition from an emerging, inexpensive approach to clearing the lungs of cystic fibrosis patients. Specifically, the use of hypertonic saline could limit or reduce penetration into specific segments of the cystic fibrosis population. Research continues on new approaches to disease modification of cystic fibrosis which

could reduce the number of patients in need of therapy.

*Lucentis:* We are aware that some retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration (or “AMD”), an unapproved use, and that there may be continued Avastin use in this setting even after Lucentis has been approved for commercial use. Laser photocoagulation, Macugen® (Pfizer/OSI

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Pharmaceuticals), and Visudyne® (Novartis) alone, or in combination with the off-label steroid kenalog, are also currently being used to treat wet AMD.

In addition to the commercial and late stage development products listed above, there are numerous products in earlier stages of development at other biotechnology and pharmaceutical companies that, if successful in clinical trials, may compete with our products.

**Decreases in third party reimbursement rates may affect our product sales, results of operations and financial condition**

Sales of our products will depend significantly on the extent to which reimbursement for the cost of our products and related treatments will be available to physicians from government health administration authorities, private health insurers and other organizations. Third party payers and governmental health administration authorities are increasingly attempting to limit and/or regulate the reimbursement for medical products and services, especially branded prescription drugs. Changes in government legislation or regulation, such as the Medicare Act, or changes in private third-party payers' policies toward reimbursement for our products may reduce reimbursement of our products' costs to physicians. Decreases in third-party reimbursement for our products could reduce physician usage of the product and may have a material adverse effect on our product sales, results of operations and financial condition.

**Protecting our proprietary rights is difficult and costly**

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the breadth of claims allowed in these companies' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material litigation and other legal proceedings relating to our proprietary rights, such as the Cabilly reexaminations discussed in Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item I of this Form 10-Q. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities to third-parties. An adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third-parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

The presence of patents or other proprietary rights belonging to other parties may lead to our termination of the R&D of a particular product, a loss of our entire investment in the product and subject us to infringement claims.

**If there is an adverse outcome in our pending litigation or other legal actions our business may be harmed**

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 judgment with significant monetary award, including the possibility of punitive damages, 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 and these lawsuits could divert management's attention from ongoing business concerns.

Our activities relating to the sale and marketing of our products are subject to regulation under the U.S. Federal Food, Drug and Cosmetic Act and other federal statutes. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care

programs (including Medicare and Medicaid). In 1999 we agreed to pay \$50 million to settle a federal investigation relating to our past clinical, sales and marketing activities associated with human growth hormone. We are currently being investigated by the Department of Justice with respect to our promotional practices of Rituxan, and may in the future be investigated for our promotional practices relating to any of our products. If the

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government were to bring charges against or convict us of violating these laws, or if we were subject to third party litigation relating to the same promotional practices, there could be a material adverse effect on our business, including our financial condition and results of operations.

We are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If a court were to find us liable for violating these laws, or if the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our business, including on our stock price.

**We may be unable to manufacture certain of our products if there is BSE contamination of our bovine source raw material**

Most biotechnology companies, including Genentech, have historically used bovine source raw materials to support cell growth in our production processes. Bovine source raw materials from within or outside the U.S. are increasingly subject to greater public and regulatory scrutiny because of the perceived risk of contamination with bovine spongiform encephalopathy (or “BSE”). Should BSE contamination occur during the manufacture of any of our products that require the use of bovine source raw materials, it would negatively impact our ability to manufacture those products for an indefinite period of time (or at least until an alternative process is approved), negatively affect our reputation and could result in a material adverse effect on our product sales, financial condition and results of operations.

**We may be unable to retain skilled personnel and maintain key relationships**

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, (ii) successfully integrate large numbers of new employees into our corporate culture, and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense.

Among other benefits, we use stock options to attract and retain personnel. The number of shares management and our board of directors choose to grant under our stock option plans may be affected by our affiliation agreement with Roche, which provides that 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. In addition, stock option accounting rules require us to recognize all employee stock-based compensation costs as expenses. These or other factors could reduce the number of shares management and our board of directors choose to grant. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships or that the costs of retaining such personnel or maintaining such relationships will not materially increase.

**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, as well as the pricing decisions of our competitors, any of which could affect the utilization of our products.

- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party could cause the sales of our products to decrease or a product to be recalled.
- Negative safety or efficacy data from post-approval marketing experience could cause sales of our products to decrease or a product to be recalled.
- 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.
  - The increasing use and development of alternate therapies.
  - The rate of market penetration by competing products.
- Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers who supply our products.

Any of these factors could have a material adverse effect on our sales and results of operations.

#### **Our results of operations are affected by our royalty and contract revenues**

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 U.S.
- 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 milestones are achieved.
  - The failure of or refusal of a licensee to pay royalties.



- The expiration or invalidation of our patents or licensed intellectual property. For example, patent litigations, interferences, oppositions, and other proceedings involving our patents often include claims by third-parties that such patents are invalid or unenforceable. If a court, patent office, or other authority were to determine that a patent under which we receive royalties and/or other revenues is invalid or unenforceable, that determination could cause us to suffer a loss of such royalties and/or revenues, and could cause us to incur other monetary damages.
- Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

### **Our affiliation agreement with Roche Holdings, Inc. 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 discussion below in "Liquidity and Capital Resources—Cash Used in Financing Activities." See Note 5, "Relationship with Roche and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for information regarding the Minimum Percentage.

While the dollar amounts associated with future stock repurchase programs cannot currently be determined, 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 limit our ability to make acquisitions**

The affiliation agreement between us and Roche contains provisions that:

- Require the approval of the directors designated by Roche to make any acquisition or any sale or disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues.
  - Enable Roche to maintain its percentage ownership interest in our Common Stock.
- Require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For information regarding Minimum Percentage, see Note 5, "Relationship with Roche and Related Party Transactions," 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.

### **Future sales of our Common Stock by Roche could cause the price of our Common Stock to decline**

As of March 31, 2006, Roche owned 587,189,380 shares of our Common Stock, or 55.7% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by Roche in the public market could adversely affect the market price of our Common Stock.

**Roche Holdings, Inc., our controlling stockholder, may seek to influence our business in a manner that is adverse to us or adverse to other stockholders who may be unable to prevent actions by Roche**

Roche, as our majority stockholder, controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our board of directors shall consist of at least three

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directors designated by Roche, three independent directors nominated by the nomination committee and one Genentech executive officer nominated by the nominations committee. Our bylaws also provide that Roche will have the right to obtain proportional representation on our board until such time that Roche owns less than 5% of our stock. Currently, three of our directors, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles, also serve as officers and employees of Roche Holding Ltd and its affiliates. As long as Roche owns in excess of 50% of our Common Stock, Roche directors will comprise two of the three members of the nominations committee. Our certificate of incorporation includes provisions relating to competition by Roche affiliates with us, offering of corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of specified employees. We cannot assure you that Roche will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, 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.

Additionally, 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.

#### **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 and costly to obtain or maintain**

While we currently have a certain amount of insurance to minimize our direct exposure to certain business risks, premiums are generally increasing and coverage is narrowing in scope. As a result, we may be required to assume more risk in the future or make significant expenditures to maintain our current levels of insurance. If we are subject to third-party claims or suffer a loss or damages in excess of our insurance coverage, we will incur the cost of the portion of the retained risk. Furthermore, any claims made on our insurance policies may affect our ability to obtain or maintain insurance coverage at reasonable costs.

#### **We are subject to environmental and other risks**

We use certain hazardous materials in connection with our research and manufacturing activities. In the event such hazardous materials are stored, handled or released into the environment in violation of law or any permit, we could be subject to loss of our permits, government fines or penalties and/or other adverse governmental or private actions. 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.

We also have acquired, and may continue to acquire in the future, land and buildings as we expand our operations. Some of these properties are “brownfields” for which redevelopment or use is complicated by the presence or potential presence of a hazardous substance, pollutant or contaminant. Certain events could occur which may require us to pay significant clean-up or other costs in order to maintain our operations on those properties. Such events include, but are not limited to, changes in environmental laws, discovery of new contamination, or unintended exacerbation of existing contamination. The occurrence of any such event could materially affect our ability to continue our business operations on those properties.



### **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 U.S. 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 U.S. and the amount and timing of sales to their respective customers, which directly impacts both our product sales and royalty revenues.
  - The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of therapy.
  - The extent of product discounts extended to customers.
- The effectiveness and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.
  - The rate of adoption by physicians and use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
    - The potential introduction of new products and additional indications for existing products.
  - The ability to successfully manufacture sufficient quantities of any particular marketed product.
    - Pricing decisions we may adopt.

### **Our integration of new information systems could disrupt our internal operations, which could harm our revenues and increase our expenses**

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors. As part of our Enterprise Resource Planning efforts, we are implementing new information systems, but we may not be successful in implementing all of the new systems, and transitioning data and other aspects of the process could be expensive, time consuming, disruptive and resource intensive. Any disruptions that may occur in the implementation of new systems or any future systems could adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows. Disruptions to these systems also could adversely affect our ability to fulfill orders and interrupt other operational processes. Delayed sales, lower margins or lost customers resulting from these disruptions could adversely affect our financial results.

### **Our stock price, like that of many biotechnology companies, is 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.

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In addition, the following factors may have a significant impact on the market price of our Common Stock.

- Announcements of technological innovations or new commercial products by us or our competitors.
- Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors.
  - Concerns about the pricing of our products and the potential impact of such on their utilization.
  - Developments or outcome of litigation, including litigation regarding proprietary and patent rights.
  - Regulatory developments or delays concerning our products in the U.S. 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.

#### **Our effective income tax rate may vary significantly**

Various internal and external factors may have favorable or unfavorable effects on our future effective income 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, changes in estimates of prior years' items, past and future levels of R&D spending, and changes in overall levels of income before taxes.

#### **To pay our indebtedness will require a significant amount of cash and may adversely affect our operations and financial results**

As of March 31, 2006, we had approximately \$2.0 billion of long-term debt. Our ability to make payments on and to refinance our indebtedness, including our long-term debt obligations, and to fund planned capital expenditures, R&D, as well as stock repurchases and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase our vulnerability to general adverse economic and industry conditions, require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts and other general corporate purposes, and limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

#### **Accounting pronouncements may affect our future financial position and results of operations**

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" (or "FAS 123R"). As a result, we have included employee stock-based compensation costs in our results of operations for the quarter ended March 31, 2006, as discussed in Note 2, "Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements of Part I, Item I of this Form 10-Q. Our adoption of FAS 123R is expected to result in compensation expense that will reduce diluted net income per share by approximately \$0.15 to \$0.17 per share for 2006. However, our estimate of future employee stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are

not limited to, the volatility of our stock price and employee stock option exercise behaviors.

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**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2006, we are authorized to repurchase up to 100,000,000 shares of our Common Stock for an aggregate amount of up to \$6.0 billion through June 30, 2007. In this stock repurchase program, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. Genentech intends to use the repurchased stock to offset dilution caused by the issuance of shares in connection with Genentech's employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to make prudent investments of our cash resources; (ii) to allow for an effective mechanism to provide stock for our employee stock plans; and (iii) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage. See above in "Relationship with Roche" for more information on Roche's minimum ownership percentage. We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately 2 million shares and will run through June 30, 2006.

Our shares repurchased for the three months ended March 31, 2006 were as follows (*shares in millions*):

	<b>Total Number of Shares Purchased in 2006</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
January 1-31, 2006	0.9	\$ 88.37		
February 1-28, 2006	0.7	85.31		
March 1-31, 2006	1.0	84.24		
Total	2.6	\$ 85.95	52	48

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.

**Item 6. Exhibits****Exhibit****No. Description**

10.1 Genentech, Inc. Employee Stock Plan, as amended

**Location**

Filed on a Current Report on Form 8-K with the U.S. Securities and Exchange Commission on April 25, 2006, and incorporated herein by reference.

15.1 Letter regarding Unaudited Interim Financial Information.

Filed herewith

31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of

Filed herewith

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1934, as amended

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 Filed herewith

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 Furnished herewith

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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: May 1, 2006

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

Date: May 1, 2006

/s/DAVID A. EBERSMAN  
David A. Ebersman  
Executive Vice President and  
Chief Financial Officer

Date: May 1, 2006

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

