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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, 2008

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, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (do not check if a smaller reporting company)

Smaller reporting company

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.

Class

Common Stock \$0.02 par value

Number of Shares Outstanding

1,050,891,782 Outstanding at April 30, 2008

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

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Activase<sup>®</sup> (alteplase, recombinant) tissue-plasminogen activator; Avastin<sup>®</sup> (bevacizumab) anti-VEGF antibody; Cathflo<sup>®</sup> Activase<sup>®</sup> (alteplase for catheter clearance); Genentech<sup>®</sup>; Herceptin<sup>®</sup> (trastuzumab) anti-HER2 antibody; Lucentis<sup>®</sup> (ranibizumab) anti-VEGF antibody fragment; Nutropin<sup>®</sup> (somatropin [rDNA origin] for injection) growth hormone; Nutropin AQ<sup>®</sup> and Nutropin AQ Pen<sup>®</sup> (somatropin [rDNA origin] for injection) liquid formulation growth hormone; Pulmozyme<sup>®</sup> (dornase alfa, recombinant) inhalation solution; Raptiva<sup>®</sup> (efalizumab) anti-CD11a antibody; and TNKase<sup>®</sup> (tenecteplase) single-bolus thrombolytic agent. Rituxan<sup>®</sup> (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva<sup>®</sup> (erlotinib) is a registered trademark of OSI Pharmaceuticals, Inc.; and Xolair<sup>®</sup> (omalizumab) anti-IgE antibody is a registered 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>2008</b>	<b>2007</b>
<b>Revenue</b>		
Product sales (including amounts from related parties: 2008—\$140; 2007—\$266)	\$ 2,379	\$ 2,329
Royalties (including amounts from related parties: 2008—\$423; 2007—\$260)	616	419
Contract revenue (including amounts from related parties: 2008—\$31; 2007—\$70)	68	95
<b>Total operating revenue</b>	<b>3,063</b>	<b>2,843</b>
<b>Costs and expenses</b>		
Cost of sales (including amounts for related parties: 2008—\$66; 2007—\$124)	389	392
Research and development (including amounts associated with related party collaborations: 2008—\$79; 2007—\$68) (including amounts where reimbursement was recorded as contract revenue: 2008—\$50; 2007—\$46)	617	610
Marketing, general and administrative	517	491
Collaboration profit sharing (including related party amounts: 2008—\$41; 2007—\$47)	279	252
Recurring amortization charges related to redemption and acquisition	43	26
Special items: litigation-related	(301)	13
<b>Total costs and expenses</b>	<b>1,544</b>	<b>1,784</b>
Operating income	1,519	1,059
Other income (expense):		
Interest and other income, net	74	74
Interest expense	(18)	(18)
Total other income, net	56	56
Income before taxes	1,575	1,115
Income tax provision	592	409
<b>Net income</b>	<b>\$ 983</b>	<b>\$ 706</b>
<b>Earnings per share</b>		
Basic	\$ 0.93	\$ 0.67
Diluted	\$ 0.92	\$ 0.66
Shares used to compute basic earnings per share	1,053	1,053
Shares used to compute diluted earnings per share	1,068	1,071

*See Notes to Condensed Consolidated Financial Statements.*

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

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 983	\$ 706
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	139	106
Employee stock-based compensation	110	100
Deferred income taxes	75	(81)
Deferred revenue	(9)	(15)
Litigation-related special items	(302)	13
Excess tax benefit from stock-based compensation arrangements	(39)	(99)
Gain on sales of securities available-for-sale and other	(7)	(8)
Loss on sales and write-downs of securities available-for-sale and other	31	3
Loss on property and equipment dispositions	1	11
Changes in assets and liabilities:		
Receivables and other current assets	(11)	(31)
Inventories	22	(115)
Investments in trading securities	(6)	(9)
Accounts payable, other accrued liabilities, and other long-term liabilities	12	179
<b>Net cash provided by operating activities</b>	<b>999</b>	<b>760</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(654)	(122)
Proceeds from sales of securities available-for-sale	341	37
Proceeds from maturities of securities available-for-sale	75	126
Capital expenditures	(200)	(209)
Change in other intangible and long-term assets	22	31
<b>Net cash used in investing activities</b>	<b>(416)</b>	<b>(137)</b>
<b>Cash flows from financing activities</b>		
Stock issuances	147	174
Stock repurchases	-	(392)
Excess tax benefit from stock-based compensation arrangements	39	99
<b>Net cash provided by (used in) financing activities</b>	<b>186</b>	<b>(119)</b>
Net increase in cash and cash equivalents	769	504
Cash and cash equivalents at beginning of period	2,514	1,250
<b>Cash and cash equivalents at end of period</b>	<b>\$ 3,283</b>	<b>\$ 1,754</b>
<b>Supplemental cash flow data</b>		
Cash paid during the period for:		
Interest	\$ 42	\$ 42
Income taxes	129	163
Non-cash investing and financing activities		
Capitalization of construction in progress related to financing lease transactions	42	57

*See Notes to Condensed Consolidated Financial Statements.*

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

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 3,283	\$ 2,514
Short-term investments	1,574	1,461
Restricted cash and investments	788	788
Accounts receivable—product sales (net of allowances of: 2008—\$135; 2007—\$116; including amounts from related parties: 2008—\$47; 2007—\$2)	889	847
Accounts receivable—royalties (including amounts from related parties: 2008—\$541; 2007—\$463)	701	620
Accounts receivable—other (net of allowances of: 2008—\$5; 2007—\$0; including amounts from related parties: 2008—\$139; 2007—\$233)	228	299
Inventories	1,469	1,493
Prepaid expenses and other current assets	645	731
Total current assets	9,577	8,753
Long-term marketable debt and equity securities	2,201	2,090
Property, plant and equipment, net	5,135	4,986
Goodwill	1,577	1,577
Other intangible assets	1,127	1,168
Other long-term assets	378	366
<b>Total assets</b>	<b>\$ 19,995</b>	<b>\$ 18,940</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable (including amounts to related parties: 2008 and 2007—\$2)	\$ 278	\$ 420
Commercial paper	600	599
Deferred revenue	78	73
Taxes payable	517	173
Accrued litigation	473	776
Other accrued liabilities (including amounts to related parties: 2008—\$176; 2007—\$230)	1,711	1,877
Total current liabilities	3,657	3,918
Long-term debt	2,460	2,402
Deferred revenue	424	418
Other long-term liabilities	348	297
Total liabilities	6,889	7,035
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock	21	21
Additional paid-in capital	11,245	10,695
Accumulated other comprehensive income	123	197
Retained earnings since June 30, 1999	1,717	992
Total stockholders' equity	13,106	11,905
<b>Total liabilities and stockholders' equity</b>	<b>\$ 19,995</b>	<b>\$ 18,940</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 United States (U.S.) Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (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, 2007. In the opinion of management, the financial statements include all adjustments, consisting only of normal and recurring adjustments, considered necessary for the fair presentation of our financial position and operating results.

Revenue, 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 consolidated financial statements include the accounts of Genentech and all of our wholly owned subsidiaries. Material intercompany accounts and transactions have been eliminated.

***Use of Estimates***

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 the estimates.

***Recent Accounting Pronouncements***

In February 2008, the Financial Accounting Standards Board (FASB) issued Statement of Financial Position (FSP) No. 157-2 which delays the effective date of FASB Statement of Financial Accounting Standard (FAS) No. 157, "*Fair Value Measurements*" (FAS 157) for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value on a recurring basis (items that are remeasured at least annually). The FSP defers the effective date of FAS 157 until our fiscal year beginning on January 1, 2009.

In March 2008, the FASB issued FAS No. 161, "*Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133*" (FAS 161). FAS 161 requires us to provide greater transparency about how and why we use derivative instruments, how the instruments and related hedged items are accounted for under FAS 133, and how the instruments and related hedged items affect our financial position, results of operations, and cash flows. FAS 161 is effective for us beginning on January 1, 2009. The principal impact to us will be to require us to expand our disclosure regarding our derivative instruments.

***Revenue Recognition***

We recognize revenue from the sale of our products, royalties earned, and contract arrangements. Certain of our revenue arrangements that contain multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are

applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

The Avastin Patient Assistance Program is a voluntary program that enables eligible patients who have received 10,000 milligrams (mg) of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 mg during the remainder of the 12-month period. Based on the current wholesale acquisition cost, 10,000 mg is valued at \$55,000 in gross revenue. We defer a portion of our gross Avastin product sales revenue to reflect our estimate of the commitment to supply free Avastin to patients who elect to enroll in the program. To calculate our deferred revenue, we estimate several factors, most notably: the number of patients who are currently being treated for U.S. Food and Drug Administration (FDA)-approved indications and the start date of their treatment regimen, the extent to which patients may elect to enroll in the program, the number of patients who meet the financial eligibility requirements of the program, and the duration and extent of treatment for the FDA-approved indications, among other factors. We will continue to update our estimates each reporting period as new information becomes available. Based on these estimates, we defer a portion of the Avastin revenue on product vials sold through normal commercial channels. The deferred revenue is recognized when free Avastin vials are delivered or after the associated patient eligibility period has passed.

### ***Earnings Per Share***

Basic earnings per share (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>2008</b>	<b>2007</b>
<b>Numerator</b>		
Net income	\$ 983	\$ 706
<b>Denominator</b>		
Weighted-average shares outstanding used to compute basic earnings per share	1,053	1,053
Effect of dilutive stock options	15	18
Weighted-average shares outstanding and dilutive securities used to compute diluted earnings per share	1,068	1,071

Outstanding employee stock options to purchase approximately 49 million shares of our Common Stock were excluded from the computation of diluted EPS for the first quarter of 2008 because the effect would have been anti-dilutive.

### ***Comprehensive Income***

Comprehensive income comprises net income and other comprehensive income (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 securities available-for-sale. The gains or losses and prior service costs or credits related to our post-retirement benefit plan that arise during the period, but are not recognized as components of net periodic benefit cost, have also been recognized in OCI.

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

	March 31, 2008	December 31, 2007
Net unrealized gains on securities available-for-sale	\$ 205	\$ 219
Net unrealized losses on cash flow hedges	(74)	(14)
Accumulated changes in post-retirement benefit obligation	(8)	(8)
Accumulated other comprehensive income	<u>\$ 123</u>	<u>\$ 197</u>

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

	Three Months Ended March 31,	
	2008	2007
Net income	\$ 983	\$ 706
(Decrease) increase in net unrealized gains on securities available-for-sale	(14)	5
(Increase) decrease in net unrealized losses on cash flow hedges	(60)	3
Comprehensive income, net of income taxes	<u>\$ 909</u>	<u>\$ 714</u>

The increase in net unrealized losses on cash flow hedges during the first quarter of 2008 was primarily due to the weakening of the U.S. dollar during this period. However, in the periods in which these cash flow hedges expire, the losses will be offset by revenue denominated in the underlying foreign currency.

#### ***Fair Value of Financial Instruments***

The fair value of our financial instruments reflects the amounts that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value estimates presented in this report reflect the information available to us as of March 31, 2008 and December 31, 2007. See Note 4, "Fair Value Measurements."

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

Our derivative instruments, designated as cash flow hedges, consist of foreign currency exchange options and forwards. As of March 31, 2008, unrealized net losses of \$87 million are expected to be reclassified from accumulated OCI to earnings within the next 12 months. If realized, these amounts are expected to be reflected primarily as a reduction of the underlying foreign-currency-denominated royalty revenue over this same 12-month period.

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

##### ***Stock-Based Compensation Expense under FAS 123R***

Employee stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS No. 123(R), "Share-Based Payment" (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 123R was as follows (*in millions*):

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Cost of sales	\$ 22	\$ 16
Research and development	42	38
Marketing, general and administrative	46	46
Total employee stock-based compensation expense	<u>\$ 110</u>	<u>\$ 100</u>

As of March 31, 2008, total compensation cost related to unvested stock options not yet recognized was \$750 million, which is expected to be allocated to expense and production costs over a weighted-average period of 32 months. The portion allocated to production costs will be recognized as cost of sales (COS) when the related products are estimated to be sold.

The carrying value of inventory on our Condensed Consolidated Balance Sheets as of March 31, 2008 and 2007 includes employee stock-based compensation costs of \$70 million and \$71 million, respectively.

#### **Valuation Assumptions**

The employee stock-based compensation expense recognized under FAS 123R 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 were as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Risk-free interest rate	2.7%	4.6%
Dividend yield	0.0%	0.0%
Expected volatility	25.0%	27.0%
Expected term (years)	5.0	4.6

Due to the redemption of our Special Common Stock in June 1999 by Roche Holdings, Inc. (RHI), there is limited historical information available to support our estimate of certain assumptions required to value our employee stock options. In developing our estimate of expected term, we have assumed that our recent historical stock option exercise experience is a relevant indicator of future exercise patterns. We base our determination of expected volatility predominantly on the implied volatility of our traded options with consideration of our historical volatilities and the volatilities of comparable companies.

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

#### **Inventories**

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

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Raw materials and supplies	\$ 116	\$ 119
Work-in-process	1,122	1,062
Finished goods	231	312
Total	<u>\$ 1,469</u>	<u>\$ 1,493</u>

Included in work-in-process as of March 31, 2008 are approximately \$46 million of Rituxan inventories that were manufactured through a process that is awaiting regulatory licensure.

#### Note 4. Fair Value Measurements

On January 1, 2008, we adopted FAS 157, which established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. FAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, FAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be used for financial reporting purposes. The fair value of our financial instruments reflects the amounts that we estimate to receive in connection with the sale of an asset or paid in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). FAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

Level 1—quoted prices in active markets for identical assets and liabilities.

Level 2—observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3—unobservable inputs.

The adoption of FAS 157 did not have an effect on our financial condition or results of operations, but FAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. The substantial majority of our financial instruments are valued using quoted prices in active markets or based on other observable inputs.

The following table sets forth the fair value of our financial assets and liabilities measured on a recurring basis including those pledged as collateral, or restricted. Assets and liabilities are measured on a recurring basis if they are remeasured at least annually.

<i>(in millions)</i>	March 31, 2008		December 31, 2007	
	Assets	Liabilities	Assets	Liabilities
Cash and cash equivalents	\$ 3,283	\$ —	\$ 2,514	\$ —
Restricted cash	788	—	788	—
Short-term investments	1,574	—	1,461	—
Long-term marketable debt securities	1,785	—	1,674	—
Total fixed income investment portfolio	\$ 7,430	—	\$ 6,437	—
Long-term marketable equity securities	416	—	416	—
Total derivative financial instruments	32	130	30	19
Total	\$ 7,878	\$ 130	\$ 6,883	\$ 19

The following table sets forth the fair value of our financial assets and liabilities that were measured on a recurring basis during the three months ended March 31, 2008 *(in millions)*.

	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Cash and cash equivalents	\$ 2,219	\$ 1,064	\$ —	\$ 3,283
Trading securities	68	937	2	1,007
Securities available-for-sale	244	2,735	161	3,140
Equity securities	416	—	—	416
Derivative financial instruments	11	21	—	32
Total	\$ 2,958	\$ 4,757	\$ 163	\$ 7,878
<b>Liabilities</b>				
Derivative financial instruments	\$ —	\$ 130	\$ —	\$ 130

Our Level 1 assets include cash, money market instruments, U.S. Treasury securities, marketable equity securities and equity forwards. Level 2 assets include other government and agency securities, commercial paper, corporate bonds, asset-backed securities, municipal bonds, preferred securities and other derivatives. As of March 31, 2008, we held \$163 million of investments, which were measured using unobservable (Level 3) inputs, representing approximately 2% of our total fair value investments portfolio. The assets include \$161 million of student loan auction-rate securities and \$2 million of structured investment vehicle securities for which fair value was determined based on broker-provided valuations, which approximate fair value. In February 2008, the auction-rate securities market experienced a number of failed auctions for student loan-backed securities, including those we held and continue to hold, which severely limited the liquidity for these securities. Due to market liquidity constraints related to the failed auctions, we classified the auction-rate securities as non-current assets consistent with the long-term maturity dates of the underlying student loans. As of March 31, 2008, we believe the unrealized losses in the auction-rate securities are temporary and we have the ability to hold the assets to maturity. All of our auction-rate securities are AAA/Aaa-rated and are collateralized by student loans which are guaranteed by the U.S. government to be repaid at no less than 95% of par value.

The following table sets forth a summary of the changes in the fair value of our Level 3 financial assets, which are measured at fair value on a recurring basis for the three months ended March 31, 2008 (*in millions*).

	<b>Structured Investment Vehicle Securities</b>	<b>Auction-Rate Securities<sup>(1)</sup></b>
Balance at December 31, 2007	\$ 7	\$ –
Transfer into Level 3 <sup>(2)</sup>	–	174
Total unrealized losses	(1)	(13)
Purchases, issuances, settlement <sup>(3)</sup>	(4)	–
Balance at March 31, 2008	\$ 2	\$ 161

(1) The unrealized loss of \$13 million was included in OCI.

(2) During the first quarter of 2008, we held \$174 million of auction-rate securities that were transferred to Level 3 assets.

(3) During the first quarter of 2008, \$4 million of our structured investment vehicle was “called” or redeemed for cash.

## Note 5. Contingencies

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

On October 4, 2004, we received a subpoena from the U.S. Department of Justice requesting documents related to the promotion of Rituxan, a prescription treatment now approved for five indications. We are cooperating with the associated investigation, which is both civil and criminal in nature, and through counsel we are having discussions with government representatives about the status of their investigation and Genentech’s views on this matter, including potential resolution. The government has called, and may continue 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.

We and the City of Hope National Medical Center (COH) are parties to a 1976 agreement related 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 manufacture, use, and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to 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 COH approximately \$300 million in compensatory damages. On June 24, 2002, a jury voted to award 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 “Accrued litigation” at March 31, 2008 and December 31, 2007. 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 California Supreme Court heard our appeal on this matter on February 5, 2008, and on April 24, 2008 overturned the award of \$200 million in punitive damages to COH but upheld the award of \$300 million in compensatory damages. We expect to pay approximately \$477 million to COH in the second quarter of 2008, reflecting the amount of compensatory damages awarded plus interest thereon from the date of the original decision, June 10, 2002.

As a result of the April 24, 2008 California Supreme Court decision, we recorded a net favorable litigation settlement of \$301 million in the first quarter of 2008, which included \$9 million of accrued interest and bond costs primarily related to the compensatory damages. In the first quarter of 2007, we recorded accrued interest and bond costs on both the compensatory and punitive damages totaling \$13 million. In conjunction with the COH judgment in 2002, we posted a surety bond and were required to pledge cash and investments of \$788 million to secure the bond. Our payment in the second quarter of 2008 for the compensatory damages award of approximately \$477 million will be made from the restricted cash and investments, and this balance is reflected in "Restricted cash and investments" in the accompanying Condensed Consolidated Balance Sheets. We also expect approximately \$313 million to be released from restricted cash and investments during the second quarter of 2008 and made available for use in our operations. Included within current liabilities in "Accrued litigation" in the accompanying Condensed Consolidated Balance Sheets at March 31, 2008 and December 31, 2007 are \$473 million and \$776 million, respectively, which represents our estimate of the costs for the resolution of the COH matter as of each of these reporting dates.

On April 11, 2003, MedImmune, Inc. 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 (the 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 violation of anti-trust, patent, and unfair competition laws. MedImmune is seeking a ruling that the Cabilly patent is invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the Cabilly patent on sales of its Synagis<sup>®</sup> antibody product, an injunction to prevent us from enforcing the Cabilly patent, an award of actual and exemplary damages, and other relief. On January 14, 2004, the U.S. District Court, amending a December 23, 2003 order, granted summary judgment in our favor on all of MedImmune's anti-trust 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 U.S. Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune's petition, and the oral argument of this case before the Supreme Court occurred on October 4, 2006. On January 9, 2007, the Supreme Court issued a decision reversing the Federal Circuit's decision and remanding the case to the lower courts for further proceedings in connection with the patent and contract claims. On August 16, 2007, the U.S. District Court entered a Claim Construction Order defining several terms used in the Cabilly patent. On October 29, 2007, MedImmune filed a motion for partial summary judgment of non-infringement, and in connection with that motion MedImmune conceded that its Synagis product infringes claim 33 of the Cabilly patent. Genentech responded to this motion in part by granting MedImmune, with respect to the Synagis product only, a covenant not to sue for infringement under any claim of the Cabilly patent other than claim 33. The trial of this matter has been scheduled for June 23, 2008. 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 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 and Trademark Office (Patent Office) ordered reexamination of the Cabilly patent. On September 13, 2005, the Patent Office mailed an initial non-final Patent Office action rejecting all 36 claims of the Cabilly patent. We filed our response to the Patent Office action on November 25, 2005. On December 23, 2005, a second request for reexamination of the Cabilly patent was filed by another third party, and on January 23, 2006, the Patent Office granted that request. On June 6, 2006, the two reexaminations were merged into one proceeding. On August 16, 2006, the Patent Office mailed a non-final Patent Office action in the merged proceeding, rejecting all the claims of the Cabilly patent based on issues raised in the two reexamination requests. We filed our response to the Patent Office action on October 30, 2006. On February 16, 2007, the Patent Office mailed a final Patent Office action

rejecting all the claims of the Cabilly patent. We responded to the final Patent Office action on May 21, 2007 and requested continued reexamination. On May 31, 2007, the Patent Office granted the request for continued reexamination, and in doing so withdrew the finality of the February 2007 Patent Office action and agreed to treat our May 21, 2007 filing as a response to a first Patent Office action. On February 25, 2008, the Patent Office mailed a final Patent Office action rejecting all the claims of the Cabilly patent. We intend to file a response to this action and, if necessary, appeal the rejection. We requested and the Patent Office granted us an extension of time to June 6, 2008 for filing a response. The Cabilly patent, which expires in 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and deoxyribonucleic acid (DNA) used in these methods. We have licensed the Cabilly patent to other companies and derive significant royalties from those licenses. The claims of the Cabilly patent remain valid and enforceable throughout the reexamination and appeals processes. Because the above-described proceeding is ongoing, the outcome of this matter cannot be determined at this time.

In 2006, we made development decisions involving our humanized anti-CD20 program, and our collaborator, Biogen Idec Inc., disagreed with certain of our development decisions related to humanized anti-CD20 products. Under our 2003 collaboration agreement with Biogen Idec, we believe that we are permitted to proceed with further trials of certain humanized anti-CD20 antibodies, and Biogen Idec disagreed with our position. The disputed issues have been submitted to arbitration. In the arbitration, Biogen Idec filed motions for a preliminary injunction and summary judgment seeking to stop us from proceeding with certain development activities, including planned clinical trials. On April 20, 2007, the arbitration panel denied Biogen Idec's motion for a preliminary injunction and Biogen Idec's motion for summary judgment. Resolution of the arbitration could require that both parties agree to certain development decisions before moving forward with humanized anti-CD20 antibody clinical trials (and possibly clinical trials of other collaboration products, including Rituxan), in which case we may have to alter or cancel planned clinical trials in order to obtain Biogen Idec's approval. The hearing of this matter is scheduled to begin in June 2008. We expect a final decision within six months of the hearing, unless the parties are able to resolve the matter earlier through settlement discussions or otherwise. The outcome of this matter cannot be determined at this time.

On June 28, 2003, Mr. Ubaldo Bao Martinez filed a lawsuit against Porriño Town Council and Genentech España S.L. in the Contentious Administrative Court Number One of Pontevedra, Spain. The lawsuit challenges the Town Council's decision to grant licenses to Genentech España S.L. for the construction and operation of a warehouse and biopharmaceutical manufacturing facility in Porriño, Spain. On January 16, 2008, the Administrative Court ruled in favor of Mr. Bao on one of the claims in the lawsuit and ordered the closing and demolition of the facility, subject to certain further legal proceedings. On February 12, 2008, we and the Town Council filed appeals of the Administrative Court decision at the High Court in Galicia, Spain. In addition, we are evaluating with legal counsel in Spain whether there may be other administrative remedies available to overcome the Administrative Court's ruling. We sold the assets of Genentech España S.L., including the Porriño facility, to Lonza Group Ltd. (Lonza) in December 2006, and Lonza has operated the facility since that time. Under the terms of that sale, we retained control of the defense of this lawsuit and agreed to indemnify Lonza against certain contractually defined liabilities up to a specified limit, which is currently estimated to be approximately \$100 million. The outcome of this matter, and our indemnification obligation to Lonza, if any, cannot be determined at this time.

#### **Note 6. Relationship with Roche Holdings, Inc. and Related Party Transactions**

##### ***Roche Holdings, Inc.'s Ability to Maintain Percentage Ownership Interest in Our Stock***

We issue 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 RHI provides, among other things, that with respect to any issuance of our Common Stock in the future, we will repurchase a sufficient number of shares so that immediately after such issuance, the percentage of our Common Stock owned by RHI will be no lower than 2% below the "Minimum Percentage" (subject to certain conditions). The Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by RHI since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech Common Stock by RHI as well as for stock splits or stock combinations) divided by 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech Common Stock outstanding at the time of the July 1999 offering, as adjusted

for stock splits. We have repurchased shares of our Common Stock since 2001. The affiliation agreement also provides that, upon RHI's request, we will repurchase shares of our Common Stock to increase RHI's ownership to the Minimum Percentage. In addition, RHI will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. Under the terms of the affiliation agreement, RHI's Minimum Percentage is 57.7%, and RHI's ownership percentage is to be no lower than 55.7%. As of March 31, 2008, RHI's ownership percentage was 55.8%.

### **Related Party Transactions**

We enter into transactions with our related parties, Roche Holding AG and affiliates (Roche) and Novartis AG and affiliates (Novartis). The accounting policies that 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.

In our royalty and supply arrangements with related parties, we are the principal, as defined under Emerging Issues Task Force (EITF) Issue No. 99-19, "*Reporting Revenue Gross as a Principal versus Net as an Agent*" (EITF 99-19), because we bear the manufacturing risk, general inventory risk, and the risk to defend our intellectual property. For circumstances in which we are the principal in the transaction, we record the transaction on a gross basis in accordance with EITF 99-19; otherwise, our transactions are recorded on a net basis.

### **Roche**

We signed two product supply agreements with Roche in July 2006, each of which was amended in November 2007. The Umbrella Manufacturing Supply Agreement (Umbrella Agreement) supersedes our previous product supply agreements with Roche. The Short-Term Supply Agreement (Short-Term Agreement) supplements the terms of the Umbrella Agreement. Under the Short-Term Agreement, Roche has agreed to purchase specified amounts of Herceptin, Avastin, and Rituxan through 2008. Under the Umbrella Agreement, Roche has agreed to purchase specified amounts of Herceptin and Avastin through 2012 and, on a perpetual basis, either party may order other collaboration products from the other party, including Herceptin and Avastin after 2012, pursuant to certain forecast terms. The Umbrella Agreement also provides that either party may terminate its obligation to purchase and/or supply Avastin and/or Herceptin with six years notice on or after December 31, 2007. To date, we have not received such notice of termination from Roche.

In December 2007, Roche opted-in to our trastuzumab drug conjugate products under terms similar to those of the existing anti-HER2 agreement. As part of the opt-in, Roche paid us \$113 million and will pay 50% of subsequent development costs related to the trastuzumab drug conjugate products. In March 2008, Roche opted-in to our Avastin glioblastoma multiforme indication under the terms of our July 1999 amended and restated licensing and marketing agreement with Roche. As part of the opt-in, Roche paid us \$19 million and will pay 75% of ongoing development costs related to the Avastin glioblastoma multiforme indication. We recognized the payments received from Roche as deferred revenue, which will be recognized over the expected development periods.

Late in the first quarter of 2008, Roche acquired Ventana Medical Systems, Inc. (Ventana), and as a result of the acquisition, Ventana is considered a related party. We have engaged in transactions with Ventana prior to and since the acquisition, but these transactions have not been material to our results of operations.

We currently have no active profit sharing arrangements with Roche.

Under our existing arrangements with Roche, including our licensing and marketing agreements, we recognized the following amounts (*in millions*):

	Three Months Ended March 31,	
	2008	2007
Product sales to Roche	\$ 136	\$ 264
Royalties earned from Roche	\$ 370	\$ 255
Contract revenue from Roche	\$ 20	\$ 30
Cost of sales on product sales to Roche	\$ 63	\$ 121
Research and development expenses incurred on joint development projects with Roche	\$ 70	\$ 58

Certain research and development (R&D) expenses are partially reimbursable to us by Roche. Amounts that Roche owes us, net of amounts reimbursable to Roche by us on these projects, are recorded as contract revenue. Conversely, R&D expenses may include the net settlement of amounts we owe Roche on R&D expenses that Roche incurred on joint development projects, less amounts reimbursable to us by Roche on these projects.

#### **Novartis**

Based on information available to us at the time of filing this Quarterly Report on Form 10-Q, we believe that the Novartis Group holds approximately 33.3% of the outstanding voting shares of Roche. As a result of this ownership, the Novartis Group is deemed to have an indirect beneficial ownership interest under FAS No. 57, “*Related Party Disclosures*” (FAS 57), of more than 10% of our voting stock.

We have an agreement with Novartis Pharma AG (a wholly owned subsidiary of Novartis AG; Novartis Pharma AG and affiliates are collectively referred to hereafter as Novartis) under which it has the exclusive right to develop and market Lucentis outside the U.S. for indications related to diseases or disorders of the eye. As part of this agreement, the parties will share the cost of certain of our ongoing development expenses for Lucentis.

We, along with Novartis, are co-developing and co-promoting Xolair in the U.S. We record all sales, COS, and marketing and sales expenses in the U.S.; Novartis markets the product in and records all sales, COS, and marketing and sales expenses in Europe. We and Novartis share the resulting U.S. and European operating profits according to prescribed profit sharing percentages. We record Novartis’s share of the U.S. operating profits as collaboration profit sharing expense. Our share of the European operating results was recorded as contract revenue in the first quarter of 2008 and collaboration profit sharing expense in the first quarter of 2007. Effective with our acquisition of Tanox, Inc. on August 2, 2007, Novartis also makes: (1) additional profit sharing payments to us on U.S. sales of Xolair, which reduces our profit sharing expense; (2) royalty payments to us on sales of Xolair worldwide, which we record as royalty revenue; and (3) manufacturing service payments related to Xolair, which we record as contract revenue.

Under our existing arrangements with Novartis, we recognized the following amounts (*in millions*):

	Three Months Ended March 31,	
	2008	2007
Product sales to Novartis	\$ 4	\$ 2
Royalties earned from Novartis	\$ 53	\$ 5
Contract revenue from Novartis	\$ 11	\$ 40
Cost of sales on product sales to Novartis	\$ 3	\$ 3
Research and development expenses incurred on joint development projects with Novartis	\$ 9	\$ 10
Collaboration profit sharing expense to Novartis	\$ 41	\$ 47

Contract revenue in the first quarter of 2007 included a \$30 million milestone payment from Novartis for European Union approval of Lucentis for the treatment of neovascular (wet) age-related macular degeneration (AMD).

Certain R&D expenses are partially reimbursable to us by Novartis. Amounts that Novartis owes us, net of amounts reimbursable to Novartis by us on these projects, are recorded as contract revenue. Conversely, R&D expenses may include the net settlement of amounts we owe Novartis on R&D expenses that Novartis incurred on joint development projects, less amounts reimbursable to us by Novartis on these projects.

**Note 7. Income Taxes**

Our effective income tax rate was 38% in the first quarter of 2008, an increase from 37% in the first quarter of 2007, mainly due to increased income before taxes as a result of the April 24, 2008 COH decision.

**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, 2008, and the related condensed consolidated statements of income and cash flows for the three-month periods ended March 31, 2008 and 2007. 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 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, 2007, 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 5, 2008, we expressed an unqualified opinion on those consolidated financial statements and included an explanatory paragraph relating to the change in method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-based Payment." In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2007, 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 28, 2008

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

### GENENTECH, INC. FINANCIAL REVIEW

#### Overview

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, 2007.

#### *The Company*

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes pharmaceutical products to treat patients with 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.

#### *Recent Major Developments*

We primarily earn revenue and income and generate cash from product sales and royalty revenue. In the first quarter of 2008, our total operating revenue was \$3,063 million, an increase of 8% from \$2,843 million in the first quarter of 2007. Our net income for the first quarter of 2008 was \$983 million, an increase of 39% from \$706 million in the first quarter of 2007.

On February 12, 2008, we announced that AVADO, Roche's study evaluating two doses of Avastin in first-line metastatic breast cancer (BC), met its primary endpoint of prolonging progression-free survival (PFS). Both doses of Avastin in combination with chemotherapy showed statistically significant improvement in the time patients lived without their disease advancing compared to chemotherapy and placebo.

On February 22, 2008, we received accelerated approval from the FDA to market Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not received prior chemotherapy for metastatic human epidermal growth factor receptor 2 (HER2)-negative BC. As a condition of the accelerated approval, we are required to make future submissions to the FDA, including the final study reports for two Phase III studies, AVADO and RIBBON-1, which are ongoing studies of Avastin in first-line metastatic HER2-negative BC. Based on the FDA's review of our future submissions, the FDA may decide to withdraw or modify the accelerated approval, request additional post-marketing studies, or grant full approval.

On February 25, 2008, the Patent Office issued a final Patent Office action rejecting all 36 claims of the Cabilly patent. We intend to file a response to the final Patent Office action and, if necessary, appeal the rejection. We requested and the Patent Office granted us an extension of time to June 6, 2008 for filing a response. The claims of the patent remain valid and enforceable throughout the reexamination and appeals processes.

On April 14, 2008, we and Biogen Idec Inc. announced that OLYMPUS, a Phase II/III study of Rituxan for primary-progressive multiple sclerosis (PPMS), did not meet its primary endpoint as measured by the time to confirmed disease progression during the 96-week treatment period. We will continue to analyze the study results with Biogen Idec and will submit the data for presentation at an upcoming medical meeting.

On April 20, 2008, we announced an update to the previously reported Roche-sponsored international Phase III clinical study of Avastin in combination with gemcitabine and cisplatin chemotherapy in patients with advanced, non-squamous, non-small cell lung cancer (NSCLC). The update confirmed the clinically and statistically significant improvement in the primary endpoint of PFS for the two different doses of Avastin studied in the trial (15 mg/kg/every-three-weeks and 7.5 mg/kg/every-three-weeks) compared to chemotherapy alone. The study did not demonstrate a statistically significant prolongation of overall survival, a secondary endpoint, for either dose in

combination with gemcitabine and cisplatin chemotherapy compared to chemotherapy alone. Median survival of patients in all arms of the study exceeded one year, longer than previously reported survival times in this indication.

On April 24, 2008, we announced that the California Supreme Court overturned the award of \$200 million in punitive damages to COH but upheld the award of \$300 million in compensatory damages resulting from a contract dispute brought by COH. The punitive damages were part of a 2004 decision of the California Court of Appeal, which upheld a 2002 Los Angeles County Superior Court jury verdict awarding these amounts. We expect to pay approximately \$477 million to COH in the second quarter of 2008, reflecting the amount of compensatory damages awarded, plus interest thereon from the date of the original decision in 2002. We recorded a favorable litigation settlement of \$315 million in the first quarter of 2008 as a result of the California Supreme Court decision.

On April 29, 2008, we announced that the Phase II/III study of Rituxan for systemic lupus erythematosus (SLE, commonly called lupus) did not meet its primary endpoint defined as the proportion of Rituxan treated patients who achieved a major clinical response (MCR) or partial clinical response (PCR) measured by British Isles Lupus Assessment Group (BILAG), a lupus activity response index, compared to placebo at 52 weeks. The study also did not meet any of the six secondary endpoints.

### ***Our Strategy and Goals***

As announced in 2006, our business objectives for the years 2006 through 2010 include bringing at least 20 new molecules into clinical development, bringing at least 15 major new products or indications onto the market, becoming the number one U.S. oncology company in sales, and achieving certain financial growth measures. These objectives are reflected in our revised Horizon 2010 strategy and goals summarized on our website at [www.gene.com/gene/about/corporate/growthstrategy](http://www.gene.com/gene/about/corporate/growthstrategy). In 2007, we announced an internal stretch goal to add a total of 30 molecules into development during the five-year period from the beginning of 2006 through the end of 2010.

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

Our strategy and goals are challenged by economic and industry-wide factors that affect our business. Key factors that affect our future growth are discussed below.

- We face significant competition in the diseases of interest to us from pharmaceutical companies and biotechnology companies. The introduction of new competitive products or follow-on biologics, new information about existing products, and pricing decisions by us or our competitors may result in lost market share for us, reduced utilization of our products, lower prices, and/or reduced product sales, even for products protected by patents.
- Our long-term business growth depends upon our ability to continue to successfully develop and commercialize important novel therapeutics to treat unmet medical needs, such as cancer. We recognize that the successful development of pharmaceutical products is highly difficult and uncertain, and that it will be challenging for us to continue to discover and develop innovative treatments. Our business requires significant investment in R&D over many years, often for products that fail during the R&D process. Once a product receives FDA approval, it remains subject to ongoing FDA regulation, including changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisement to physicians, and product recalls or withdrawals.
- Our business model requires appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. Some of the pricing and distribution of our products have received negative press coverage and public and governmental scrutiny. We will continue to meet with patient groups, payers, and other stakeholders in the healthcare system to understand their issues and concerns. The reimbursement environment for our products may change in the future and become more challenging.

- As the Medicare and Medicaid programs are the largest payers for our products, rules related to the programs' coverage and reimbursement continue to represent an important issue for our business. New regulations related to hospital and physician payment continue to be implemented annually. As a result of the Deficit Reduction Act of 2005, new regulations became effective in the fourth quarter of 2007 that will affect the discounted price for our products paid by Medicaid and government-affiliated customers.
- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection could result in lost sales to competing products and loss of royalty payments (for example, royalty income associated with the Cabilly patent) from licensees, and may negatively affect our sales, royalty revenue, 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 pharmaceutical products is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. Difficulties or delays in product manufacturing or in obtaining materials from our suppliers, or difficulties in accurately forecasting manufacturing capacity needs or complying with regulatory requirements, could negatively affect our business. Additionally, we may have an excess of available capacity, which could lead to idling of a portion of our manufacturing facilities during which time we would incur unabsorbed or idle plant charges, or other excess capacity charges, resulting in an increase in our COS.
- 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. 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 the pharmaceutical products listed below in the U.S.:

*Avastin* (bevacizumab) is an anti-VEGF (vascular endothelial growth factor) humanized antibody approved for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first- or second-line metastatic cancer of the colon or rectum. It is also approved for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. On February 22, 2008, we received accelerated approval from the FDA to market Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not received prior chemotherapy for metastatic HER2-negative BC.

*Rituxan* (rituximab) is an anti-CD20 antibody that we commercialize with Biogen Idec Inc. It is approved for first-line treatment of patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) in combination with cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy regimens or following CVP chemotherapy in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy. Rituxan is also approved for treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL, including retreatment and bulky diseases. Rituxan is indicated for first-line treatment of patients with diffuse large B-cell, CD20-positive, NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy. Rituxan is also indicated for use in combination with methotrexate to reduce signs and symptoms and slow the progression of structural damage in adult patients with moderate-to-severe rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

*Herceptin* (trastuzumab) is a humanized anti-HER2 antibody approved for treatment of patients with node-positive or node-negative BC as part of an adjuvant treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel (for patients who have tumors that overexpress the HER2 protein). It is also approved for use as a first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy for patients with

HER2-positive metastatic BC.

*Lucentis* (ranibizumab) is an anti-VEGF antibody fragment approved for the treatment of neovascular (wet) AMD.

*Xolair* (omalizumab) is a humanized anti-IgE (immunoglobulin E) antibody that we commercialize with Novartis Pharma AG. Xolair is approved for adults and adolescents (age 12 or older) with moderate-to-severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

*Tarceva* (erlotinib), which we commercialize with OSI Pharmaceuticals, Inc., is a small-molecule tyrosine kinase inhibitor of the HER1/epidermal growth factor receptor signaling pathway. Tarceva is approved for the treatment of patients with locally advanced or metastatic 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.

*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, for catheter clearance) is a tissue-plasminogen activator (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 I, approved for the treatment of cystic fibrosis.

*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.

### **Licensed Products**

We receive royalty revenue from various licensees, including significant royalty revenue from Roche on sales of:

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

See Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding certain patent-related legal proceedings.

## **Available Information**

The following information can be found on our website at [www.gene.com](http://www.gene.com), or can be obtained free of charge by contacting our Investor Relations Department at (650) 225-4150 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 is reasonably practicable after such material is electronically filed with the U.S. Securities and Exchange Commission;
- Our policies related to corporate governance, including our Principles of Corporate Governance, Good Operating Principles, and Code of Ethics, which apply to our Chief Executive Officer, Chief Financial Officer, and senior financial officials; and
- The charters of the Audit Committee and the Compensation 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 on our Condensed Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with U.S. 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 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 expectations for 2008, because these policies require management to make significant estimates, assumptions, and judgments about matters that are inherently uncertain.

### ***Loss Contingencies***

We are currently, and have been, involved in certain legal proceedings, including licensing and contract disputes, and other matters. See Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on these matters. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. We record an estimated loss as a charge to income if we determine that, based on information available at the time, the loss is probable and the amount of loss can be reasonably estimated. 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 that differs from our current estimates could have a material effect on our financial position or our results of operations in any one quarter. On April 24, 2008, we announced that the California Supreme Court overturned the award of \$200 million in punitive damages to COH but upheld the award of \$300 million in compensatory damages resulting from a contract dispute brought by COH. Included within current liabilities in "Accrued litigation" in the accompanying Condensed Consolidated Balance Sheet as of March 31, 2008 is \$473 million, which represents our estimate of the costs for the resolution of the COH matter.

### ***Revenue Recognition—Avastin U.S. Product Sales and Patient Assistance Program***

In February 2007, we launched the Avastin Patient Assistance Program, which is a voluntary program that enables eligible patients who have received 10,000 mg of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 mg during the remainder of the 12-month period. Based on the current wholesale acquisition cost, the 10,000 mg is valued at \$55,000 in gross revenue. Eligible patients include those who are being treated for an FDA-approved indication and who meet the financial eligibility requirements for this program. The program is available

for eligible patients who enroll, regardless of whether they are insured. We defer a portion of our gross Avastin product sales revenue to reflect our estimate of the commitment to supply free Avastin to patients who elect to enroll in the program.

In order to estimate the amount of free Avastin to be provided to patients under the Avastin Patient Assistance Program, we need to estimate several factors, most notably: the number of patients who are currently being treated for FDA-approved indications and the start date for their treatment regimen, the extent to which patients may elect to enroll in the program, the number of patients who will meet the financial eligibility requirements of the program, and the duration and extent of treatment for the FDA-approved indications, among other factors. We have based our enrollment assumptions on physician surveys and other information that we consider relevant. We will continue to update our estimates in each reporting period as new information becomes available. If the actual results underlying this deferred revenue accounting vary significantly from our estimates, we will need to adjust these estimates. Based on these estimates, we defer a portion of Avastin revenue on product vials sold through normal commercial channels. The deferred revenue will be recognized when free Avastin vials are delivered. In the first quarter of 2008, we deferred \$1 million of Avastin product sales, resulting in a total deferred revenue liability in connection with the Avastin Patient Assistance Program of \$3 million in our Condensed Consolidated Balance Sheet as of March 31, 2008. Usage of the Avastin Patient Assistance Program may increase with the approval of Avastin for the treatment of metastatic HER2-negative BC. As we continue to evaluate the amount of revenue to defer related to the Avastin Patient Assistance Program, we may recognize previously deferred revenue in Avastin U.S. product sales in future periods or increase the amount of revenue deferred.

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

Revenue from U.S. product sales is recorded net of allowances and accruals for rebates, healthcare provider contractual chargebacks, prompt-pay sales discounts, product returns, and wholesaler inventory management allowances, all of which are established at the time of sale. Sales allowances and accruals are based on estimates of the amounts earned or to be claimed on the related sales. The amounts reflected in our Condensed Consolidated Statements of Income as product sales allowances have been relatively consistent at approximately seven to eight percent of gross sales. 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.

Definitions for the product sales allowance types are as follows:

- Rebate allowances and accruals include both direct and indirect rebates. Direct rebates are contractual price adjustments payable to direct customers, mainly to wholesalers and specialty pharmacies that purchase products directly from us. Indirect rebates are contractual price adjustments payable to healthcare providers and organizations such as clinics, hospitals, pharmacies, Medicaid, and group purchasing organizations that do not purchase products directly from us.
- Product return allowances are established in accordance with our Product Returns Policy. Our returns policy allows product returns within the period beginning two months prior to and six months following product expiration.
- Prompt-pay sales discounts are credits granted to wholesalers for remitting payment on their purchases within established cash payment incentive periods.
- Wholesaler inventory management allowances are credits granted to wholesalers for compliance with various contractually defined inventory management programs. These programs were created to align purchases with underlying demand for our products and to maintain consistent inventory levels, typically at two to three weeks of sales depending on the product.
- Healthcare provider contractual chargebacks are the result of our contractual commitments to provide products to healthcare providers at specified prices or discounts.

We believe that our estimates related to wholesaler inventory management payments are not material amounts, based on the historical levels of credits and allowances as a percentage of product sales. We believe that our

estimates related to healthcare provider contractual chargebacks and prompt-pay sales discounts do not have a high degree of estimation complexity or uncertainty, as the related amounts are settled within a short period of time. We consider rebate allowances and accruals and product returns allowances to be the only estimations that involve material amounts and require a higher degree of subjectivity and judgment to account for the obligations. As a result of the uncertainties involved in estimating rebate allowances and accruals and product returns allowances, there is a possibility that materially different amounts could be reported under different conditions or using different assumptions.

Our rebates are based on definitive agreements or legal requirements (such as Medicaid). These rebates are primarily estimated using historical and other data, including patient usage, customer buying patterns, applicable contractual rebate rates, and contract performance by the benefit providers. Direct rebates are accrued at the time of sale and recorded as allowances against trade accounts receivable; indirect rebates (including Medicaid) are accrued at the time of sale and recorded as liabilities. Rebate estimates are evaluated quarterly and may require changes to better align our estimates with actual results. As part of this evaluation, we review changes to Medicaid legislation and state rebate contracts, changes in the level of discounts, and significant changes in product sales trends. Although rebates are accrued at the time of sale, rebates are typically paid out, on average, up to six months after the sale. We believe that our rebate allowances and accruals estimation process provides a high degree of confidence in the annual allowance amounts established. Based on our estimation, the changes in rebate allowances and accruals estimates related to prior years have not exceeded 3%. To further illustrate our sensitivity to changes in the rebate allowances and accruals process, a 10% change in our annualized rebate allowances and accruals provision experienced to date in 2008 (which is in excess of three times the level of variability that we reasonably expect to observe for rebates) would have an approximate \$21 million unfavorable effect on our results (or approximately \$0.01 per share). The total rebate allowances and accruals recorded in our Condensed Consolidated Balance Sheet were \$76 million as of March 31, 2008.

At the time of sale, we record product returns allowances based on our best estimate of the portion of sales that will be returned by our customers in the future. Product returns allowances are established in accordance with our returns policy, which allows buyers to return our products with two months or less remaining prior to product expiration and up to six months following product expiration. As part of the estimating process, we compare historical return data to the related sales on a production lot basis. Historical rates of return are then determined by product and may be adjusted for known or expected changes in the marketplace. Actual annual product returns processed were less than 0.5% of gross product sales in all periods from 2005 and 2007, while annual provisions for expected future product returns were less than 1% of gross product sales in all such periods. Although product returns allowances are recorded at the time of sale, the majority of the returns are expected to occur within two years of sale. Therefore, our provisions for product returns allowances may include changes in estimate for a prior period due to the lag time. However, to date, such changes have not been material. For example, in 2007, changes in estimates related to prior years were approximately 0.3% of 2007 gross product sales. To illustrate our sensitivity to changes in the product returns allowances, if we were to experience an adjustment rate of 0.5% of 2007 gross product sales, which is nearly twice the level of annual variability that we have historically observed for product returns, that change in estimate would likely have an unfavorable effect of approximately \$50 million (or approximately \$0.03 per share) on our results of operations. Product returns allowances recorded in our Condensed Consolidated Balance Sheet were \$75 million as of March 31, 2008.

All of the aforementioned categories of allowances and accruals are evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could materially affect our results of operations or financial position; however, to date they have not been material. It is possible that we may need to adjust our estimates in future periods. Our Condensed Consolidated Balance Sheet reflected estimated product sales allowance reserves and accruals totaling approximately \$202 million as of March 31, 2008.

### ***Royalties***

For substantially all of our agreements with licensees, we estimate royalty revenue and royalty receivables in the period the royalties are earned, which is in advance of collection. Royalties from Roche, which are approximately 60% of our total royalty revenue, are reported based on actual sales reports from Roche. Our estimates of royalty revenue and receivables from non-Roche licensees are primarily based on communication with some licensees, historical information, forecasted sales trends, and our assessment of collectibility. Differences between actual

royalty revenue and estimated royalty revenue are adjusted for in the period in which they become known, typically the following quarter. Since 2005, the adjustment to our royalty revenue related to prior periods has not exceeded 1% of total annual royalty revenue. To further illustrate our sensitivity to the royalty estimation process, a 1% adjustment to total annual royalty revenue, which is at the upper end of the range of our historic experience, would result in an adjustment to total 2007 annual royalty revenue of approximately \$25 million (or approximately \$0.01 to \$0.02 per share, net of any related royalty expenses).

In cases where the collectibility of a royalty amount is doubtful, royalty revenue is not recorded in advance of payment but is recognized as cash is received. In the case of a receivable related to previously recognized royalty revenue that is subsequently determined to be uncollectible, the receivable is reserved for by reversing the previously recorded royalty revenue in the period in which the circumstances that make collectibility doubtful are determined, and future royalties from the licensee are recognized on a cash basis until it is determined that collectibility is reasonably assured.

We have confidential licensing agreements with a number of companies under which we receive royalty revenue on sales of products that are covered by the Cabilly patent. The Cabilly patent, which expires in 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in those methods. The Patent Office is performing a reexamination of the patent, and on February 25, 2008, issued a final Patent Office action rejecting all the claims of the Cabilly patent. We intend to file a response to the final Patent Office action and, if necessary, appeal the rejection. We requested and the Patent Office granted us an extension of time to June 6, 2008 for filing a response. The claims of the patent remain valid and enforceable throughout the reexamination and appeals processes. In addition, in April 2003, MedImmune filed a lawsuit against us challenging the Cabilly patent. See also Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on our Cabilly patent reexamination and the MedImmune lawsuit.

Cabilly patent royalties are generally due 60 days after the end of the quarter in which they are earned and recorded by us as royalty revenue. Additionally, we pay COH a percentage of our Cabilly patent royalty revenue 60 days after the quarter in which we receive payments from our licensees. As of March 31, 2008, our Condensed Consolidated Balance Sheet included Cabilly patent receivables totaling approximately \$73 million and related COH payables totaling approximately \$31 million.

### ***Income Taxes***

Our income tax provision is based on income before taxes and is computed using the liability method in accordance with FAS No. 109, "Accounting for Income Taxes." Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be 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, or the findings or expected results from any tax examinations. 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, the results of any tax examinations, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past and future levels of R&D spending, acquisitions, changes in our corporate structure, and changes in overall levels of income before taxes all of which may result in periodic revisions to our effective income tax rate. Uncertain tax positions are accounted for in accordance with FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes." We accrue tax related interest and penalties related to uncertain tax positions and include these with income tax expense in the Condensed Consolidated Statements of Income.

### ***Inventories***

Inventories may include currently marketed products manufactured under a new process or at facilities awaiting regulatory licensure. These inventories are capitalized based on our judgment of probable near-term regulatory licensure. Excess or idle capacity costs, based on estimated plant capabilities, are expensed in the period in which they are incurred. The valuation of inventory requires us to estimate the value of inventory that may expire prior to use or that may fail to be released for commercial sale. The determination of obsolete inventory requires us to

estimate the future demands for our products, and in the case of pre-approval inventories, to estimate the regulatory approval date for the product or for the licensure of either the manufacturing facility or the new manufacturing process. We may be required to expense previously capitalized inventory costs upon a change in our estimate, due to, among other potential factors, the denial or delay of approval of a product or the licensure of either a manufacturing facility or a new manufacturing process by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable.

### ***Valuation of Acquired Intangible Assets***

We have acquired intangible assets in connection with our acquisition of Tanox, Inc. These intangible assets consist of developed product technology and core technologies associated with intellectual property and rights thereon, primarily related to the Xolair molecule, and assets related to the fair value write-up of Tanox's royalty contracts, as well as goodwill. When significant identifiable intangible assets are acquired, we determine the fair value of these assets as of the acquisition date, using valuation techniques such as discounted cash flow models. These models require the use of significant estimates and assumptions including, but not limited to, determining the timing and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed products and in-process projects, and developing appropriate discount rates and probability rates by project.

We believe that the fair value assigned to the intangible assets acquired is based on reasonable estimates and assumptions, given the available facts and circumstances as of the acquisition date. However, we may record adjustments to goodwill resulting from our acquisition of Tanox, Inc. for the resolution of pre-acquisition contingencies, our restructuring activities, tax matters, and other estimates related to the acquisition for a period of up to one year after the acquisition date. Further, we will have to continually evaluate whether the fair value of any or all intangible assets has been impaired.

### ***Employee Stock-Based Compensation***

Under the provisions of FAS 123R, employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model 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 (Redemption) by RHI, 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 recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under GAAP, we review our valuation assumptions at each grant date, and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. See Note 2, "Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

## Results of Operations

(In millions, except per share amounts)

	Three Months Ended March 31,		% Change
	2008	2007	
Product sales	\$ 2,379	\$ 2,329	2%
Royalties	616	419	47
Contract revenue	68	95	(28)
Total operating revenue	<u>3,063</u>	<u>2,843</u>	8
Cost of sales	389	392	(1)
Research and development	617	610	1
Marketing, general and administrative	517	491	5
Collaboration profit sharing	279	252	11
Recurring amortization charges related to redemption and acquisition	43	26	65
Special items: litigation-related	(301)	13	*
Total costs and expenses	<u>1,544</u>	<u>1,784</u>	(13)
Operating income	1,519	1,059	43
Other income (expense):			
Interest and other income, net	74	74	0
Interest expense	(18)	(18)	0
Total other income, net	<u>56</u>	<u>56</u>	0
Income before taxes	1,575	1,115	41
Income tax provision	592	409	45
Net income	<u>\$ 983</u>	<u>\$ 706</u>	39
Earnings per share:			
Basic	<u>\$ 0.93</u>	<u>\$ 0.67</u>	39
Diluted	<u>\$ 0.92</u>	<u>\$ 0.66</u>	39
Cost of sales as a % of product sales	16%	17%	
Research and development as a % of operating revenue	20	21	
Marketing, general and administrative as a % of operating revenue	17	17	
Pretax operating margin	50%	37%	
Effective income tax rate	38%	37%	

\* Calculation not meaningful.

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

### Total Operating Revenue

Total operating revenue increased 8% from the comparable period in 2007. This increase was primarily due to higher product sales and royalty revenue, and is discussed below.

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

	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2008</b>	<b>2007</b>	
Net U.S. product sales			
Avastin	\$ 600	\$ 533	13%
Rituxan	605	535	13
Herceptin	339	311	9
Lucentis	198	211	(6)
Xolair	117	111	5
Tarceva	111	102	9
Nutropin products	84	91	(8)
Thrombolytics	67	68	(1)
Pulmozyme	57	52	10
Raptiva	26	24	8
Total U.S. product sales <sup>(1)</sup>	2,205	2,037	8
Net product sales to collaborators	174	292	(40)
Total product sales	\$ 2,379	\$ 2,329	2

(1) The totals may not appear to equal the sum of the individual entries due to rounding.

Total product sales increased 2% in the first quarter of 2008 from the comparable period in 2007. Total U.S. product sales increased 8% from the comparable period in 2007. The increases in U.S. sales were due to higher sales across most products, in particular higher sales of our oncology products. Increased U.S. sales volume accounted for 69%, or \$116 million, of the increase in U.S. net product sales in the first quarter of 2008. Changes in net U.S. sales prices across the majority of products in the portfolio accounted for most of the remainder of the increases in U.S. net product sales in the first quarter of 2008.

Our references below to market adoption and penetration, as well as patient share, are derived from our analyses of market tracking studies and surveys that we undertake with physicians. We consider these tracking studies and surveys indicative of trends and information with respect to our end users' buying patterns. We use statistical analyses and management judgment to interpret the data that we obtain, and as such, the adoption, penetration, and patient share data presented herein represent estimates. Limitations in sample size and the timeliness in receiving and analyzing this data result in inherent margins of error; thus, where presented, we have rounded our percentage estimates to the nearest 5%.

**Avastin**

Net U.S. sales of Avastin increased 13% to \$600 million in the first quarter of 2008 from the comparable period in 2007. Net U.S. sales in the first quarter of 2008 excluded net revenue of \$1 million that was deferred in connection with our Avastin Patient Assistance Program. The increase in sales in the first quarter of 2008 was primarily a result of increased use of Avastin in first-line metastatic NSCLC and first-line metastatic BC, which received accelerated approval from the FDA in the first quarter of 2008.

Among first-line metastatic NSCLC patients, we estimate that Avastin penetration in the first quarter of 2008 was approximately 35%, which was in line with penetration in the fourth quarter of 2007 and an increase from the first quarter of 2007. Among the approximately 50%-60% of patients in first-line metastatic lung cancer who are eligible for Avastin therapy, we estimate that penetration was approximately 60%. With respect to dose, the percentage of lung cancer patients receiving the high dose of Avastin, defined as at least 5mg/kg/weekly-equivalent, was approximately 70% in the first quarter of 2008, a slight increase from the fourth quarter of 2007. The recommended dose of Avastin in lung cancer is 15mg/kg, administered intravenously every three weeks. However, we expect dose in metastatic NSCLC to continue to be a source of uncertainty for Avastin. The Roche-sponsored BO17704 study, which was presented at the American Society of Clinical Oncology (ASCO) in June 2007, evaluated a

15mg/kg/every-three-weeks dose of Avastin (the dose approved in the U.S. for use in combination with carboplatin and paclitaxel) and a 7.5mg/kg/every-three-weeks dose of Avastin (a dose not approved for use in the U.S.) in combination with gemcitabine and cisplatin chemotherapy compared to chemotherapy alone in patients with previously untreated, advanced NSCLC. Both doses met the primary endpoint of prolonging PFS compared to chemotherapy alone. Although the study was not designed to compare the Avastin doses, a similar treatment effect in PFS was observed between the two arms. On April 20, 2008, we announced that the study did not demonstrate a statistically significant prolongation of overall survival, a secondary endpoint, for either dose in combination with gemcitabine and cisplatin chemotherapy compared to chemotherapy alone. Median survival of patients in all arms of the study exceeded one year, longer than previously reported survival times in this indication. Based on these results, additional physicians may adopt Avastin at the lower dose of 7.5mg/kg/every-three-weeks or choose not to prescribe Avastin.

On February 12, 2008, we announced that AVADO, Roche's study evaluating two doses of Avastin in first-line metastatic BC, met its primary endpoint of prolonging PFS. Both doses of Avastin in combination with chemotherapy showed statistically significant improvement in the time patients lived without their disease advancing compared to chemotherapy and placebo, although the study was not designed to compare the Avastin doses. On February 22, 2008, the FDA notified us that Avastin received accelerated approval for use in combination with paclitaxel chemotherapy, for patients who have not received prior chemotherapy for metastatic HER2-negative BC. Based on our first quarter 2008 market research, which was conducted prior to these two announcements, Avastin adoption in first-line HER2-negative metastatic BC patients in the first quarter of 2008 was in-line with the fourth quarter of 2007. We anticipate increased use of Avastin in BC as a result of the FDA accelerated approval. With respect to dose, the percentage of BC patients receiving the high dose of Avastin, defined as 5mg/kg/weekly-equivalent, was approximately 75% in the first quarter of 2008. This is down slightly from approximately 80% in the fourth quarter of 2007. The recommended dose of Avastin in BC is 10 mg/kg, administered intravenously every two weeks. Data from the AVADO study is expected to be presented at ASCO during the second quarter of 2008 and will provide additional information regarding Avastin dosage in BC.

In first-line metastatic colorectal cancer (CRC), penetration in the first quarter of 2008 was approximately 70%, which was consistent with penetration in the first and fourth quarters of 2007. In second-line CRC, we estimate that Avastin penetration was approximately 40% in the first quarter of 2008, an increase from that seen in the first quarter of 2007.

#### *Rituxan*

Net U.S. sales of Rituxan increased 13% to \$605 million in the first quarter of 2008 from the comparable period in 2007. Sales growth resulted from increased sales volume and price increases in 2007.

In the oncology setting, the increases came from Rituxan's use following chemotherapy in indolent NHL, including areas of unapproved use, and chronic lymphocytic leukemia (CLL), an unapproved use. We estimate that Rituxan's overall adoption rate in the combined NHL and CLL markets increased to approximately 85% in the first quarter of 2008 from approximately 80% in the first quarter of 2007.

In the RA setting, the primary drivers of growth were an increased percentage of prescribers, to approximately 85% of targeted rheumatologists, and an increased share of patients who have failed anti-TNF therapies. It remains difficult to precisely determine the sales split between Rituxan use in oncology and immunology settings since many treatment centers treat both types of patients.

On January 25, 2008, the FDA approved our supplemental biologic license application (BLA) to expand the label for Rituxan to include slowing the progression of structural damage in adult patients with moderate-to-severe RA who have failed anti-TNF therapies.

In January 2008, we announced that the Rituxan Phase III SUNRISE trial met its primary endpoint. This study was a controlled retreatment study for patients with RA who have had an inadequate response to previous treatment with one or more TNF antagonist therapies. A preliminary review of the safety data revealed no new safety signals.

On January 24, 2008 we announced that the SERENE Phase III clinical study of Rituxan in patients who have not been previously treated with a biotherapeutic met its primary endpoint of a significantly greater proportion of Rituxan-treated patients achieving an American College of Rheumatology (ACR) 20 response at week 24, compared to placebo. In this study, patients who received a single treatment course of two infusions of either 500 mg or 1,000 mg of Rituxan in combination with a stable dose of methotrexate displayed a statistically significant improvement in ACR20 scores compared to patients who received placebo in combination with methotrexate. Although the study was not designed to compare the Rituxan doses, treatment efficacy appears to be similar between both Rituxan doses.

On April 14, 2008, we and Biogen Idec announced that OLYMPUS, a Phase II/III study of Rituxan for PPMS, did not meet its primary endpoint as measured by the time to confirmed disease progression during the 96-week treatment period. We will continue to analyze the study results with Biogen Idec and will submit the data for presentation at an upcoming medical meeting. We observed biologic activity and will continue to analyze the study results.

On April 29, 2008, we announced that the Phase II/III study of Rituxan for systemic lupus erythematosus (SLE, commonly called lupus) did not meet its primary endpoint defined as the proportion of Rituxan treated patients who achieved a MCR or PCR measured by BILAG, a lupus activity response index, compared to placebo at 52 weeks. The study also did not meet any of the six secondary endpoints. Although we do not promote off-label, our market research indicates that lupus constitutes significantly less than five percent of U.S. sales of Rituxan.

### *Herceptin*

Net U.S. sales of Herceptin increased 9% to \$339 million in the first quarter of 2008 from the comparable period in 2007. The sales growth was due to price increases in 2007 and increased use of Herceptin in the treatment of early-stage HER2-positive BC. We estimate Herceptin's penetration in the adjuvant setting in the first quarter of 2008 was approximately 85%, an increase from the first quarter of 2007, but in-line with the fourth quarter of 2007. In first-line HER2-positive metastatic BC patients, Herceptin's penetration was approximately 70% for the first quarter of 2008, which was consistent with the first and fourth quarters of 2007.

On January 18, 2008, the FDA expanded the Herceptin label, based on the HERA study, for the treatment of patients with early-stage HER2-positive BC to include treatment for patients with node-negative BC. Herceptin also may now be administered for one year in an every-three-week dosing schedule, instead of weekly.

### *Lucentis*

Net U.S. sales of Lucentis decreased 6% to \$198 million in the first quarter of 2008 from the comparable period in 2007. We believe that the percentage of newly diagnosed patients who were treated with Lucentis during the first quarter of 2008 was approximately 40% compared to approximately 50% during the fourth quarter of 2007 and 55% during the first quarter of 2007. We believe that the main factors affecting the decline in new patient share were the continued unapproved use of Avastin and reimbursement concerns from retinal specialists. Lucentis received a permanent J-code classification from the Centers for Medicare and Medicaid Services in January 2008, which we believe will help address some of the reimbursement concerns.

The unapproved use of Avastin and reimbursement concerns have created a difficult environment for the promotion of Lucentis. Our continuing efforts will be focused on achieving new patient share growth, however, this will be challenging based on current market conditions.

### *Xolair*

Net U.S. sales of Xolair increased 5% to \$117 million in the first quarter of 2008 from the comparable period in 2007.

On April 10, 2008, we and Novartis announced that a Phase III study evaluating Xolair in patients 6 to 11 years of age with moderate-to-severe, persistent, inadequately controlled allergic asthma met its primary endpoint,

demonstrating a statistically significant reduction in exacerbations in Xolair-treated patients compared with placebo treated patients, with no new safety signals reported. We will work with Novartis to evaluate the complete study results, including feedback from the FDA, to determine the next steps.

#### *Tarceva*

Net U.S. sales of Tarceva increased 9% to \$111 million in the first quarter of 2008 from the comparable period in 2007, primarily due to price increases in 2007 and 2008. We estimate that Tarceva's penetration in second-line NSCLC was approximately 35%, an increase from the first quarter of 2007, but in-line with the fourth quarter of 2007. In the first-line pancreatic cancer setting, we estimate that Tarceva's penetration was approximately 45% in the first quarter of 2008, an increase from the first quarter of 2007, but stable compared to the fourth quarter of 2007.

#### *Nutropin Products*

Combined net U.S. sales of our Nutropin products decreased 8% to \$84 million in the first quarter of 2008 from the comparable period in 2007. Nutropin sales have decreased due to increased rebates in the managed care contracting environment and fewer patients being treated. The decrease in sales volume was partially offset by price increases in 2007 and 2008.

#### *Thrombolytics*

Combined net U.S. sales of our three thrombolytics products—Activase, Cathflo Activase, and TNKase—decreased 1% to \$67 million in the first quarter of 2008 from the comparable period in 2007. Sales were favorably affected by increases in sales volume compared to the first quarter of 2007 and price increases in 2007 and 2008. However, these increases were offset by increased product return reserve requirements.

#### *Pulmozyme*

Net U.S. sales of Pulmozyme increased 10% to \$57 million in the first quarter of 2008 from the comparable period in 2007.

#### *Raptiva*

Net U.S. sales of Raptiva increased 8% to \$26 million in the first quarter of 2008 from the comparable period in 2007.

#### *Sales to Collaborators*

Product sales to collaborators, which were for non-U.S. markets, decreased 40% to \$174 million in the first quarter of 2008 from the comparable period in 2007. The decrease was primarily due to the timing of Avastin and Herceptin sales to Roche. For 2008, we forecast sales to collaborators to increase by approximately 10% to 15% over 2007 with the usual quarter-to-quarter fluctuations due to the timing of the production and order plan.

Herceptin sales to Roche since the third quarter of 2006 reflect more favorable pricing terms that were part of the supply agreement with Roche signed at that time. These pricing terms will continue through the end of 2008.

#### *Royalties*

Royalty revenue increased 47% to \$616 million in the first quarter of 2008 from \$419 million in the comparable period in 2007. The majority of the increase was due to higher sales by Roche of our Avastin, Herceptin, and Rituxan products, and higher sales by Novartis of our Lucentis product. In addition, approximately \$50 million of the increase was due to net foreign exchange-related benefits from the weaker U.S. dollar during the first quarter of 2008 compared to the first quarter of 2007. The first quarter 2008 results also included approximately \$20 million of net adjustments increasing royalty revenue due to changes in estimates for amounts reported in prior periods, as compared to immaterial amounts of such net adjustments recorded in the first quarter of 2007. Of the overall

royalties received, royalties from Roche represented approximately 60% in the first quarter of 2008 compared to approximately 61% in the first quarter of 2007. Royalties from other licensees included royalty revenue on our patent licenses, including our Cabilly patent, as discussed below.

Cash flows from royalty income include revenue denominated in foreign currencies. We currently enter into foreign currency option contracts (options) and forwards to hedge a portion of these foreign currency cash flows. These existing options and forwards are due to expire in 2008 and 2009, and we expect to continue to enter into similar contracts in accordance with our hedging policy.

We have confidential licensing agreements with a number of companies under which we receive royalty revenue on sales of products covered by the Cabilly patent. The Cabilly patent expires in December 2018, but is the subject of an ongoing reexamination and likely appeals process, and the MedImmune litigation. The net pretax contributions related to the Cabilly patent were as follows (*in millions, except per share amounts*):

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Royalty revenue	\$ 84	\$ 62
Gross expenses <sup>(1)</sup>	\$ 36	\$ 30
Net of tax effect of Cabilly patent on diluted EPS	\$ 0.03	\$ 0.02

(1) Gross expenses include COH's share of royalty revenue and royalty COS on our U.S. product sales

See also Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on our Cabilly patent reexamination and the MedImmune lawsuit related to the Cabilly patent.

Royalties are difficult to forecast because of the number of products involved, availability of licensee sales data, potential licensing and intellectual property disputes, and the volatility of foreign currency exchange rates. For 2008, we forecast royalty revenue to grow approximately 15% to 25% relative to 2007, but a number of factors could affect these results. Most notably, a continued weakness in the U.S. dollar could positively affect royalty revenue. However, royalty revenue growth could be negatively affected by a number of factors, including the strengthening of the U.S. dollar, lower than expected sales of licensees' products, the termination of licenses, changes to the terms of contracts under which licenses have been granted, or the failure of licensees to meet their contractual payment obligations for any reason, including an adverse decision or ruling in the Cabilly patent reexamination, the MedImmune lawsuit, or appeals of these matters.

### **Contract Revenue**

Contract revenue decreased 28% to \$68 million in the first quarter of 2008 from the comparable period in 2007. The decrease was mainly due to the receipt of a milestone payment from Novartis Pharma AG in the first quarter of 2007 related to European Union approval of Lucentis. Contract revenue in the first quarter of 2008 included manufacturing service payments related to Xolair, which Novartis pays us as a result of our acquisition of Tanox, Inc., and our share of European profits related to Xolair. See "Related Party Transactions" below for more information on contract revenue from Roche and Novartis.

For 2008, we forecast contract revenue to grow by approximately 5% relative to 2007. However, contract revenue varies each quarter and is dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones, opt-in payments received, new contract arrangements, and foreign exchange rates.

### **Cost of Sales**

Cost of sales as a percentage of product sales was 16% in the first quarter of 2008 compared to 17% in the first quarter of 2007. COS as a percentage of product sales during the first quarter of 2008 was favorably affected by a

decreased volume of lower-margin sales to collaborators, partially offset by a charge resulting from a voluntary severance program announced in February 2008 that provided certain manufacturing employees the opportunity to voluntarily resign from the company in exchange for a severance package. Enrollment in the program closed in March 2008. We recorded compensation charges in COS associated with this program of \$18 million in the first quarter of 2008, and we expect to record charges totaling approximately \$10 million in the second and third quarters of 2008 related to this program.

### **Research and Development**

Research and development expenses increased slightly to \$617 million in the first quarter of 2008 from the comparable period in 2007. The higher levels of expenses in the first quarter of 2008 reflected increased development activity mainly as a result of collaboration arrangements entered into in 2007, increased spending on clinical trials, clinical manufacturing expenses, and higher research expenses. The increases in R&D expenses were offset by a reduction of in-licensing expenses of approximately \$110 million in the first quarter of 2008 compared to the first quarter of 2007, due to significant new collaborations entered into during the first quarter of 2007. R&D as a percentage of operating revenue was 20% in the first quarter of 2008 compared to 21% in the first quarter of 2007.

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

Marketing, general and administrative (MG&A) expenses increased 5% to \$517 million in the first quarter of 2008 from the comparable period in 2007. This increase was primarily due to an increase in royalty expense, primarily to Biogen Idec, resulting from higher Roche sales of Rituxan. MG&A as a percentage of operating revenue was 17% in the first quarters of 2008 and 2007.

### **Collaboration Profit Sharing**

Collaboration profit sharing expenses increased 11% to \$279 million in the first quarter of 2008 from the comparable period in 2007, primarily due to higher sales of Rituxan and Tarceva.

The following table summarizes the amounts resulting from the respective profit sharing collaborations for the periods presented (*in millions*):

	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2008</b>	<b>2007</b>	
U.S. Rituxan profit sharing expense	\$ 190	\$ 166	14%
U.S. Tarceva profit sharing expense	48	39	23
Total Xolair profit sharing expense	41	47	(13)
Total collaboration profit sharing expenses	<u>\$ 279</u>	<u>\$ 252</u>	11

Currently, our most significant collaboration profit sharing agreement is with Biogen Idec, with which we co-promote Rituxan in the U.S. Under the collaboration agreement, Biogen Idec granted us a worldwide license to develop, commercialize, and market Rituxan for multiple indications. In exchange for these worldwide rights, Biogen Idec has co-promotion rights in the U.S. and a contractual arrangement under which we share a portion of the pretax U.S. co-promotion profits of Rituxan and pay royalty expense based on sales of Rituxan outside the U.S. In June 2003, we amended and restated the collaboration agreement with Biogen Idec to include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to Rituxan, for a broad range of indications.

Under the amended and restated collaboration agreement, our share of the current pretax U.S. co-promotion profit sharing formula is approximately 60% of operating profits, and Biogen Idec's share is approximately 40%. For each calendar year or portion thereof following the approval date of the first new anti-CD20 product, after a period of transition, our share of the pretax U.S. co-promotion profits will change to approximately 70% of operating profits, and Biogen Idec's share will be approximately 30%.

Collaboration profit sharing expense, exclusive of R&D expenses, related to Biogen Idec for the periods ended March 31, 2008 and 2007 consisted of the following (*in millions*):

	Three Months Ended March 31,		% Change
	2008	2007	
Product sales, net	\$ 605	\$ 535	13%
Combined commercial and expenses	144	130	11
Combined co-promotion profits	<u>\$ 461</u>	<u>\$ 405</u>	14
Amount due to Biogen Idec for its share of co-promotion profits–included in collaboration profit sharing expense	\$ 190	\$ 166	14

In addition to Biogen Idec’s share of the combined co-promotion profits for Rituxan, collaboration profit sharing expense includes the quarterly settlement of Biogen Idec’s portion of the combined commercial costs. Since we and Biogen Idec each individually incur commercial costs related to Rituxan and the spending mix between the parties can vary, collaboration profit sharing expense as a percentage of sales can also vary accordingly.

Total revenue and expenses related to our collaboration with Biogen Idec included the following (*in millions*):

	Three Months Ended March 31,		% Change
	2008	2007	
Contract revenue from Biogen Idec (R&D reimbursement)	\$ 33	\$ 21	57%
Co-promotion profit sharing expense	\$ 190	\$ 166	14%
Royalty expense on sales of Rituxan outside the U.S. and other patent costs–included in MG&A expenses	\$ 68	\$ 56	21%

#### ***Recurring Amortization Charges Related to Redemption and Acquisition***

On June 30, 1999, RHI exercised its option to cause us to redeem all of our Special Common Stock held by stockholders other than RHI. The Redemption was reflected as the purchase of a business, which under GAAP required push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value.

On August 2, 2007, we acquired Tanox, Inc. In connection with the acquisition, we recorded approximately \$814 million of intangible assets, representing developed product technology and core technology, which are being amortized over 12 years.

We recorded recurring charges related to the amortization of intangibles associated with the Redemption and push-down accounting and our acquisition of Tanox, Inc. These charges were \$43 million in the first quarter of 2008 and \$26 million in the first quarter of 2007.

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

The California Supreme Court heard our appeal on the COH matter on February 5, 2008, and on April 24, 2008 overturned the award of \$200 million in punitive damages to COH but upheld the award of \$300 million in compensatory damages. As a result of the California Supreme Court decision, we recorded a net favorable litigation settlement of \$301 million in the first quarter of 2008, which included \$9 million of accrued interest and bond costs primarily related to the compensatory damages. In the first quarter of 2007, we recorded accrued interest and bond costs on both the compensatory and punitive damages totaling \$13 million. Because the California Supreme Court decision occurred after we furnished our financial results for the quarter ended March 31, 2008 on Form 8-K, the net \$301 million favorable litigation-related amount presented in our Condensed Consolidated Statement of Income for the three months ended March 31, 2008 is updated from the amount previously furnished

with the Form 8-K dated April 10, 2008. See Note 5, “Contingencies,” in the Notes to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information regarding the COH litigation.

### **Operating Income**

Operating income was \$1,519 million in the first quarter of 2008, a 43% increase from the first quarter of 2007. Our operating income as a percentage of operating revenue (pretax operating margin) was 50% in the first quarter of 2008 and 37% in the first quarter of 2007.

### **Other Income (Expense)**

The components of “Other income (expense)” were as follows (*in millions*):

	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2008</b>	<b>2007</b>	
Gains on sales of biotechnology equity securities, net	\$ 1	\$ 8	(88) %
Write-downs of biotechnology debt and equity securities	–	(3)	(100)
Interest income <sup>(1)</sup>	69	69	0
Interest expense	(18)	(18)	0
Other miscellaneous income	4	–	–
Total other income, net	<u>\$ 56</u>	<u>\$ 56</u>	0

(1) Interest income includes interest and dividend income, bond-related amortization, realized gains and losses on available-for-sale securities and trading securities, and changes in unrealized gains and losses on trading securities.

Other income, net for the first quarter of 2008 remained flat compared to the first quarter of 2007, as increased interest income in the first quarter of 2008 due to higher cash balances was offset by decreases in interest rates and losses on the sales of certain securities.

In 2008, we forecast “Other income, net” to decrease by more than 20% relative to 2007.

### **Income Tax Provision**

Our effective income tax rate was 38% in the first quarter of 2008, an increase from 37% from the first quarter of 2007, mainly due to increased income before taxes as a result of the April 24, 2008 COH decision.

### **Financial Assets and Liabilities**

On January 1, 2008, we adopted FAS 157, which established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. FAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, FAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be used for financial reporting purposes. The fair value of our financial instruments reflects the amounts that would be received in connection with the sale of an asset or paid in connection with the transfer a liability in an orderly transaction between market participants at the measurement date (exit price). FAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

Level 1—quoted prices in active markets for identical assets and liabilities.

Level 2—observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3—unobservable inputs.

The adoption of FAS 157 did not have an effect on our financial condition or results of operations but FAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable

(Level 3) inputs. The substantial majority of our financial instruments are valued using quoted prices in active markets or based on other observable inputs. Our Level 1 assets include cash, money market instruments, U.S. Treasury securities, marketable equity securities and equity forwards. Level 2 assets include other government and agency securities, commercial paper, corporate bonds, asset-backed securities, municipal bonds, preferred securities and other derivatives. As of March 31, 2008, we held \$163 million of investments, which were measured using unobservable (Level 3) inputs representing approximately 2% of our total fair value investments portfolio. The assets include \$161 million of student loan auction-rate securities and \$2 million of structured investment vehicle securities, for which fair value was determined based on broker-provided valuations, which approximate fair value. In February 2008, the auction-rate securities market experienced a number of failed auctions for student loan-backed securities, such as those held by us, which severely limited the liquidity for these securities. Due to market liquidity constraints related to the failed auctions, we classified the auction-rate securities as non-current assets consistent with the long-term maturity dates of the underlying student loans. As of March 31, 2008, we believe the unrealized losses in the auction rate securities are temporary and we have the ability to hold the assets to maturity. All of our auction-rate securities are AAA/Aaa-rated and are collateralized by student loans which are guaranteed by the U.S. government to be repaid at no less than 95% of par value. We held no auction rate securities as of December 31, 2007.

The following table sets forth the fair value of our financial assets and liabilities reported on a recurring basis including those pledged as collateral, or restricted (*in millions*).

	March 31, 2008		December 31, 2007	
	Assets	Liabilities	Assets	Liabilities
Cash and cash equivalents	\$ 3,283	\$ –	\$ 2,514	\$ –
Restricted cash	788	–	788	–
Short-term investments	1,574	–	1,461	–
Long-term marketable debt securities	1,785	–	1,674	–
Total fixed income investment portfolio	\$ 7,430	–	\$ 6,437	–
Long-term marketable equity securities	416	–	416	–
Total derivative financial instruments	32	130	30	19
Total	\$ 7,878	\$ 130	\$ 6,883	\$ 19

#### Liquidity and Capital Resources

(*In millions*)

	March 31, 2008	December 31, 2007
Unrestricted cash, cash equivalents, short-term investments, and long-term marketable debt and equity securities	\$ 7,058	\$ 6,065
Net receivable—equity hedge instruments	11	24
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	\$ 7,069	\$ 6,089
Working capital	\$ 5,920	\$ 4,835
Current ratio	2.6:1	2.2:1

Total unrestricted cash, cash equivalents, short-term investments, and long-term marketable securities, including the fair value of the equity hedge instruments, was \$7,069 million as of March 31, 2008, an increase of \$980 million from December 31, 2007. This increase primarily reflects cash generated from operations and increases from stock option exercises, partially offset by cash used for capital expenditures. To mitigate the risk of market value fluctuations, certain of our biotechnology equity securities are hedged with forward contracts, which are carried at estimated fair value. See Note 4, “Investment Securities and Financial Instruments,” in the Notes to the Consolidated Financial Statements in Part II, Item 8 of the Form 10-K for the year ended December 31, 2007 for further information regarding activity in our marketable investment portfolio and derivative instruments.

### ***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:

Accounts payable, other accrued liabilities, and other long-term liabilities increased \$12 million in the first quarter of 2008, mainly due to an increase in taxes payable, accrued clinical expenses, and accrued royalties related to growth in the business and timing of payments. These were partially offset by decreases in accrued compensation and other accrued liabilities due to the timing of payments.

Inventories decreased \$22 million in the first quarter of 2008, as more products were sold than produced during the quarter.

Accounts receivable—product sales increased \$42 million from December 31, 2007, primarily due to increased product sales and a decrease in outstanding credit notes applied to certain accounts receivable balances as of March 31, 2008 compared to December 31, 2007, mainly due to the timing of their application. The average collection period of our accounts receivable—product sales as measured in days sales outstanding (DSO) was 34 days as of March 31, 2008, compared to 33 days as of December 31, 2007 and 42 days as of March 31, 2007. The decrease in DSO from the first quarter of 2007 was primarily due to the reduction in the extended payment terms that we offered to certain wholesalers in conjunction with the launch of Lucentis on June 30, 2006. Accounts receivable related to royalties increased \$82 million from December 31, 2007, due to increased royalty revenue. These increases in accounts receivable were partially offset by the receipt of payment from Roche of \$113 million in the first quarter of 2008 related to their opt-in to our trastuzumab drug conjugate products. See “Related Party Transactions” below for further information on our relationship with Roche.

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

Cash used in investing activities was primarily due to capital expenditures, and purchases, sales, and maturities of investments. Capital expenditures were \$200 million in the first quarter of 2008. During the first quarter of 2008, capital expenditures were related to construction of our fill-finish facility in Hillsboro, Oregon and our E. coli production facility in Singapore; leasehold improvements for newly constructed buildings on our South San Francisco, California campus; and purchases of equipment and information systems.

We forecast that our 2008 capital expenditures will be approximately \$900 million, excluding capitalized costs related to construction costs for which we are considered to be the owner during the construction period.

### ***Cash Used in or Provided by Financing Activities***

Cash used in or provided by financing activities includes activity under our employee stock plans. We received \$147 million in the first quarter of 2008 related to stock option exercises and stock issuances under our employee stock purchase plan.

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2008, we are authorized to repurchase up to 150 million shares of our Common Stock for an aggregate amount of up to \$10.0 billion through June 30, 2009. In this program, as in previous stock repurchase programs, purchases may be made in the open market or in privately negotiated transactions from time to time at management’s discretion. We also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities, although as of March 31, 2008, we have not engaged in any such transactions. We intend to use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock purchase plan. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (1) to address provisions of our affiliation agreement with RHI related to maintaining RHI’s minimum ownership percentage, (2) to make prudent investments of our cash resources, and (3) to allow for an effective mechanism to provide stock for our employee stock purchase

plans. See “Relationship with Roche Holdings, Inc.” below for more information on RHI’s minimum ownership percentage.

We enter into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods when trading in our stock is restricted under our insider trading policy.

In November 2007, we entered into a prepaid share repurchase arrangement with an investment bank pursuant to which we delivered \$300 million to the investment bank. Pursuant to this arrangement, the investment bank delivered approximately four million shares to us on March 31, 2008. The prepaid amount was reflected as a reduction of our stockholders’ equity as of December 31, 2007.

As of March 31, 2008, 79 million cumulative shares had been purchased under our stock repurchase program for \$5.7 billion, and a maximum of 71 million additional shares for amounts totaling up to \$4.3 billion may be purchased under the program through June 30, 2009.

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 retained earnings.

### **Off-Balance Sheet Arrangements**

We have certain contractual arrangements that create potential risk for us and are not recognized in our Condensed Consolidated Balance Sheets. We believe that there have been no significant changes in the off-balance sheet arrangements disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007 that have, or are reasonably likely to have, a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources.

### ***Contractual Obligations***

During the first quarter of 2008, we believe that 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, 2007.

### **Contingencies**

We are party to various legal proceedings, licensing and contract disputes, and other matters. See Note 5, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

### **Relationship with Roche Holdings, Inc.**

We issue 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 RHI provides, among other things, that with respect to any issuance of our Common Stock in the future, we will repurchase a sufficient number of shares so that immediately after such issuance, the percentage of our Common Stock owned by RHI will be no lower than 2% below the “Minimum Percentage” (subject to certain conditions). The Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by RHI since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech Common Stock by RHI as well as for stock splits or stock combinations) divided by 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech Common Stock outstanding at the time of the July 1999 offering, as adjusted for 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 RHI’s request, we will repurchase shares of our Common Stock to increase RHI’s ownership to the Minimum Percentage. In addition, RHI will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. Under the terms of the affiliation agreement, RHI’s Minimum Percentage is 57.7% and RHI’s ownership percentage is to be no lower than 55.7%. As of March 31, 2008, RHI’s ownership percentage was 55.8%.

## Related Party Transactions

We enter into transactions with our related parties, Roche and Novartis. The accounting policies that 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.

In our royalty and supply arrangements with related parties, we are the principal, as defined under EITF 99-19, because we bear the manufacturing risk, general inventory risk, and the risk to defend our intellectual property. For circumstances in which we are the principal in the transaction, we record the transaction on a gross basis in accordance with EITF 99-19; otherwise our transactions are recorded on a net basis.

### Roche

We signed two product supply agreements with Roche in July 2006, each of which was amended in November 2007. The Umbrella Agreement supersedes our previous product supply agreements with Roche. The Short-Term Agreement supplements the terms of the Umbrella Agreement. Under the Short-Term Agreement, Roche has agreed to purchase specified amounts of Herceptin, Avastin, and Rituxan through 2008. Under the Umbrella Agreement, Roche has agreed to purchase specified amounts of Herceptin and Avastin through 2012 and, on a perpetual basis, either party may order other collaboration products from the other party, including Herceptin and Avastin after 2012, pursuant to certain forecast terms. The Umbrella Agreement also provides that either party may terminate its obligation to purchase and/or supply Avastin and/or Herceptin with six years notice on or after December 31, 2007. To date, we have not received such notice of termination from Roche.

In December 2007, Roche opted-in to our trastuzumab drug conjugate products under terms similar to those of the existing anti-HER2 agreement. As part of the opt-in, Roche paid us \$113 million and will pay 50% of subsequent development costs related to the trastuzumab drug conjugate products. In March 2008, Roche opted-in to our Avastin glioblastoma multiforme indication under the terms of our July 1999 amended and restated licensing and marketing agreement with Roche. As part of the opt-in, Roche paid us \$19 million and will pay 75% of ongoing development costs related to the Avastin glioblastoma multiforme indication. We recognized the payments received from Roche as deferred revenue, which will be recognized over the expected development periods.

Late in the first quarter of 2008, Roche acquired Ventana Medical Systems, Inc., and as a result of the acquisition, Ventana is considered a related party. We have engaged in transactions with Ventana prior to and since the acquisition, but these transactions have not been material to our results of operations.

We currently have no active profit sharing arrangements with Roche.

Under our existing arrangements with Roche, including our licensing and marketing agreement, we recognized the following amounts (*in millions*):

	Three Months Ended March 31,	
	2008	2007
Product sales to Roche	\$ 136	\$ 264
Royalties earned from Roche	\$ 370	\$ 255
Contract revenue from Roche	\$ 20	\$ 30
Cost of sales on product sales to Roche	\$ 63	\$ 121
Research and development expenses incurred on joint development projects with Roche	\$ 70	\$ 58

Certain R&D expenses are partially reimbursable to us by Roche. Amounts that Roche owes us, net of amounts reimbursable to Roche by us on these projects, are recorded as contract revenue. Conversely, R&D expenses may include the net settlement of amounts that we owe Roche for R&D expenses that Roche incurred on joint development projects, less amounts reimbursable to us by Roche on these projects.

**Novartis**

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

We have an agreement with Novartis Pharma AG under which Novartis Pharma AG has the exclusive right to develop and market Lucentis outside the U.S. 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 development expenses for Lucentis.

We, along with Novartis, are co-developing and are co-promoting Xolair in the U.S. We record all sales, COS, and marketing and sales expenses in the U.S.; Novartis markets the product in and records all sales, COS, and marketing and sales expenses in Europe. We and Novartis share the resulting U.S. and European operating profits according to prescribed profit sharing percentages. We record Novartis's share of the U.S. operating profits as collaboration profit sharing expense. Our share of the European operating results was recorded as contract revenue in the first quarter of 2008 and collaboration profit sharing expense in the first quarter of 2007. Effective with our acquisition of Tanox, Inc. on August 2, 2007, Novartis also makes: (1) additional profit sharing payments to us on U.S. sales of Xolair, which reduces our profit sharing expense; (2) royalty payments to us on sales of Xolair worldwide, which we record as royalty revenue; and (3) manufacturing service payments related to Xolair, which we record as contract revenue.

Under our existing arrangements with Novartis, we recognized the following amounts (*in millions*):

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Product sales to Novartis	\$ 4	\$ 2
Royalties earned from Novartis	\$ 53	\$ 5
Contract revenue from Novartis	\$ 11	\$ 40
Cost of sales on product sales to Novartis	\$ 3	\$ 3
Research and development expenses incurred on joint development projects with Novartis	\$ 9	\$ 10
Collaboration profit sharing expense to Novartis	\$ 41	\$ 47

Contract revenue in the first quarter of 2007 included a \$30 million milestone payment from Novartis for European Union approval of Lucentis for the treatment of AMD.

Certain R&D expenses are partially reimbursable to us by Novartis. Amounts that Novartis owes us, net of amounts reimbursable to Novartis by us on these projects, are recorded as contract revenue. Conversely, R&D expenses may include the net settlement of amounts that we owe Novartis for R&D expenses that Novartis incurred on joint development projects, less amounts reimbursable to us by Novartis on these projects.

## 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 2004 Equity Incentive Plan (the Plan), a broad-based plan under which stock options, restricted stock, stock appreciation rights, and performance shares and units may be 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 1999 Stock Plan, 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 almost all of these plans are still outstanding.

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors or an authorized delegate. See "Compensation Discussion and Analysis" in our 2008 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, 2006</b>	68.7	88.3	\$ 54.43
Grants	(17.8)	17.8	79.40
Exercises	–	(10.4)	32.76
Cancellations	3.5	(3.5)	76.45
<b>December 31, 2007</b>	54.4	92.2	\$ 60.94
Grants	(0.3)	0.3	72.17
Exercises	–	(3.5)	35.05
Cancellations	1.2	(1.2)	79.96
<b>March 31, 2008 (Year to Date)</b>	55.3	87.8	\$ 61.76

#### 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, 2008</b>						
In-the-Money	43	\$ 41.70	28	\$ 77.20	71	\$ 55.78
Out-of-the-Money <sup>(1)</sup>	10	86.05	7	85.84	17	85.97
<b>Total Options Outstanding</b>	<b>53</b>		<b>35</b>		<b>88</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, \$81.18, at the close of business on March 31, 2008.

### Dilutive Effect of Options

Grants, net of cancellations, as a percentage of outstanding shares were (0.08)% for the first quarter of 2008, 1.36% for the year ended December 31, 2007, and 1.43% for the year ended December 31, 2006.

### *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 new molecules into clinical development, bringing major new products or indications onto the market, becoming the number one U.S. oncology company in sales, and achieving certain financial growth measures; our internal stretch goal to add a total of 30 molecules into development; the evaluation of data from clinical studies; Avastin sales growth; reimbursement for Lucentis; sales to collaborators; Herceptin pricing terms; foreign currency option contracts and forwards; royalty and contract revenue; other income, net; auction rate securities; payments related to the City of Hope litigation; our rights and liabilities under collaboration agreements; compensation charges associated with voluntary severance; and capital expenditures.

These forward-looking statements involve risks and uncertainties, and the cautionary statements set forth below and those contained in “Risk Factors” in this Quarterly Report on Form 10-Q 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, difficulty in enrolling patients in clinical trials; the need for additional data, data analysis or clinical studies; BLA preparation and decision making; FDA actions or delays; failure to obtain or maintain FDA approval; difficulty in obtaining materials from suppliers; unexpected safety, efficacy or manufacturing issues for us or our contract/collaborator manufacturers; increased capital expenditures including greater than expected construction and validation costs; product withdrawals; competition; efficacy data concerning any of our products which shows or is perceived to show similar or improved treatment benefit at a lower dose or shorter duration of therapy; pricing decisions by us or our competitors; our ability to protect our proprietary rights; the outcome of, and expenses associated with, litigation or legal settlements; increased R&D, MG&A, stock-based compensation, environmental and other expenses, and increased COS; variations in collaborator sales and expenses; our indebtedness and ability to pay our indebtedness; actions by Roche that are adverse to our interests; decreases in third party reimbursement rates; and greater than expected income tax rate. We disclaim and do not undertake any obligation to update or revise any forward-looking statement in this Quarterly Report on Form 10-Q.

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

Our market risks as of March 31, 2008 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007, on file with the U.S. Securities and Exchange Commission.

See also Note 1, "Summary of Significant Accounting Policies—Derivative Instruments," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

### **Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures:* Our principal executive and financial officers reviewed and evaluated our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our principal executive and financial officers concluded that our disclosure controls and procedures are effective in providing them with timely material information related to Genentech, as required to be disclosed in the reports that we file under the Exchange Act of 1934.

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

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

See Note 5, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for a description of legal proceedings as well as certain other matters.

See also Item 3, “Legal Proceedings,” of our Annual Report on Form 10-K for the year ended December 31, 2007.

### Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, 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 revenue, expenses, net income, and earnings per share.

#### **The successful development of pharmaceutical products is highly uncertain and requires significant expenditures and time.**

Successful development of pharmaceutical products is highly uncertain. Products that appear promising in research or 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 United States (U.S.) and international 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 license application (BLA) or new drug application (NDA) preparation; discussions with the U.S. Food and Drug Administration (FDA); FDA requests for additional preclinical or clinical data; FDA delays due to staffing or resource limitations at the agency; analyses of or changes to study design; or unexpected safety, efficacy, or manufacturing issues.
- Difficulties in formulating the product, scaling the manufacturing process, or getting approval for manufacturing.
- Manufacturing costs, pricing, reimbursement issues, or other factors may make the product uneconomical.
- The proprietary rights of others and their competing products and technologies may prevent the product from being developed or commercialized.
- The contractual rights of our collaborators or others 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 for a product are not successful, we will not recover our substantial investments in that product.

Factors affecting our research and development (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 a sufficient number of product candidates that are ready to move into development or that product candidates will be available for in-licensing on terms acceptable to us and permitted under the anti-trust laws.
- Decisions by Roche Holding AG and affiliates (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.
- Our ability to in-license projects of interest to us, and the timing and amount of related development funding or milestone payments for such licenses. For example, we may enter into agreements requiring us to pay a significant up-front 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 below in "Difficulties or delays in product manufacturing or in obtaining materials from our suppliers, or difficulties in accurately forecasting manufacturing capacity needs could harm our business and/or negatively affect our financial performance."
- Future levels of revenue.
- Our ability to supply product for use in clinical trials.

**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. 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 BLA or NDA are substantial and can require a number of years. In addition, even if our products receive regulatory approval, they remain subject to ongoing FDA regulations, including, for example, obligations to conduct additional clinical trials or other testing, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

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 we may not 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 approvals, as described above in "The successful development of pharmaceutical products is highly uncertain and requires significant expenditures and time."

- Loss of, or changes to, previously obtained approvals or accelerated approvals, including those resulting from post-approval safety or efficacy issues. For example, with respect to the FDA's accelerated approval of Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not received prior chemotherapy for metastatic HER2-negative breast cancer (BC), the FDA may withdraw or modify such approval, or request additional post-marketing studies.
- Failure to comply with existing or future regulatory requirements.
- A determination by the FDA that any study endpoints used in clinical trials for our products are not sufficient for product approval.
- Changes to manufacturing processes, manufacturing process standards, or current Good Manufacturing Practices (GMP) 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 that 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.

### **We face competition.**

We face competition from pharmaceutical companies and biotechnology companies.

The introduction of new competitive products or follow-on biologics, new information about existing products or pricing decisions by us or our competitors, rate of market penetration by competitors' products, and/or development and use of alternate therapies may result in lost market share for us, reduced utilization of our products, lower prices, and/or reduced product sales, even for products protected by patents.

*Avastin*: Avastin competes in metastatic colorectal cancer (CRC) with Erbitux<sup>®</sup> (Imclone/Bristol-Myers Squibb), which is an epidermal growth factor receptor (EGFR) inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic CRC patients; and with Vectibix<sup>™</sup> (Amgen), which is indicated for the treatment of patients with EGFR-expressing metastatic CRC who have disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing regimens. Avastin could also face competition from Erbitux<sup>®</sup> in metastatic non-small cell lung cancer (NSCLC). In the third quarter of 2007, ImClone Systems Incorporated and Bristol-Myers Squibb Company announced that a Phase III study of Erbitux<sup>®</sup> in combination with vinorelbine plus cisplatin met its primary endpoint of increasing overall survival compared with chemotherapy alone in patients with advanced NSCLC. Data from this study are expected in 2008. In addition, Avastin competes with Nexavar<sup>®</sup> (sorafenib, Bayer Corporation/Onyx Pharmaceuticals, Inc.), Sutent<sup>®</sup> (sunitinib malate, Pfizer, Inc.), and Torisel<sup>®</sup> (Wyeth) for the treatment of patients with advanced renal cell carcinoma (an unapproved use of Avastin).

Avastin could face competition from products in development that currently do not have regulatory approval. Sanofi-Aventis is developing a vascular endothelial growth factor (VEGF) inhibitor VEGF-Trap in multiple indications, including metastatic CRC and metastatic NSCLC. There are also ongoing head-to-head clinical trials comparing both Sutent<sup>®</sup> and AZD2171 (AstraZeneca) to Avastin. Likewise, Amgen has initiated head-to-head clinical trials comparing AMG 706 and Avastin in NSCLC and metastatic BC; Pfizer has initiated a head-to-head trial comparing Sutent<sup>®</sup> to Avastin in BC. Overall, there are more than 65 molecules in clinical development that target VEGF inhibition, and over 130 companies are developing molecules that, if successful in clinical trials, may compete with Avastin.

*Rituxan*: Rituxan's current competitors in hematology-oncology include Bexxar<sup>®</sup> (GlaxoSmithKline [GSK]) and Zevalin<sup>®</sup> (Cell Therapeutics), 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 (NHL). Other potential competitors include Campath<sup>®</sup> (Bayer Corporation/Genzyme) in previously untreated and relapsed chronic lymphocytic leukemia (CLL) (an unapproved use of Rituxan); Velcade<sup>®</sup> (Millennium Pharmaceuticals, Inc.), which is indicated for multiple myeloma and more recently, mantle cell lymphoma (both unapproved uses of Rituxan); and Revlimid<sup>®</sup> (Celgene), which is indicated for multiple myeloma and myelodysplastic syndromes (both unapproved).

uses of Rituxan); and Treanda<sup>®</sup> (Cephalon), which was recently approved for the treatment of CLL (an unapproved use of Rituxan).

Rituxan's current competitors in rheumatoid arthritis (RA) include Enbrel<sup>®</sup> (Amgen/Wyeth), Humira<sup>®</sup> (Abbott Laboratories), Remicade<sup>®</sup> (Johnson & Johnson), Oencia<sup>®</sup> (Bristol-Myers Squibb), and Kineret<sup>®</sup> (Amgen). These products are approved for use in an RA patient population that is broader than the approved population for Rituxan. In addition, molecules in development that, if approved by the FDA, may compete with Rituxan in RA include: Actemra<sup>™</sup>, an anti-interleukin-6 receptor being developed by Chugai Pharmaceutical Co. Ltd. and Roche; Cimzia<sup>™</sup> (certolizumab pegol), an anti-tumor necrosis factor (TNF) antibody being developed by UCB; and CNTO 148 (golimumab), an anti-TNF antibody being developed by Centocor, Inc. (a wholly owned subsidiary of Johnson & Johnson) and Schering-Plough.

Rituxan may face future competition in both hematology-oncology and RA from HuMax-CD20<sup>®</sup> (ofatumumab), an anti-CD20 antibody being co-developed by Genmab and GSK. Genmab and GSK announced their plans to file for approval of HuMax-CD20<sup>®</sup> in 2008 for monotherapy use in refractory CLL and to complete a monotherapy trial for refractory indolent NHL. In addition, we are aware of other anti-CD20 molecules in development that, if successful in clinical trials, may compete with Rituxan. Rituxan could also face competition from Treanda<sup>®</sup> (Cephalon, Inc.), an NHL treatment candidate that was approved by the FDA on March 20, 2008. There are several therapeutic vaccines currently in development that may seek approval in indolent NHL in the future.

*Herceptin:* Herceptin faces competition in the relapsed metastatic setting from Tykerb<sup>®</sup> (lapatinib ditosylate) which is manufactured by GSK. Tykerb<sup>®</sup> is approved in combination with capecitabine, for the treatment of patients with advanced or metastatic BC whose tumors overexpress HER2 and who have received prior therapy, including an anthracycline, a taxane, and Herceptin. Market research indicates that lapatinib use in the first quarter was primarily within the later lines of metastatic BC, with limited impact on Herceptin sales. We will continue to monitor the clinical development of lapatinib in early lines of metastatic and adjuvant BC.

*Lucentis:* We are aware that retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration (AMD), an unapproved use for Avastin, which results in significantly less revenue to us per treatment compared to Lucentis. As of January 1, 2008, we no longer directly supply Avastin to compounding pharmacies. We expect ocular use of Avastin to continue as physicians can purchase Avastin from authorized distributors and have it shipped to the destination of the physicians' choice. Additionally, an independent head-to-head trial of Avastin and Lucentis in wet AMD is being partially funded by the National Eye Institute, which announced that enrollment had commenced in February 2008. Lucentis also competes with Macugen<sup>®</sup> (Pfizer/OSI Pharmaceuticals), and with Visudyne<sup>®</sup> (Novartis) alone, in combination with Lucentis, in combination with Avastin, or in combination with the off-label steroid triamcinolone in wet AMD. In addition, VEGF-Trap-Eye, a vascular endothelial growth factor blocker being developed by Bayer Corporation and Regeneron Pharmaceuticals, Inc., is in Phase III clinical trials for treatment of wet AMD.

*Xolair:* Xolair 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 and immunotherapy.

*Tarceva:* Tarceva competes with the chemotherapy agents Taxotere<sup>®</sup> (Sanofi-Aventis) and Alimta<sup>®</sup> (Eli Lilly and Company), both of which are indicated for the treatment of relapsed NSCLC. Tarceva may face future competition from Zactima<sup>™</sup> (AstraZeneca), and from a potential re-filing of Iressa<sup>®</sup> (AstraZeneca) in the U.S. In first-line NSCLC (an unapproved use of Tarceva), positive results from pivotal studies have been announced for Alimta<sup>®</sup> (Eli Lilly) and Erbitux<sup>®</sup> (ImClone/Bristol-Myers Squibb). Alimta<sup>®</sup> received approval for this indication in the European Union. In front-line pancreatic cancer, Tarceva primarily competes with Gemzar<sup>®</sup> (Eli Lilly) monotherapy and Gemzar<sup>®</sup> in combination with other chemotherapeutic agents. Tarceva could face competition in the future from products in late-phase development, such as Erbitux<sup>®</sup>, in the treatment of relapsed NSCLC and Xeloda<sup>®</sup> (Roche), in the treatment of pancreatic cancer.

*Nutropin*: Nutropin faces competition in the growth hormone market from five (5) branded competitors:

- Humatrope<sup>®</sup> (Lilly)
- Genotropin<sup>®</sup> (Pfizer)
- Norditropin<sup>®</sup> (Novo Nordisk)
- Saizen<sup>®</sup> (Merck Serono)
- Tev-Tropin<sup>®</sup> (Teva)

Nutropin also faces competition from three (3) follow-on biologics:

- Omnitrope<sup>®</sup> (Sandoz)
- Valtropin<sup>®</sup> (LG Life Sciences)
- Accretropin<sup>®</sup> (Cangene)

As a result of this competition, we have experienced and may continue to experience a loss of patient share and increased competition for managed care product placement. Obtaining placement on the preferred product lists of managed care companies may require that we further discount the price of Nutropin. In addition to managed care placement, patient and healthcare provider services provided by growth hormone manufacturers are increasingly important to creating brand preference.

*Thrombolytics*: Our thrombolytic products face competition in the 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 for acute myocardial infarction also faces competition from Retavase<sup>®</sup> (EKR Therapeutics).

*Pulmozyme*: Pulmozyme currently faces competition from the use of hypertonic saline, an inexpensive approach to clearing sputum from the lungs of cystic fibrosis patients. Approximately 25% of cystic fibrosis patients receive hypertonic saline and it is estimated that in a small percentage of patients (less than 5%), this use will impact how a physician may prescribe or a patient may use Pulmozyme.

*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 biologic agents Amevive<sup>®</sup> (Astellas), Enbrel<sup>®</sup> (Amgen), and Remicade<sup>®</sup> (Centocor). Raptiva also competes with the biologic agent Humira<sup>®</sup> (Abbott Laboratories), which was approved by the FDA for use in moderate-to-severe psoriasis on January 18, 2008, and was used off-label in psoriasis prior to FDA approval. Raptiva may face future competition from the biologic Ustekinumab/CNTO-1275 (Centocor), which was filed with the FDA for approval in the treatment of psoriasis on December 4, 2007.

In addition to the commercial and late-stage development products listed above, numerous products are 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 and patients from U.S. and international government health administration authorities, private health insurers, and other organizations. Third-party payers and government health administration authorities increasingly attempt to limit and/or regulate the reimbursement of medical products and services, including branded prescription drugs. Changes in government legislation or regulation, such as the Medicare Prescription Drug Improvement and Modernization Act of 2003, the Deficit Reduction Act of 2005, and the Medicare, Medicaid and SCHIP (State Children's Health Insurance Program) Extension Act of 2007; changes in formulary or compendia listings; or changes in private third-party payers' policies toward reimbursement for our products may reduce reimbursement of our products' costs to physicians, pharmacies, and distributors. Decreases in third-party reimbursement for our products could reduce usage of the products, sales to collaborators, and royalties, and may have a material adverse effect on our product sales, results of operations, and financial condition.

**Difficulties or delays in product manufacturing or in obtaining materials from our suppliers, or difficulties in accurately forecasting manufacturing capacity needs, could harm our business and/or negatively affect our financial performance.**

Manufacturing pharmaceutical products is difficult and complex, and requires facilities specifically designed and validated for this purpose. It can take more 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, Vacaville, and Oceanside, California and through various contract-manufacturing arrangements. Maintaining an adequate supply to meet demand for our products depends on our ability to execute on our production plan. Any significant problem in the operations of our or our contractors' manufacturing facilities could result in cancellation of shipments; loss of product in the process of being manufactured; a shortfall, stock-out, or recall of available product inventory; or unplanned increases in production costs—any of which could have a material adverse effect on our business. A number of factors could cause significant production problems or interruptions, including:

- The inability of a supplier to provide raw materials used to manufacture our products.
- Equipment obsolescence, malfunctions, or failures.
- Product quality or contamination problems, due to a number of factors including, but not limited to, human error.
- Damage to a facility, including our warehouses and distribution facilities, due to events such as fires or earthquakes, as our South San Francisco, Vacaville, and Oceanside facilities are located in areas where earthquakes and/or fires have occurred.
- Changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes.
- Action by the FDA or by us which results in the halting or slowdown of production of one or more of our products or products that we make for others.
- A contract manufacturer going out of business or failing to produce product as contractually required.
- Failure to maintain an adequate state of current GMP compliance.
- Problems in implementing and integrating our new enterprise resource planning system, including the portions related to manufacturing and distribution.

In addition, there are inherent uncertainties associated with forecasting future demand for our products or those products we produce for others, and as a consequence we may have inadequate capacity to meet actual demand. Alternatively, we may have excess capacity, which could lead to an idling of a portion of our manufacturing facilities during which time we would incur unabsorbed or idle plant charges, costs associated with the termination of existing contract manufacturing relationships, costs associated with a reduction in workforce, or other excess capacity charges, resulting in an increase in our cost of sales (COS).

Furthermore, certain of our raw materials and supplies required for the production of our principal products, or products that 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). If such sole-source or single-source suppliers were to limit or terminate production or otherwise fail to supply these materials for any reason, we may not be able to obtain such raw materials and supplies without significant delay or at all, and such failures could have a material adverse effect on our product sales and our business.

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 result in a material adverse effect on our product sales, financial condition, and results of operations.

**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 that will be allowed in companies' patents. Patent disputes are frequent and may ultimately 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 related to our proprietary rights, such as the Cabilly patent re-examination and the MedImmune lawsuit (discussed in Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q), and disputes in connection with licenses granted to or obtained from third parties. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities with third parties, including the payment of significant royalty expenses, the loss of significant royalty income, or other expenses or losses. Furthermore, an adverse decision or ruling 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 or ruling with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of sales and/or 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, or to 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 and other legal actions to which we are currently or have been subjected to relate to, among other things, our patent and other intellectual property rights, licensing arrangements and other contracts with third parties, and product liability. We cannot predict with certainty the eventual outcome of pending proceedings, which may include an injunction against the development, manufacture, or sale of a product or potential product; a judgment with a 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 these proceedings, and such matters could divert management's attention from ongoing business concerns.

Our activities related 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 healthcare programs (including Medicare and Medicaid). In 1999, we agreed to pay \$50 million to settle a federal investigation related 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 and may in the future be investigated for our promotional practices related to any of our products. If the government were to bring charges against us or convict us of violating federal statutes, or if we were subject to third-party litigation-related 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 in part 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 healthcare 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 us or convict us of violating these laws, there could be a material adverse effect on our business, including our stock price.

**Other factors could affect our product sales.**

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

- Efficacy data from clinical studies conducted by any party in the U.S. or internationally showing, or perceived to show, a similar or improved treatment benefit at a lower dose or shorter duration of therapy could cause the sales of our products to decrease.
- Our pricing decisions, including a decision to increase or decrease the price of a product; the pricing decisions of our competitors; as well as our Avastin Patient Assistance Program, which is a voluntary program that enables eligible patients who have received 10,000 milligrams (mg) of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 mg during the remainder of the 12-month period.
- 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 or withdrawn.
- Negative safety or efficacy data from post-approval marketing experience or production-quality problems could cause sales of our products to decrease or a product to be recalled or withdrawn.
- 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.
- Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers that supply our products.
- Our decision to no longer allow compounding pharmacies to purchase Avastin directly from wholesale distributors, which could have a negative impact on Lucentis sales as a result of negative reaction by retinal specialists to our decision.
- Product returns and allowances greater than expected or historically experienced.
- That we have three major customers and the inability of one or more of them to meet their payment obligations to us.

Any of these additional 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 revenue, and sales to collaborators.**

Royalty and contract revenue, and sales to collaborators in future periods, could vary significantly. Major factors affecting this revenue include, but are not limited to:

- Roche's decisions about 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 Roche's sales and other licensees' sales of licensed products.
- The expiration or termination of existing arrangements with other companies and Roche, which may include development and marketing arrangements for our products in the U.S., Europe, and other countries.
- The timing of non-U.S. approvals, if any, for products licensed to Roche and other licensees.

- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- The initiation of new contractual arrangements with other companies.
- Whether and when contract milestones are achieved.
- The failure or refusal of a licensee to pay royalties, the termination of a contract under which we receive royalties or other revenue, or changes to the terms of such a contract.
- The expiration or invalidation of our patents or licensed intellectual property. See Risk Factor “Protecting our proprietary rights is difficult and costly.”
- Decreases in licensees’ sales of our products due to competition, manufacturing difficulties, or other factors that affect the sales of product.
- Fluctuations in foreign currency exchange rates.

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

Most biotechnology companies, including Genentech, have historically used, and continue to use, bovine source raw materials to support cell growth in certain production processes. Bovine source raw materials from within or outside the U.S. are subject to public and regulatory scrutiny because of the perceived risk of contamination with the infectious agent that causes BSE. Should such BSE contamination occur, it would likely negatively affect our ability to manufacture certain 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 (1) attract and retain highly qualified management, scientific, manufacturing, and sales and marketing personnel, (2) successfully integrate large numbers of new employees into our corporate culture, and (3) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense. 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.

**Our affiliation agreement with Roche Holdings, Inc. (RHI) could adversely affect our cash position.**

Under our affiliation agreement with RHI, we have established a stock repurchase program designed to maintain RHI’s percentage ownership interest in our Common Stock based on an established Minimum Percentage. For more information on our stock repurchase program, see “Liquidity and Capital Resources—Cash Used in or Provided by Financing Activities,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 2 of this Quarterly Report on Form 10-Q. For information on the Minimum Percentage, see Note 6, “Relationship with Roche Holdings, Inc. and Related Party Transactions,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

RHI’s ownership percentage is diluted by the exercise of stock options to purchase shares of our Common Stock by our employees and the purchase of shares of our Common Stock through our employee stock purchase plan. See Note 2, “Employee Stock-Based Compensation,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding employee stock plans. In order to maintain RHI’s Minimum Percentage, we repurchase shares of our Common Stock under the stock repurchase program. In the first quarter of 2008, we received approximately four million shares under a \$300 million prepaid share repurchase arrangement that we entered into and funded in 2007. As of March 31, 2008, there were

approximately 43 million in-the-money exercisable options. While the U.S. dollar amounts associated with future stock repurchase programs cannot currently be determined, future stock repurchases could have a material adverse effect on our liquidity, credit rating, and ability to access additional capital in the financial markets.

**Our affiliation agreement with RHI could limit our ability to make acquisitions or divestitures.**

Our affiliation agreement with RHI contains provisions that:

- Require the approval of the directors designated by RHI to make any acquisition that represents 10 percent or more of our assets, net income or revenue; or any sale or disposal of all or a portion of our business representing 10 percent or more of our assets, net income, or revenue.
- Enable RHI to maintain its percentage ownership interest in our Common Stock.
- Require us to establish a stock repurchase program designed to maintain RHI's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For information regarding the Minimum Percentage, see Note 6, "Relationship with Roche Holdings, Inc. and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**Sales of our Common Stock by RHI could cause the price of our Common Stock to decline.**

As of March 31, 2008, RHI owned 587,189,380 shares of our Common Stock, or 55.8% of our outstanding shares. All of our shares owned by RHI are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon RHI's request, we will file one or more registration statements under the Securities Act of 1933 in order to permit RHI to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by RHI in the public market could adversely affect the market price of our Common Stock.

**RHI, 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 RHI.**

As our majority stockholder, RHI controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our Board of Directors shall consist of at least three directors designated by RHI, three independent directors nominated by the Nominations Committee, and one Genentech executive officer nominated by the Nominations Committee. Our bylaws also provide that RHI will have the right to obtain proportional representation on our Board of Directors until such time that RHI owns less than five percent 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. As long as RHI owns more than 50 percent of our Common Stock, RHI directors will be two of the three members of the Nominations Committee. Our certificate of incorporation includes provisions related to competition by RHI affiliates with Genentech, offering of corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of specified employees. We cannot assure that RHI 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 of Genentech and who are also directors and/or officers of RHI may decline to take action in a manner that might be favorable to us but adverse to RHI.

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 related to competition with RHI, conflicts of interest with RHI, the offer of corporate opportunities to RHI, and intercompany agreements with RHI. This deemed consent might restrict our 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 entails an inherent risk of product liability. Liability exposures for pharmaceutical products can 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 may be more difficult and costly to obtain or maintain.**

We currently have a limited amount of insurance to minimize our direct exposure to certain business risks. In the future, we may be exposed to an increase in premiums and a narrowing scope of coverage. As a result, we may be required to assume more risk 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 that 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 that could occur 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, but not limited to, the following:

- 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.
- Increased COS; R&D and marketing, general and administrative expenses; stock-based compensation expenses; litigation-related expenses; asset impairments; and equity securities write-downs.
- Changes in interest rates, credit ratings, and the liquidity of our interest-bearing investments, and the effects that such changes may have on the value of those investments.
- Changes in foreign currency exchange rates and the effects that such changes may have on our royalty revenue and foreign currency denominated investments.

- The amount and timing of our sales to Roche and our other collaborators of products for sale outside the U.S., and the amount and timing of sales to their respective customers, which directly affect both our product sales and royalty revenue.
- The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of our products.
- The extent of product discounts extended to customers.
- The efficacy 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 the use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and the use of our products may be affected by the 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 that we or our competitors have adopted or may adopt, as well as our Avastin Patient Assistance Program.
- Our distribution strategy, including the termination of, or any change in, an existing arrangement with any major wholesalers that supply our products.

Fluctuation in our operating results due to factors described above or for any other reason could affect the price of our Common Stock.

**Our integration of new information systems could disrupt our internal operations, which could decrease revenue and increase 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, 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. Among other factors, the following may have a significant effect 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 related to products under development or being commercialized by us or our competitors.

- Our financial results.
- Concerns about our pricing initiatives and distribution strategy, and the potential effect of such initiatives and strategy on the utilization of our products or our product sales.
- Developments or outcomes of litigation, including litigation regarding proprietary and patent rights (including, for example, the Cabilly patent discussed in Note 5, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q), and governmental investigations.
- Regulatory developments or delays affecting our products in the U.S. and other countries.
- Issues concerning the efficacy or safety of our products, or of biotechnology products generally.
- Economic and other external factors or a disaster or crisis.
- New proposals to change or reform the U.S. healthcare system, including, but not limited to, new regulations concerning reimbursement or follow-on biologics.

**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; the results of any tax examinations; changing interpretations of existing tax laws or regulations; changes in estimates of prior years’ items; past and future levels of R&D spending; acquisitions; changes in our corporate structure; and changes in overall levels of income before taxes, all of which may result in periodic revisions to our effective income tax rate.

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

As of March 31, 2008, we had approximately \$2.0 billion of long-term debt and \$600 million of commercial paper notes payable. Our ability to make payments on or to refinance our indebtedness, and to fund planned capital expenditures and R&D, as well as stock repurchases and expansion efforts, will depend on our ability to generate cash in the future. This ability, 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, and 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.**

Under Financial Accounting Standards Board Interpretation No. 46R (FIN 46R), a revision to FIN 46, “*Consolidation of Variable Interest Entities*,” we are required to assess new business development collaborations as well as reassess, upon certain events, some of which are outside our control, the accounting treatment of our existing business development collaborations based on the nature and extent of our variable interests in the entities, as well as the extent of our ability to exercise influence over the entities with which we have such collaborations. Our continuing compliance with FIN 46R may result in our consolidation of companies or related entities with which we have a collaborative arrangement, and this may have a material effect on our financial condition and/or results of operations in future periods.

## 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 2008, we are authorized to repurchase up to 150 million shares of our Common Stock for an aggregate amount of up to \$10.0 billion through June 30, 2009. In this program, as in previous stock repurchase programs, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. We also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. As of March 31, 2008, we have not engaged in any such transactions. We intend to use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock purchase plan. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (1) to address provisions of our affiliation agreement with RHI related to maintaining RHI's minimum ownership percentage, (2) to make prudent investments of our cash resources, and (3) to allow for an effective mechanism to provide stock for our employee stock purchase plan. See Note 6, "Relationship with Roche Holdings, Inc. and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on RHI's minimum ownership percentage.

We enter into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods when trading in our stock is restricted under our insider trading policy.

Our shares repurchased for the three months ended March 31, 2008 were as follows (*shares in millions*):

	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs<sup>(2)</sup></b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs<sup>(2)</sup></b>
January 1–31, 2008	–	–		
February 1–29, 2008	–	–		
March 1–31, 2008 <sup>(1)</sup>	4.2	\$ 72.00		
Total	4.2	\$ 72.00	79	71

(1) In November 2007, we entered into a prepaid share repurchase arrangement with an investment bank pursuant to which we delivered \$300 million to the investment bank. Pursuant to this arrangement, the investment bank delivered approximately 4.2 million shares to us on March 31, 2008. The prepaid amount was reflected as a reduction of our stockholders' equity as of December 31, 2007.

(2) As of March 31, 2008, 79 million cumulative shares have been purchased under our stock repurchase program for \$5.7 billion, and a maximum of 71 million additional shares for amounts totaling up to \$4.3 billion may be purchased under the program through June 30, 2009.

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 retained earnings.

**Item 6. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>	<u>Location</u>
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 1934, as amended	Filed herewith
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

**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 5, 2008

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

Date: May 5, 2008

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

Date: May 5, 2008

/s/ROBERT E. ANDREATTA  
Robert E. Andreatta  
Controller and Chief Accounting Officer

May 5, 2008

The Board of Directors and Stockholders of Genentech, Inc.

We are aware of the incorporation by reference in the Registration Statements pertaining to the Genentech, Inc. Tax Reduction Investment Plan, the 2004 Equity Incentive Plan, the 1999 Stock Plan, the 1996 Stock Option/Stock Incentive Plan, the 1994 Stock Option Plan, the 1990 Stock Option/Stock Incentive Plan, the 1991 Employee Stock Plan, and the Registration Statement (Form S-3 No. 333-37072) related to the resale of common shares deliverable upon the exchange of Liquid Yield Option Notes, and in the related Prospectuses, as applicable, contained in such Registration Statements of our report dated April 28, 2008, relating to the unaudited condensed consolidated interim financial statements of Genentech, Inc. that are included in its Form 10-Q for the quarter ended March 31, 2008.

Very truly yours,

/s/ Ernst & Young LLP

Palo Alto, California

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CERTIFICATIONS

I, Arthur D. Levinson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genentech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2008

By: /s/ ARTHUR D. LEVINSON  
Arthur D. Levinson, Ph.D.  
Chief Executive Officer

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CERTIFICATIONS

I, David A. Ebersman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genentech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2008

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

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**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**

I, Arthur D. Levinson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genentech, Inc. on Form 10-Q for the quarter ended March 31, 2008 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Genentech, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genentech, Inc.

By: /s/ ARTHUR D. LEVINSON  
Name: Arthur D. Levinson, Ph.D.  
Title: Chief Executive Officer  
Date: May 5, 2008

I, David A. Ebersman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Genentech, Inc. on Form 10-Q for the quarter ended March 31, 2008 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Genentech, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Genentech, Inc.

By: /s/ DAVID A. EBERSMAN  
Name: David A. Ebersman  
Title: Executive Vice President and  
Chief Financial Officer  
Date: May 5, 2008

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