

GENENTECH INC  
Form 10-Q  
May 04, 2007

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

(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, 2007**

or

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

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

**Commission File Number: 1-9813**

**GENENTECH, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**94-2347624**

(I.R.S. Employer Identification Number)

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

(Address of principal executive offices and Zip Code)

**(650) 225-1000**

(Registrant's telephone number, including area code)

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

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

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Large accelerated filer

Accelerated filer

Non-accelerated filer

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

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

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock \$0.02 par value	1,053,169,937 Outstanding at April 27, 2007

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

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

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

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**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>2007</b>	<b>2006</b>
<b>Revenues</b>		
Product sales (including amounts from related parties: 2007-\$266; 2006-\$59)	\$ 2,329	\$ 1,644
Royalties (including amounts from related parties: 2007-\$260; 2006-\$167)	419	286
Contract revenue (including amounts from related parties: 2007-\$70; 2006-\$28)	95	56
<b>Total operating revenues</b>	<b>2,843</b>	<b>1,986</b>
<b>Costs and expenses</b>		
Cost of sales (including amounts for related parties: 2007-\$124; 2006-\$50)	392	262
Research and development (including amounts for related parties: 2007-\$68; 2006-\$53) (including contract related: 2007-\$46; 2006-\$36)	610	374
Marketing, general and administrative	491	441
Collaboration profit sharing (including amounts for a related party: 2007-\$47; 2006-\$43)	252	226
Recurring charges related to redemption	26	26
Special items: litigation-related	13	13
<b>Total costs and expenses</b>	<b>1,784</b>	<b>1,342</b>
Operating income	1,059	644
Other income (expense):		
Interest and other income (expense), net	74	53
Interest expense	(18)	(19)
Total other income, net	56	34
Income before taxes	1,115	678
Income tax provision	409	257
<b>Net income</b>	<b>\$ 706</b>	<b>\$ 421</b>
<b>Earnings per share</b>		
Basic	\$ 0.67	\$ 0.40
Diluted	\$ 0.66	\$ 0.39
Shares used to compute basic earnings per share	1,053	1,054
Shares used to compute diluted earnings per share	1,071	1,075



**GENENTECH, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

*(In millions)*

*(Unaudited)*

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 706	\$ 421
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	106	96
Employee stock-based compensation	100	74
Deferred income taxes	(81)	(50)
Deferred revenue	(15)	10
Litigation-related liabilities	13	13
Excess tax benefit from stock-based compensation arrangements	(99)	(49)
Gain on sales of securities available-for-sale and other, net	(8)	(3)
Write-down of securities available-for-sale and other	3	-
Loss on property and equipment dispositions	11	-
Changes in assets and liabilities:		
Receivables and other current assets	(31)	(96)
Inventories	(115)	(86)
Investments in trading securities	(9)	(7)
Accounts payable, other accrued liabilities, and other long-term liabilities	179	139
<b>Net cash provided by operating activities</b>	<b>760</b>	<b>462</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(122)	(454)
Proceeds from sales of securities available-for-sale	37	75
Proceeds from maturities of securities available-for-sale	126	118
Capital expenditures	(209)	(253)
Change in other intangible and long-term assets	31	(13)
<b>Net cash used in investing activities</b>	<b>(137)</b>	<b>(527)</b>
<b>Cash flows from financing activities</b>		
Stock issuances	174	89
Stock repurchases	(392)	(227)
Excess tax benefit from stock-based compensation arrangements	99	49
<b>Net cash used in financing activities</b>	<b>(119)</b>	<b>(89)</b>
Net increase (decrease) in cash and cash equivalents	504	(154)
Cash and cash equivalents at beginning of period	1,250	1,225
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,754</b>	<b>\$ 1,071</b>
<b>Supplemental cash flow data</b>		
Cash paid during the period for:		
Interest	\$ 42	\$ 42
Income taxes	163	6
Non-cash investing and financing activities		

Capitalization of construction in progress related to financing lease transactions

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*See Notes to Condensed Consolidated Financial Statements.*

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**GENENTECH, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In millions)

(Unaudited)

	March 31, 2007	December 31, 2006
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 1,754	\$ 1,250
Short-term investments	1,149	1,243
Accounts receivable—product sales (net of allowances: 2007-\$94; 2006-\$92; including amounts from related parties: 2007-\$113; 2006-\$56)	1,077	965
Accounts receivable—royalties (including amounts from related parties: 2007-\$340; 2006-\$316)	481	453
Accounts receivable—other (including amounts from related parties: 2007-\$56; 2006-\$150)	134	248
Inventories	1,297	1,178
Deferred tax assets	293	278
Prepaid expenses and other current assets	100	89
<b>Total current assets</b>	<b>6,285</b>	<b>5,704</b>
Long-term marketable debt and equity securities	1,889	1,832
Property, plant and equipment, net	4,353	4,173
Goodwill	1,315	1,315
Other intangible assets	449	476
Restricted cash and investments	788	788
Other long-term assets	609	554
<b>Total assets</b>	<b>\$ 15,688</b>	<b>\$ 14,842</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable (including amounts to related parties: 2007-\$15; 2006-\$7)	\$ 420	\$ 346
Deferred revenue	57	62
Taxes payable	338	111
Other accrued liabilities (including amounts to related parties: 2007-\$126; 2006-\$136)	1,263	1,491
<b>Total current liabilities</b>	<b>2,078</b>	<b>2,010</b>
Long-term debt	2,267	2,204
Deferred revenue	189	199
Litigation-related and other long-term liabilities	1,006	951
<b>Total liabilities</b>	<b>5,540</b>	<b>5,364</b>
Commitments and contingencies		
Stockholders' equity		
Common stock	21	21
Additional paid-in capital	10,422	10,091
Accumulated other comprehensive income	212	204
Accumulated deficit, since June 30, 1999	(507)	(838)
<b>Total stockholders' equity</b>	<b>10,148</b>	<b>9,478</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 15,688</b>	<b>\$ 14,842</b>



**GENENTECH, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
*(Unaudited)*

**Note 1. Summary of Significant Accounting Policies**

***Basis of Presentation***

We prepared the Condensed Consolidated Financial Statements following the requirements of the Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (or “GAAP”) can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Consolidated Financial Statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2006. 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.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those expected for the full year or any future period.

***Principles of Consolidation***

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

***Use of Estimates and Reclassifications***

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

Certain reclassifications of prior period amounts have been made to our condensed consolidated financial statements to conform to the current period presentation.

***Recent Accounting Pronouncements***

On January 1, 2007, we adopted Emerging Issues Task Force (or “EITF”) Issue No. 06-2, “*Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43, Accounting for Compensated Absences*” (or “EITF 06-2”). Prior to the adoption of EITF 06-2, we recorded a liability for a sabbatical leave when the employee vested in the benefit, which was only at the end of a six-year service period. Under EITF 06-2, we accrue an estimated liability for a sabbatical leave over the requisite six-year service period, as the employee’s services are rendered. Upon our adoption of EITF 06-2 we recorded an adjustment to accumulated deficit of \$26 million, net of tax, as a cumulative effect of a change in accounting principle.

On January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, “*Accounting for Uncertainty in Income Taxes*” (or “Interpretation 48”). Implementation of Interpretation 48 did not result in a cumulative adjustment to accumulated deficit. The total amount of unrecognized tax benefits as of the date of adoption was \$147 million. Of this total, \$112 million represents the amount of unrecognized tax benefits that, if recognized, would favorably affect our effective income tax rate in future periods. As a result of the implementation of Interpretation 48, we reclassified

\$147 million of unrecognized tax benefits from current liabilities to long-term liabilities as of January 1, 2007 and we also reclassified the balance as of December 31, 2006, for consistency, in the accompanying Condensed Consolidated Balance Sheets.

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We file income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. Substantially all U.S. federal income tax and all material state and local tax matters have been concluded for all years ended through December 31, 2000. The Internal Revenue Service (or "IRS") is currently examining our U.S. federal income tax returns for the years ended December 31, 2002 through 2004. As of March 31, 2007, the IRS has not proposed any adjustments. We are also currently under examination by several state jurisdictions. As of March 31, 2007, no material adjustments related to these examinations have been proposed.

We accrue tax-related interest expenses and include such expenses with income taxes in our condensed consolidated statements of income and financial position. We recognized approximately \$2 million in tax-related interest expense during the three months ended March 31, 2007 and had approximately \$10 million of tax-related interest accrued at January 1, 2007. Interest amounts are net of tax benefit. No penalties have been accrued.

### ***Revenue Recognition***

We recognize revenue from the sale of our products, royalties earned and contract arrangements. 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 of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 milligrams during the remainder of the 12-month period. Based on the current wholesale acquisition cost, the 10,000 milligrams 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 those patients who elect to enroll in the program. To calculate our deferred revenue, we estimate the number of patients who will receive free Avastin and the amount of free Avastin that we expect them to receive. 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 as free Avastin vials are delivered.

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

Basic earnings per share (or "EPS") are computed based on the weighted-average number of shares of our Common Stock outstanding. Diluted earnings per share 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 earnings per share computations (*in millions*):

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Numerator:</b>		
Net income	\$ 706	\$ 421
<b>Denominator:</b>		
Weighted-average shares outstanding used to compute basic earnings per share	1,053	1,054
Effect of dilutive stock options	18	21
	1,071	1,075

Weighted-average shares outstanding and dilutive securities used to compute diluted earnings per share

Outstanding employee stock options to purchase approximately 35 million shares of our Common Stock were excluded from the computation of diluted EPS for the first quarter of 2007 because the effect would have been anti-dilutive.

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**Comprehensive Income**

Comprehensive income is comprised of net income and other comprehensive income (or “OCI”). OCI includes certain changes in stockholders’ equity that are excluded from net income. Specifically, we include in OCI changes in the estimated fair value of derivatives designated as effective cash flow hedges and unrealized gains and losses on our available-for-sale securities. In accordance with our adoption of FAS 158 in 2006, the gains or losses and prior service costs or credits that arise during the period, but are not recognized as components of net periodic benefit cost, have been recognized in other comprehensive income.

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

	<b>March 31, 2007</b>		<b>December 31, 2006</b>	
Net unrealized gains on securities available-for-sale	\$	219	\$	214
Net unrealized losses on cash flow hedges		(1)		(4)
Post-retirement benefit obligation		(6)		(6)
Accumulated other comprehensive income	\$	212	\$	204

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

	<b>Three Months Ended March 31, 2007</b>		<b>2006</b>	
Net income	\$	706	\$	421
Increase in unrealized gains on securities available-for-sale		5		3
Increase (decrease) in unrealized gains on cash flow hedges		3		(1)
Comprehensive income, net of income taxes	\$	714	\$	423

**Derivative Instruments**

Our derivative instruments, designated as cash flow hedges, consist of foreign currency exchange options and marketable equity collars. At March 31, 2007, estimated net gains expected to be reclassified from accumulated OCI to “other income, net” during the next twelve months are \$3 million.

**Note 2. Employee Stock-Based Compensation****Stock-based Compensation Expense under FAS 123R**

Employee stock-based compensation expense recognized in the first quarters of 2007 and 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

	<b>Three Months Ended March 31, 2007</b>		<b>2006</b>	
Cost of sales (or “COS”)	\$	16	\$	-

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Research and development		38		33
Marketing, general and administrative		46		41
Total employee stock-based compensation expense	\$	100	\$	74

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As of March 31, 2007, total compensation cost related to unvested stock options not yet recognized was \$751 million, which is expected to be allocated to expense and production costs over a weighted-average period of 26 months.

The carrying value of inventory on our Condensed Consolidated Balance Sheets as of March 31, 2007 and 2006 includes employee stock-based compensation costs of \$71 million and \$16 million, respectively. During the first quarter of 2007, \$16 million of previously capitalized employee stock-based compensation costs were recognized in COS. Substantially all of the products sold during the first quarter of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs.

### *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 are as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Risk-free interest rate	4.6%	4.6%
Dividend yield	0.0%	0.0%
Expected volatility	27.0%	29.0%
Expected term (years)	4.6	4.2

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

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

#### *Inventories*

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

	<b>March 31, 2007</b>		<b>December 31, 2006</b>	
	\$		\$	
Raw materials and supplies	\$	117	\$	116
Work in process		889		818
Finished goods		291		244
Total	\$	1,297	\$	1,178

Included in work in process at March 31, 2007 and December 31, 2006 are approximately \$210 million and \$81 million, respectively, of Avastin inventories that were manufactured through manufacturing processes or at facilities awaiting regulatory licensure. The majority of these inventories were manufactured at our Oceanside facility for which we received U.S. Food and Drug Administration licensure on April 27, 2007.

**Note 4. Contingencies**

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

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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: (1) the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, (2) the first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens, (3) the first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with cyclophosphamide, vincristine, prednisone (or "CVP") chemotherapy, (4) the treatment of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy, and (5) for use in combination with methotrexate to reduce signs and symptoms in adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies. We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. 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.

On July 29, 2005, a former Genentech employee, whose employment ended in April 2005, filed a qui tam complaint under seal in the United States District Court for the District of Maine against Genentech and Biogen Idec, alleging violations of the False Claims Act and retaliatory discharge of employment. On December 20, 2005, the United States District Court filed notice of its election to decline intervention in the lawsuit. The complaint was subsequently unsealed and we were served on January 5, 2006. Genentech filed a motion to dismiss the complaint and on December 14, 2006, the Magistrate Judge assigned to the case issued a Recommended Decision on that motion, which is subject to review by the District Court Judge. The Magistrate Judge recommended that the False Claims Act portion of the complaint be dismissed, leaving as the only remaining claim against Genentech the plaintiff's retaliatory discharge claim. Plaintiff, Biogen Idec, and Genentech each subsequently filed objections with the District Court Judge concerning certain aspects of the Magistrate Judge's Recommended Decision. We are awaiting the District Court's decision on the Recommended Decision and the objections. The outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (or "COH") are parties to a 1976 agreement relating to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, we have entered into license agreements with various companies to make, use and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to the COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. On June 10, 2002, a jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, a jury voted to award the COH an additional \$200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and are included in the accompanying Condensed Consolidated Balance Sheets in "litigation-related and other long-term liabilities" at March 31, 2007 and December 31, 2006. 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 appeal to the California Supreme Court has been fully briefed and we are waiting to be assigned an oral argument date. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter. It may take longer than one year to resolve the matter.

We recorded \$13 million of accrued interest and bond costs related to the COH trial judgment in the first quarters of 2007 and 2006. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of \$788 million at March 31, 2007 and December 31, 2006 to secure the bond. These amounts are

reflected in “restricted cash and investments” in the accompanying Condensed Consolidated Balance Sheets. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results.

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On April 11, 2003, MedImmune, Inc. (or “MedImmune”) filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 (or “the ‘415 patent” or “Cabilly patent”) that we co-own with COH and under which MedImmune and other companies have been licensed and are paying royalties to us. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking a ruling that the ‘415 patent is invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the ‘415 patent on sales of its Synagis® antibody product, an injunction to prevent us from enforcing the ‘415 patent, an award of actual and exemplary damages, and other relief. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in our favor on all of MedImmune’s antitrust and unfair competition claims. On April 23, 2004, the District Court granted our motion to dismiss all remaining claims in the case. On October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. MedImmune filed a petition for certiorari with the United States Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune’s petition 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. The case is currently set for a status conference on June 4, 2007 in the District Court. The outcome of this matter cannot be determined at this time.

On May 13, 2005, a request was filed by a third party for reexamination of the ‘415 or Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent Office ordered reexamination of the ‘415 patent. On September 13, 2005, the Patent Office mailed an initial non-final Office action rejecting the claims of the ‘415 patent. We filed our response to the Office action on November 25, 2005. On December 23, 2005, a second request for reexamination of the ‘415 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 Office action in the merged proceeding, rejecting the claims of the ‘415 patent based on issues raised in the two reexamination requests. We filed our response to the Office action on October 30, 2006. On February 16, 2007, the Patent Office mailed a final Office action rejecting all thirty-six claims of the ‘415 patent. We intend to respond to the final Office action, to request continued reexamination, and, if necessary, to appeal the decision. The ‘415 patent, which expires in 2018, relates to methods we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. We have licensed the ‘415 patent to other companies and derive significant royalties from those licenses. The claims of the ‘415 patent remain valid and enforceable throughout the reexamination 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 disagrees with certain of our development decisions relating to humanized anti-CD20 products. Under our 2003 collaboration agreement with Biogen Idec, we believe that we are permitted under the agreement to proceed with further trials of certain humanized anti-CD20 antibodies, and Biogen Idec disagrees with our position. We continue to pursue a resolution of our differences, and 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 both 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 trials in order to obtain Biogen Idec’s approval. The outcome of this matter cannot be determined at this time.

On March 24, 2004, Dr. Kouros Dastgheib filed a lawsuit against Genentech in the U.S. District Court for the Eastern District of Pennsylvania. The lawsuit stems from Dastgheib’s claim that, based on a purported relationship

with Genentech in the mid-1990's, he is entitled to profits or proceeds from Genentech's Lucentis product. Dastgheib has asserted multiple claims for monetary damages, including a claim under an unjust enrichment theory that he is entitled to the entire net present value of projected Lucentis sales, which he claims is between approximately \$1.4 billion and \$4.1 billion. On November 8, 2006, a jury ruled unanimously against Dastgheib and in favor of Genentech on all claims, and final judgment was entered in Genentech's favor. On January 30, 2007,

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Dastgheib's motion for a new trial was denied in its entirety. Dastgheib did not appeal the judgment to the court of appeals, and accordingly the case is closed.

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

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

We issue additional shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that with respect to any issuance of 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 Roche will be no lower than 2% below the "Minimum Percentage" (as defined below), provided however, as long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, we will repurchase a sufficient number of shares of our Common Stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech Common Stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704 (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 Roche's request, we will repurchase shares of our Common Stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. Under the terms of the affiliation agreement, Roche's Minimum Percentage is 57.7% and Roche's ownership percentage is to be no lower than 55.7%. At March 31, 2007, Roche's ownership percentage was 55.7%.

### **Related Party Transactions**

We enter into transactions with our related parties, Roche Holdings AG and affiliates (or "Hoffmann-La Roche") and Novartis AG and other Novartis affiliates (or "Novartis"). The accounting policies we apply to our transactions with our related parties are consistent with those applied in transactions with independent third-parties.

In our royalty and supply arrangements with related parties, we are the principal, as defined under EITF Issue No. 99-19, "*Reporting Revenue Gross as a Principal versus Net as an Agent*" (or "EITF 99-19"), because we bear the manufacturing risk, general inventory risk, and the risk to defend our intellectual property. In circumstances where 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.

### *Hoffmann-La Roche*

We currently have no active profit sharing arrangements with Hoffmann-La Roche.

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

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Ex-U.S. product sales to Hoffmann-La Roche	\$ 264	\$ 58

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Royalties earned from Hoffmann-La Roche	\$	255	\$	167
Cost of sales on ex-U.S. product sales to Hoffmann-La Roche	\$	121	\$	49
Contract revenue from Hoffmann-La Roche	\$	30	\$	18

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R&D expenses incurred on joint development projects with Hoffmann-La Roche were \$58 million in the first quarter of 2007 and \$43 million in the first quarter of 2006. These expenses are partially reimbursable to us by Hoffmann-La Roche. In addition, these amounts include R&D expenses resulting from the net settlement of amounts owed to Hoffmann-La Roche on R&D development expenses it incurred on joint development projects, less amounts reimbursable by us on these respective projects.

### *Novartis*

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

We have an agreement with Novartis Pharma AG (a wholly-owned subsidiary of Novartis AG) under which Novartis Pharma AG has the exclusive right to develop and market Lucentis outside of 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 Pharma AG and Tanox, Inc., are co-developing Xolair in the U.S. and we and Novartis are co-promoting Xolair in the U.S. and both make certain joint and individual payments to Tanox; our joint and individual payments are in the form of royalties. We record all sales and cost of sales in the U.S. and Novartis markets the product in and records all sales and cost of sales in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages, and our U.S. and European profit sharing expenses are recorded as collaboration profit sharing expense.

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

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Ex-U.S. product sales to Novartis	\$ 2	\$ 1
Royalties earned from Novartis	\$ 5	\$ -
Cost of sales on ex-U.S. product sales to Novartis	\$ 3	\$ 1
Contract revenue from Novartis	\$ 40	\$ 10
Collaboration profit sharing expense to Novartis	\$ 47	\$ 43

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

R&D expenses incurred on joint development projects with Novartis were \$10 million in the first quarters of 2007 and 2006.

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

The effective income tax rate was 37% in the first quarter of 2007, as compared to 38% in the first quarter of 2006. The decrease in the income tax rate is primarily due to the extension of the federal R&D tax credit and an increase in the domestic manufacturing deduction in 2007.

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**Report of Independent Registered Public Accounting Firm**

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

We have reviewed the condensed consolidated balance sheet of Genentech, Inc. as of March 31, 2007, and the related condensed consolidated statements of income and cash flows for the three-month periods ended March 31, 2007 and 2006. 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, 2006, 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, 2007, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2006, 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 16, 2007

## 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, 2006.

#### *The Company*

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

#### *Major Developments in the First Quarter of 2007*

We primarily earn revenues and income and generate cash from product sales and royalty revenues. In the first quarter of 2007, our total operating revenues were \$2,843 million, an increase of 43% from \$1,986 million in the first quarter of 2006. Our net income was \$706 million, an increase of 68% from \$421 million in the first quarter of 2006.

During the first quarter of 2007, we established three major new collaborations giving us access to novel early stage drug products being developed as potential treatments for cancer, cardiovascular disease, and human growth hormone disorders. We entered into: (i) an exclusive worldwide license agreement with Seattle Genetics, Inc. for the development and commercialization of a humanized monoclonal antibody currently in Phase I clinical trials for multiple myeloma, chronic lymphocytic leukemia and non-Hodgkin's lymphoma, and a Phase II clinical trial for diffuse large B-cell lymphoma, (ii) a collaboration with BioInvent to co-develop and commercialize a monoclonal antibody currently in pre-clinical development for the potential treatment of cardiovascular disease, and (iii) a collaboration agreement with Altus to develop, manufacture and commercialize a subcutaneously administered, once-per-week formulation of human growth hormone, currently preparing for Phase II and Phase III clinical trials for patients with growth hormone deficiencies. We believe that these collaborations are an important complement to our internal R&D efforts.

On November 9, 2006, we and Tanox, Inc. announced that we entered into an agreement to acquire Tanox. On January 29, 2007, we and Tanox announced that we received a request for additional information from the U.S. Federal Trade Commission (or "FTC") in connection with the proposed acquisition. The second request extends the waiting period imposed by the Hart-Scott-Rodino Improvements Act of 1976. Assuming a successful and timely outcome from our interactions with the FTC, the absence of a material adverse effect, and the satisfaction of other closing conditions, we are now planning for the transaction to be completed within the third quarter of 2007.

#### *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 <http://www.gene.com>.



***Economic, Industry-wide, and Other 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, and/or new information about existing products or 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 near-term growth will depend on our ability to execute on recent product approvals, including Lucentis for the treatment of neovascular (wet) age-related macular degeneration (or “AMD”) and Avastin for the treatment of non-small cell lung cancer, and to successfully obtain U.S. Food and Drug Administration (or “FDA”) approvals for potential new indications for our existing products such as Avastin for the treatment of metastatic breast cancer and Rituxan for the treatment of immunological disorders.
- 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 biotherapeutics 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/or product recalls or withdrawals.
- We believe our business model is only sustainable with appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. The pricing of our products has received negative press coverage and public scrutiny. We will continue to meet with patient groups, payers and other stakeholders in the healthcare system to understand their issues and concerns. The future reimbursement environment for our products is uncertain.
- As the Medicare and Medicaid programs are the largest payers for our products, rules relating to coverage and reimbursement continue to represent an important area of focus. New regulations relating to hospital and physician payment continue to be implemented annually. To date, we have not seen any detectable effects of the new rules on our product sales, and we anticipate minimal effects on our revenues in 2007.
- Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. The manufacture of a biotherapeutic requires developing and maintaining a process to reliably manufacture and formulate the product at an appropriate scale, obtaining regulatory approval to manufacture the product, and is subject to changes in regulatory requirements or standards that may require modifications to the manufacturing process.
- 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.
- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection on one or more products could result in lost sales to competing products and may negatively affect our sales, royalty revenues and operating results. We are often involved in disputes over contracts and intellectual property and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.



## Marketed Products

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

*Avastin* (bevacizumab) is an anti-VEGF humanized antibody approved for use in combination with intravenous 5-fluorouracil based chemotherapy as a treatment for patients with first- 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 non-small cell lung cancer.

*Rituxan* (rituximab) is an anti-CD20 antibody which we commercialize with Biogen Idec, Inc. It is approved for:

- The treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin’s lymphoma, including retreatment and bulky disease;
- The first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy;
- The first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin’s lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisone) chemotherapy regimens;
- The treatment of patients with low-grade, CD20-positive, B-cell non-Hodgkin’s lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy; and
- Use in combination with methotrexate for reducing signs and symptoms in adult patients with moderately-to-severely active rheumatoid arthritis (or “RA”) who have had an inadequate response to one or more tumor necrosis factor antagonist therapies.

*Herceptin* (trastuzumab) is a humanized anti-HER2 antibody approved for use as an adjuvant treatment of node-positive breast cancer as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel for patients who have tumors that overexpress the human epidermal growth factor receptor 2 (or “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 breast cancer.

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

*Xolair* (omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis Pharma AG (or “Novartis”). Xolair is approved for adults and adolescents (12 years of age and above) 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 (or “EGFR”) signaling pathway. Tarceva is approved for the treatment of patients with locally advanced or metastatic non-small cell lung cancer 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, recombinant) is a tissue plasminogen activator (or “t-PA”) approved for the treatment of acute myocardial infarction (heart attack), acute ischemic stroke (blood clots in the brain) within three hours of the onset of symptoms and acute massive pulmonary embolism (blood clots in the lungs).

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

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

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

*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 Holding AG and affiliates (or “Hoffmann-La Roche”) on sales of:

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

Refer to Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for information regarding certain patent litigation matters.

### **Available Information**

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

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;
- our policies related to corporate governance, including Genentech’s Principles of Corporate Governance, Good Operating Principles (Genentech’s code of ethics applying to Genentech’s directors, officers and employees) as well as Genentech’s Code of Ethics applying to our CEO, CFO and senior financial officials; and
- the 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 upon our Condensed Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles (or “GAAP”). The preparation of these Condensed Consolidated Financial Statements requires management to make estimates, assumptions and judgments that affect the reported amounts in our Condensed Consolidated Financial Statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments



on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and we have established internal controls related to the preparation of these estimates. Actual results and the timing of the results could differ materially from these estimates.

We believe the following policies to be critical to understanding our financial condition, results of operations, and our expectations for 2007 because these policies require management to make significant estimates, assumptions and judgments about matters that are inherently uncertain.

### ***Contingencies***

We are currently, and have been, involved in certain legal proceedings, including patent infringement litigation. We are also involved in licensing and contract disputes, and other matters. Refer to Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on 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. Included in "litigation-related and other long-term liabilities" in the accompanying Condensed Consolidated Balance Sheets at March 31, 2007 is \$739 million, which represents our estimate of the costs for the current resolution of the City of Hope National Medical Center (or "COH") matter. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters different than previously estimated could have a material effect on our financial position or our results of operations in any one quarter.

### ***Revenue Recognition - Avastin U.S. Product Sales***

In February 2007, we launched the Avastin Patient Assistance Program, which is a voluntary program that enables eligible patients who have received 10,000 milligrams of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 milligrams during the remainder of the 12-month period. Based on the current wholesale acquisition cost, the 10,000 milligrams 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 household income criteria 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 those patients who elect to enroll in the program.

In order to make our estimate of the amount of free Avastin to be provided to patients under the 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 doctors and 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 make adjustments to these estimates, which could have a material effect on revenue and earnings in the period of adjustment. 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 as free Avastin vials are delivered. In the first quarter of 2007, we deferred a net amount of \$3 million of our Avastin sales, resulting in a total deferred revenue liability in connection with the Avastin Patient Assistance Program of \$12 million in our Condensed Consolidated Balance Sheets at March 31, 2007.

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

Revenues from U.S. product sales are 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

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Statements of Income as total product sales allowances have been relatively consistent at approximately six 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 are comprised of 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;
- Prompt pay sales discounts are credits granted to wholesalers for remitting payment on their purchases within established cash payment incentive periods;
- 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;
- 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; and
- Healthcare provider contractual chargebacks are the result of contractual commitments by us to provide products to healthcare providers at specified prices or discounts.

We believe that our estimates related to product returns allowances and wholesaler inventory management payments are not material amounts, based upon the historical levels of credits and allowances as a percentage of product sales. We believe 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 to be the only estimation that involves both material amounts and requires a higher degree of subjectivity and judgment necessary to account for the rebate allowances or accruals. As a result of the uncertainties involved in estimating rebate allowances and accruals, there is a likelihood that materially different amounts could be reported under different conditions or using different assumptions.

Our rebates are based upon 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 (including Medicaid) rebates 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, changes to 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 our rebate allowances and accruals estimation process provides a high degree of confidence in the amounts established and that the annual allowance amounts provided for would not vary by more than approximately 3% based on our estimate that our changes in rebate allowances and accruals estimates related to prior years have not exceeded 3%. To illustrate our sensitivity to changes in the rebate allowances and accruals process, as much as a 10% change in our annualized rebate allowances and accruals provision experienced to date in 2007 (which is in excess of three times the level of variability we have recently observed for rebates) would have an approximate \$18 million effect on our income before taxes (or approximately \$0.01 per share, after tax). The total rebate allowances and accruals recorded in our Condensed Consolidated Balance Sheets were \$61 million as of March 31, 2007.

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

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may need to adjust our estimates in future periods. As of March 31, 2007, our Condensed Consolidated Balance Sheets reflected estimated product sales allowance reserves and accruals totaling approximately \$149 million.

### ***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. Our estimate of royalty revenue and receivables in those instances is based upon communication with some licensees, historical information, forecasted sales trends and collectibility. Differences between actual royalty revenues and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. If the collectibility of a royalty amount is doubtful, royalty revenue is not recorded. In the case of receivables related to previously recognized royalty revenue which is subsequently determined to be uncollectible, the receivable is reserved for in the period in which the circumstances that make collectibility doubtful are determined. Historically, adjustments to our royalty receivables have not been material to our consolidated financial condition or results of operations.

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 (or “the ‘415 patent” or “Cabilly patent”), under which we receive royalty revenue on sales of products that are covered by the patent. The ‘415 patent, which expires in 2018, relates to methods we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. The U.S. Patent office is performing a reexamination of the patent and on February 16, 2007 issued a final Office action rejecting all thirty-six claims of the ‘415 patent. We intend to respond to the final Office action, to request continued reexamination, and, if necessary, to appeal the decision. The claims of the patent remain valid and enforceable throughout the reexamination and appeals processes. See also Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on our Cabilly patent reexamination. Cabilly patent royalties are generally due 60 days after quarter-end. Additionally, we pay COH a percentage of our ‘415 patent royalty revenue 60 days after the quarter in which we receive payments from our licensees. As of March 31, 2007, our Condensed Consolidated Balance Sheets included Cabilly patent receivables totaling approximately \$62 million and the related COH payable totaling approximately \$12 million.

### ***Income Taxes***

Income tax expense is based on income before taxes and is computed using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using 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. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years’ items, past and future levels of R&D spending, acquisitions, and changes in overall levels of income before taxes.

On January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, “*Accounting for Uncertainty in Income Taxes*” (or “Interpretation 48”). As a result of the implementation of Interpretation 48, we evaluated our income tax position and reclassified \$147 million of unrecognized tax benefits from current liabilities to long-term liabilities as of January 1, 2007 and we also reclassified the balance as of December 31, 2006, for consistency, in the accompanying Condensed Consolidated Balance Sheets.

### ***Inventories***



Inventories include currently marketed products manufactured under a new process or at facilities awaiting regulatory approval. These inventories are capitalized based on management's judgment of probable near-term regulatory approval. The valuation of inventory requires us to estimate the value of inventory that may become expired 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

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estimate, due to, among other potential factors, a 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.

***Employee Stock-Based Compensation***

On January 1, 2006, we began accounting for employee stock-based compensation in accordance with FAS 123R. 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 (or "Redemption") by Roche Holdings, Inc. (or "Roche"), there is limited historical information available to support our estimate of certain assumptions required to value our stock options. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. See also Note 2, "Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information.

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

	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2007</b>	<b>2006</b>	
Product sales	\$ 2,329	\$ 1,644	42%
Royalties	419	286	47
Contract revenue	95	56	70
Total operating revenues	2,843	1,986	43
Cost of sales	392	262	50
Research and development	610	374	63
Marketing, general and administrative	491	441	11
Collaboration profit sharing	252	226	12
Recurring charges related to redemption	26	26	-
Special items: litigation-related	13	13	-
Total costs and expenses	1,784	1,342	33
Operating income	1,059	644	64
Other income (expense):			
Interest and other income, net	74	53	40
Interest expense	(18)	(19)	(5)
Total other income, net	56	34	65
Income before taxes	1,115	678	64
Income tax provision	409	257	59
Net income	\$ 706	\$ 421	68
Earnings per share:			
Basic	\$ 0.67	\$ 0.40	68
Diluted	\$ 0.66	\$ 0.39	69
Cost of sales as a % of product sales	17%	16%	
Research and development as a % of operating revenues	21	19	
Marketing, general and administrative as a % of operating revenues	17	22	
Pretax operating margin	37	32	
Tax rate	37	38	

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

***Total Operating Revenues***

Total operating revenues increased 43% in the first quarter of 2007 from the comparable period in 2006. These increases were primarily due to higher product sales and royalty income, and are further discussed below.

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

	<b>Three Months Ended March 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>% Change</b>
Net U.S. Product Sales			
Avastin	\$ 533	\$ 398	34 %
Rituxan	535	477	12
Herceptin	311	290	7
Lucentis	211	-	*
Xolair	111	95	17
Tarceva	102	93	10
Nutropin products	91	87	5
Thrombolytics	68	59	15
Pulmozyme	52	49	6
Raptiva	24	21	14
Total U.S. product sales <sup>(1)</sup>	\$ 2,037	\$ 1,569	30
Net product sales to collaborators	292	75	289
Total product sales	\$ 2,329	\$ 1,644	42

\* Calculation not meaningful.

(1) The totals may not appear to sum due to rounding.

Total product sales increased 42% from the comparable period in 2006. Total U.S. product sales increased 30% to \$2,037 million in the first quarter of 2007 from the comparable period in 2006. This increase in U.S. sales over the comparable period was due to higher sales across all products, in particular higher sales of our oncology products and sales of Lucentis. Increased U.S. sales volume accounted for 88%, or \$417 million, of the increase in U.S. net product sales in the first quarter of 2007. Changes in net U.S. sales prices across the portfolio accounted for most of the remaining increase in net U.S. product sales in the first quarter of 2007.

Our references below to market adoption and penetration are derived from our analyses of market tracking studies and surveys we undertake with physicians. We consider these tracking studies and surveys as indicative of trends and information with respect to our direct customers' buying patterns. We use statistical analyses to extrapolate the data we obtain and, as such, the adoption and penetration data presented herein represents estimates. Limitations in sample size and the timeliness in receiving and analyzing this data results in inherent margins of error, thus we have rounded our percentage estimates to the nearest five percent.

*Avastin*

Net U.S. sales of Avastin increased 34% to \$533 million in the first quarter of 2007 from the comparable period in 2006. Net U.S. sales in the first quarter of 2007 excluded \$3 million of revenue we deferred in connection with our Avastin Patient Assistance Program. Net U.S. sales in the first quarter of 2006 included a \$3 million reimbursement

for a shipment that was destroyed while in transit to a wholesaler. There have been no price increases on Avastin.

The increase in sales in the first quarter of 2007 from the first quarter of 2006 was primarily a result of increased use of Avastin in metastatic non-small cell lung cancer (or "NSCLC"), approved on October 11, 2006, and in metastatic breast cancer, an unapproved use of Avastin. Growth in metastatic NSCLC was due to greater post-launch penetration rates, and increased duration of treatment and higher dosing in the first quarter of 2007 as compared to the first quarter of 2006. We estimate that Avastin penetration was approximately 25% among first-line metastatic NSCLC patients in the first quarter of 2007, an increase from the adoption rate in the first quarter of 2006, and essentially flat compared to the fourth quarter of 2006. In first-line metastatic colorectal cancer (or "CRC") we estimate that penetration, duration of treatment and dosing remained flat in the first quarter of 2007 as compared to the first and fourth quarters of 2006. In second-line CRC we estimate that Avastin penetration was approximately 35% in the first quarter of 2007, essentially flat compared to the first quarter of 2006 and a decrease from

approximately 50% in the fourth quarter of 2006 due to increased competition. We anticipate that the major driver of Avastin growth for 2007 will continue to come from use in the first-line treatment of metastatic NSCLC.

On February 21, 2007, we and Hoffmann-La Roche announced the results of a Hoffmann-La Roche-sponsored Phase III study (BO17704) in NSCLC evaluating two different doses of Avastin in combination with gemcitabine and cisplatin chemotherapy compared to chemotherapy alone in patients with previously untreated, advanced NSCLC. This study evaluated a 15 mg/kg/every 3 weeks dose of Avastin (the dose approved in the U.S. for use in combination with carboplatin and paclitaxel) and a 7.5 mg/kg/every 3 weeks dose of Avastin (a dose not approved for use in the U.S.). Both doses met the primary endpoint of prolonging progression-free survival (or "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. In the first quarter of 2007, we estimate that approximately 75% of first-line NSCLC patients treated with Avastin received the approved dosage of Avastin. Once the BO17704 data is presented at the American Society of Clinical Oncology (or "ASCO") in June 2007, we may see an increase in the number of physicians who treat certain patients with lower doses. Efficacy data from BO17704 or other clinical studies conducted by any party in the U.S. or internationally (such as AVADO, Hoffmann-La Roche's study evaluating two doses of Avastin in first-line metastatic breast cancer patients), showing or perceiving to show a similar or an improved treatment benefit at a lower dose or shorter duration of therapy could negatively affect future sales of Avastin.

#### *Rituxan*

Net U.S. sales of Rituxan increased 12% to \$535 million in the first quarter of 2007 from the comparable period in 2006. The sales growth resulted from increased use of Rituxan in rheumatoid arthritis, approved on February 28, 2006, and use of Rituxan following first-line therapy in indolent non-Hodgkin's lymphoma (or "NHL"), including areas of unapproved uses. Also contributing to the increase in product sales were price increases effective on March 29, 2006 and October 5, 2006. 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. We estimate that Rituxan's overall adoption rate in combined markets of NHL, including areas of unapproved use, and chronic lymphocytic leukemia (or "CLL"), an unapproved use, remained flat in the first quarter of 2007 and throughout 2006.

Net U.S. sales of Rituxan decreased 4% in the first quarter of 2007 from the fourth quarter of 2006. Rituxan's channel inventory finished the 2006 year at the upper level of our distributors' target range, adding approximately \$10 million to \$12 million to 2006 sales. At the end of the first quarter of 2007, Rituxan's channel inventory was at the mid level of our distributors' target range.

#### *Herceptin*

Net U.S. sales of Herceptin increased 7% to \$311 million in the first quarter of 2007 from the comparable period in 2006. The sales growth resulted from increased use of Herceptin in the treatment of early stage HER2-positive breast cancer, approved on November 16, 2006. In early stage HER2-positive breast cancer patients we estimate that Herceptin penetration was approximately 65% in the first quarter of 2007, a slight increase from the adoption rate in the first quarter of 2006. In first-line HER2-positive metastatic breast cancer we estimate that penetration and duration of treatment remained flat in the first quarter of 2007 as compared to the first and fourth quarters of 2006. Contributing to the increase in product sales were price increases effective on March 29, 2006 and October 3, 2006. Net U.S. sales in the first quarter of 2006 include a \$2 million reimbursement for a shipment that was destroyed while in transit to a wholesaler.

We expect the U.S. sales growth rate for Herceptin to be lower in 2007 relative to 2006 now that the large pool of patients who were put on therapy in the months after the adjuvant data were released have completed therapy. We believe that Herceptin sales growth will depend on increased penetration in the adjuvant setting and increased duration

of treatment.

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*Lucentis*

Lucentis was approved by the FDA for the treatment of neovascular (wet) age-related macular degeneration (or “AMD”) on June 30, 2006. Net U.S. sales were \$211 million in the first quarter of 2007, as compared to \$217 million in the fourth quarter of 2006. We believe the decrease in the first quarter of 2007 as compared to the fourth quarter of 2006 was the result of less frequent dosing of newly diagnosed and existing Lucentis patients. We believe that sales growth will depend on increased penetration in newly diagnosed patients (including gains against the unapproved use of Avastin in this setting). Growth may also be affected by frequency of dosing and duration of treatment.

*Xolair*

Net U.S. sales of Xolair increased 17% to \$111 million in the first quarter of 2007 from the comparable period in 2006. The sales growth was primarily driven by increased penetration in the asthma market and, to a lesser extent, price increases effective on April 4, 2006 and October 17, 2006. We believe that first quarter 2007 sales were modestly affected by the FDA’s request that we strengthen the existing warning on the potential risk for anaphylaxis in patients receiving Xolair by adding a boxed warning to the product label and implementing a Risk Minimization Action Plan (or “RiskMAP”), including providing a medication guide for patients. We and Novartis, our co-promotion collaborator, are continuing to work with the FDA on the final wording and placement of the information in the Xolair label and the terms of the RiskMAP.

*Tarceva*

Net U.S. sales of Tarceva increased 10% to \$102 million in the first quarter of 2007 from the comparable period in 2006. The growth was primarily due to a price increase effective on November 14, 2006, and to a lesser extent, an increase in duration of treatment in second-line NSCLC. In first- and second-line pancreatic cancer, we observed that penetration decreased at the end of the first quarter of 2007 as compared to the end of the first and fourth quarters of 2006. In second-line NSCLC we observed that penetration decreased at the end of the first quarter of 2007 as compared to the end of first quarter of 2006 and remained flat compared to the fourth quarter of 2006. Future sales growth in NSCLC will depend on an increase in duration of therapy and in penetration, particularly against chemotherapy within select second-line NSCLC patient subsets.

*Nutropin Products*

Combined net U.S. sales of our Nutropin products increased 5% to \$91 million in the first quarter of 2007 from the comparable period in 2006. The increase primarily resulted from favorable product distribution agreements that resulted in lower rebate reserves rates and, to a lesser extent, price increases effective January 10, 2006 and March 1, 2007.

Net U.S. sales of Nutropin products decreased 10% in the first quarter of 2007 from the fourth quarter of 2006, due to declining new patient market share and the loss of managed care product placement due to price discounting by competitors.

*Thrombolytics*

Combined net U.S. sales of our three thrombolytic products, Activase, Cathflo Activase, and TNKase, increased 15% to \$68 million in the first quarter of 2007 from the comparable period in 2006. The increase was primarily due to growth in Cathflo Activase sales in the catheter clearance market and increased Activase sales in the acute ischemic stroke market, partially offset by lower sales of TNKase. Also contributing to the increase in product sales were price increases effective on February 14, 2006, July 6, 2006, and January 18, 2007.





### *Pulmozyme*

Net U.S. sales of Pulmozyme increased 6% to \$52 million in the first quarter of 2007 from the comparable period in 2006. The increase primarily reflected a price increase effective on June 29, 2006, and, to a lesser extent, increased penetration in certain patient segments.

### *Raptiva*

Net U.S. sales of Raptiva increased 14% to \$24 million in the first quarter of 2007 from the comparable period in 2006. The growth was primarily due to a price increase effective on August 10, 2006.

### *Sales to Collaborators*

Product sales to collaborators, predominantly for use in non-U.S. markets, increased 289% to \$292 million in the first quarter of 2007 from the comparable period in 2006. The increase was primarily due to more favorable Herceptin pricing terms that were part of the new Hoffmann-La Roche supply agreement signed in the third quarter of 2006 and higher sales of Herceptin, Avastin and Rituxan to Hoffmann-La Roche. The favorable Hoffmann-La Roche Herceptin pricing terms will continue through the end of 2008.

For the full year 2007, we expect sales to collaborators to approximately double relative to 2006 levels.

### *Royalties*

Royalty revenues increased 47% to \$419 million in the first quarter of 2007 from the comparable period in 2006. The increase was primarily due to higher sales by F. Hoffmann-La Roche of our Herceptin, Avastin and Rituxan products. Of the overall royalties received, royalties from F. Hoffmann-La Roche represented approximately 61% in the first quarter of 2007 as compared to 58% in the first quarter of 2006. Royalties from other licensees include royalty revenue on our patent licenses, including our Cabilly patents noted below.

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 and No. 4,816,567 (or the “Cabilly patents”), under which we receive royalty revenue on sales of products that are covered by one or more of the Cabilly patents. The ‘567 patent expired in March 2006, while the ‘415 patent expires in December 2018. The licensed products for which we receive the most significant Cabilly royalties are Humira®, Remicade®, Synagis®, and ERBITUX®. Cabilly royalties affect three lines on our Condensed Consolidated Statement of Income: (i) We record gross royalties we receive from Cabilly patent licensees as royalty revenue; (ii) On royalties we receive from Cabilly licensees, we in turn pay COH a percentage of our royalty revenue and these payments to COH are recorded with our marketing, general and administrative (or “MG&A”) expenses as royalty expense; (iii) We pay royalty expenses directly to COH on sales of our products that are covered by the Cabilly patents and these payments to COH are recorded in cost of sales. The overall net pre-tax contribution from revenues and expenses related to the Cabilly patents was approximately \$32 million in the first quarter of 2007 or approximately \$0.02 per diluted share. See also Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on our Cabilly patent reexamination.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase simple foreign currency put option contracts (or “options”) and forwards to hedge these foreign currency cash flows. These options and forwards are due to expire throughout 2007 and 2008.

For the full year 2007, we expect royalty revenue to increase approximately 25% over 2006 levels of \$1,354 million; however, royalties are difficult to forecast because of the number of licensees and products involved, and potential licensing and intellectual property disputes.

***Contract Revenues***

Contract revenues increased 70% to \$95 million in the first quarter of 2007 from the comparable period in 2006. The increase was primarily due to recognition of a \$30 million milestone payment from Novartis Pharma AG for European Union

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approval of Lucentis for the treatment of patients with AMD and higher reimbursements from Hoffmann-La Roche related to R&D development efforts on Avastin. See “Related Party Transactions” below for more information on contract revenue from Hoffmann-La Roche and Novartis.

Contract revenues vary each quarter and are dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones and opt-in payments received, and new contract arrangements. For the full year 2007, we expect contract revenues to be relatively flat as compared to \$290 million in 2006.

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

Cost of sales (or “COS”) as a percentage of product sales was 17% in the first quarter of 2007 compared to 16% in the first quarter of 2006. The increase was due to the recognition of \$16 million of employee stock-based compensation expense related to products sold for which employee stock-based compensation expense was previously capitalized as part of inventory costs upon adoption of FAS 123R on January 1, 2006, and to higher volume of lower margin sales to collaborators. COS as a percentage of product sales was favorably affected by improved manufacturing performance, favorable U.S. product sales mix (increased sales of our higher margin products, primarily Lucentis, Avastin, and Herceptin in the first quarter of 2007) and price increase on sales of Herceptin to Roche.

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

Research and development (or “R&D”) expenses increased 63% to \$610 million in the first quarter of 2007 from the comparable period in 2006. A significant portion of the increase in R&D expenses was due to \$110 million of in-licensing expense for new collaborations with Seattle Genetics, BioInvent, and Altus. The higher levels of expenses also reflected increased development activity across our entire product portfolio, including increased spending on clinical trials (notably Avastin, Rituxan Immunology, and humanized anti-CD20) and early stage projects, higher clinical manufacturing expenses in support of early development and development pipeline, as well as higher research expenses due to increased headcount and headcount related expenses.

R&D as a percentage of operating revenues was 21% in the first quarter of 2007 as compared to 19% in the first quarter of 2006.

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

<b><u>Research and Development</u></b>	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2007</b>	<b>2006</b>	
Product development (including post-marketing)	\$ 390	\$ 283	38%
Research	89	74	20
In-licensing	131	17	671
Total R&D	\$ 610	\$ 374	63

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

Marketing, general and administrative (or “MG&A”) expenses increased 11% to \$491 million in the first quarter of 2007 from the comparable period in 2006. The increase was primarily due to: (i) an increase in royalty expense, primarily to Biogen Idec resulting from higher Hoffmann-La Roche sales of Rituxan, (ii) an increase in corporate expenses, including charitable donations and losses on fixed asset disposals, and (iii) an increase in marketing and sales expense primarily in support of post-launch activities related to Lucentis, Rituxan Immunology, and Herceptin (adjuvant setting).

MG&A as a percentage of operating revenues was 17% in the first quarter of 2007 as compared to 22% from the comparable period in 2006.

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**Collaboration Profit Sharing**

Collaboration profit sharing expenses increased 12% to \$252 million in the first quarter of 2007 from the comparable period in 2006 due to higher sales of Tarceva, Xolair and Rituxan and the related profit sharing expenses.

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>2007</b>		<b>2006</b>	
U.S. Rituxan profit sharing expense	\$	166	\$ 151	10%
U.S. Tarceva profit sharing expense		39	32	22
U.S. and ex-U.S. Xolair profit sharing expense		47	43	9
Total collaboration profit sharing expense	\$	252	\$ 226	12

Currently, our most significant collaboration profit sharing agreement is with Biogen Idec, with whom 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 in 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 royalty revenue on sales of Rituxan by collaborators. 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% of operating profits. 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% of operating profits.

Collaboration profit sharing expense, exclusive of research and development expenses, related to Biogen Idec for the periods ended March 31, 2007 and 2006, consisted of the following (*in millions*):

	<b>Three Months Ended March 31,</b>			<b>% Change</b>
	<b>2007</b>		<b>2006</b>	
Product sales, net	\$	535	\$ 477	12%
Combined commercial and manufacturing costs and expenses		130	115	13
Combined co-promotion profits	\$	405	\$ 362	12
Amount due to Biogen Idec for their share of co-promotion profits - included in collaboration profit sharing expense	\$	166	\$ 151	10

Biogen Idec's relative share of combined commercial costs determines the amount shown as collaboration profit sharing expense, exclusive of research and development expenses.

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

**Three Months**

	<b>Ended March 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>% Change</b>
Contract revenue from Biogen Idec (R&D reimbursement)	\$ 21	\$ 17	24%
Royalty expense on ex-U.S. sales of Rituxan and other patent costs - included in MG&A expense	\$ 56	\$ 35	60

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**Recurring Charges Related to Redemption**

We recorded recurring charges related to the June 1999 redemption of our Special Common Stock and push-down accounting. These charges were \$26 million in the first quarters of 2007 and 2006, and were comprised of the amortization of Redemption-related other intangible assets in the periods presented.

On June 30, 1999, Roche Holdings Inc., (a wholly owned subsidiary of Roche Holding AG) exercised its option to cause us to redeem all of our Special Common Stock held by stockholders other than Roche. The Redemption was reflected as a purchase of a business, which under U.S. generally accepted accounting principles required push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value.

**Special Items: Litigation-Related**

We recorded \$13 million of accrued interest and bond costs related to the COH trial judgment in the first quarters of 2007 and 2006. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results. The amount of cash to be paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter. It may take longer than one year to resolve this matter. See Note 4, "Contingencies," in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding our litigation.

**Operating Income**

Operating income was \$1,059 million in the first quarter of 2007, a 64% increase from the first quarter of 2006. Our operating income as a percentage of operating revenues (or "pretax operating margin") was 37% in the first quarter of 2007 and 32% in the first quarter of 2006.

**Other Income (Expense)**

The components of "other income (expense)" are as follows (*in millions*):

<b>Other Income, Net</b>	<b>Three Months Ended March 31,</b>		<b>% Change</b>
	<b>2007</b>	<b>2006</b>	
Gains on sales of biotechnology equity securities and other	\$ 8	\$ 3	167%
Write-downs of biotechnology debt, equity securities and other	(3)	-	-
Interest income	69	49	41
Interest expense	(18)	(19)	(5)
Other miscellaneous income	-	1	(100)
Total other income, net	\$ 56	\$ 34	65

Other income, net, increased 65% to \$56 million in the first quarter of 2007 over the comparable period in 2006. Interest income increased primarily due to higher yields and higher average cash balances in the first quarter of 2007 from the comparable period in 2006.

**Income Tax Provision**



The effective income tax rate was 37% in the first quarter of 2007, as compared to 38% in the first quarter of 2006. The decrease in the income tax rate was primarily due to the extension of the federal R&D tax credit and an increase in the domestic manufacturing deduction in 2007.

We adopted the provisions of Interpretation 48 on January 1, 2007. Implementation of Interpretation 48 did not result in any adjustment to our condensed consolidated statements of income or a cumulative adjustment to accumulated deficit. As a result of the implementation of Interpretation 48, we reclassified \$147 million of unrecognized tax benefits from current liabilities to long-term liabilities as of January 1, 2007 and we also reclassified the balance as of December 31, 2006, for consistency, in the accompanying Condensed Consolidated

Balance Sheets, none of which would have been considered as due in 2007 in the presentation of our Contractual Obligations table in our Annual Report on Form 10-K for the year ended December 31, 2006.

## Liquidity and Capital Resources

(In millions)

	March 31, 2007	December 31, 2006
Unrestricted cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	\$ 4,792	\$ 4,325
Net receivable - equity hedge instruments	64	50
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	\$ 4,856	\$ 4,375
Working capital	\$ 4,207	\$ 3,694
Current ratio	3.0:1	2.8:1

Total unrestricted cash, cash equivalents, short-term investments and long-term marketable securities, including the fair value of the equity hedge instruments, were approximately \$4.9 billion at March 31, 2007, an increase of approximately \$480 million from December 31, 2006. This increase primarily reflects cash generated from operations and cash increases from stock option exercises; partially offset by cash used for repurchases of our Common Stock and capital expenditures. To mitigate the risk of market value fluctuation, certain of our biotechnology marketable equity securities are hedged with zero-cost collars and forward contracts, which are carried at fair value. See Note 1, "Summary of Significant Accounting Policies—Comprehensive Income," in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding activity in our marketable investment portfolio and derivative instruments.

See "Our affiliation agreement with Roche Holdings, Inc. could adversely affect our cash position" among other risk factors below in Part II, Item 1A "Risk Factors" of this Form 10-Q, and "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q, for factors that could negatively affect our cash position.

### Cash Provided by Operating Activities

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

Our "accounts receivable—product sales" was \$1,077 million at March 31, 2007, an increase of \$112 million from December 31, 2006. The increase is primarily due to higher product sales of Avastin and higher sales of Herceptin and Avastin to Hoffmann-La Roche. The average collection period of our "accounts receivable—product sales" as measured in days sales outstanding (or "DSO") was 42 days for the first quarter 2007, compared to 34 days in the first quarter of 2006. The increase from the first quarter of 2006 is primarily due to the extended payment terms we offered to certain wholesalers in conjunction with the launch of Lucentis on June 30, 2006. This program is planned to be in effect for 12 months following the launch date; therefore, we currently expect our DSO to decrease during the second half of 2007.

Our inventory balance was \$1,297 million at March 31, 2007, an increase of \$119 million from December 31, 2006. The increase was primarily due to bulk campaign production of our Avastin and Herceptin products.

Accounts payable, other accrued liabilities and other long-term liabilities increased \$179 million in the first quarter of 2007. This increase is mainly due to increases in taxes payable, accrued royalties and accrued marketing expenses, which are mainly due to the growth in the business; partially offset by decreases in accrued compensation and other liabilities due to payments made during the first quarter of 2007.

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***Cash Used in Investing Activities***

Cash used in investing activities was primarily related to purchases, sales and maturities of investments and capital expenditures. Capital expenditures were \$209 million during the first quarter of 2007 compared to \$253 million during the first quarter of 2006. Capital expenditures in the first quarter of 2007 included ongoing construction of our second manufacturing facility in Vacaville, California, validation costs at our manufacturing facility in Oceanside, California, purchase of equipment and information systems, and ongoing expenditures to support our corporate infrastructure needs.

***Cash Used in Financing Activities***

Cash used in financing activities was primarily related to activities under our employee stock plans and our stock repurchase program. We used cash for stock repurchases of \$392 million during the first quarter of 2007 and \$227 million during the first quarter of 2006 pursuant to our stock repurchase program approved by our Board of Directors. We also received \$174 million during the first quarter of 2007 and \$89 million during the first quarter of 2006 related to stock option exercises and stock issuances under our employee stock plans. The excess tax benefits from stock-based compensation arrangements were \$99 million in the first quarter of 2007 and \$49 million in the first quarter of 2006.

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2007, we are authorized to repurchase up to 100,000,000 shares of our Common Stock for an aggregate price of up to \$8.0 billion through June 30, 2008. 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, 2007, 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 plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage; (ii) to make prudent investments of our cash resources; and (iii) to allow for an effective mechanism to provide stock for our employee stock plans. See below in "Relationship with Roche" for more information on Roche's minimum ownership percentage.

We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately four million shares and is effective through June 30, 2007.

Our shares repurchased during the first quarter of 2007 were as follows (*shares in millions*):

	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>
January 1-31, 2007	3.0	\$ 87.33
February 1-28, 2007	0.9	86.54
March 1-31, 2007	0.6	82.33
Total	4.5	\$ 86.47

As of March 31, 2007, 67 million shares have been purchased under our stock repurchase program for \$4.8 billion, and a maximum of 33 million additional shares may be purchased under the program through June 30, 2008.

**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 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, 2006 that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operation, liquidity, capital expenditures or capital resources.

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### ***Contractual Obligations***

During the first quarter of 2007, we believe there have been no significant changes in our payments due under contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2006, except as noted above in Income Tax Provision.

### **Contingencies**

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

### **Relationship with Roche**

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

We issue additional shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that with respect to any issuance of 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 Roche will be no lower than 2% below the "Minimum Percentage" (as defined below), provided however, as long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, we will repurchase a sufficient number of shares of our Common Stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech Common Stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704, (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 Roche's request, we will repurchase shares of our Common Stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. Under the terms of the affiliation agreement, Roche's Minimum Percentage is 57.7% and Roche's ownership percentage is to be no lower than 55.7%. At March 31, 2007, Roche's ownership percentage was 55.7%.

### **Related Party Transactions**

We enter into transactions with our related parties, Roche Holding AG and affiliates (or "Hoffmann-La Roche") and Novartis AG and other Novartis affiliates (or "Novartis"). The accounting policies we apply to our transactions with our related parties are consistent with those applied in transactions with independent third-parties and all related party agreements are negotiated on an arm's-length basis.

In our royalty and supply arrangements with related parties, we are the principal, as defined under Emerging Issues Task Force Issue No. 99-19, "*Reporting Revenue Gross as a Principal Versus Net as an Agent*" (or "EITF 99-19"), because we bear the manufacturing risk, general inventory risk, and the risk to defend our intellectual property. In circumstances where 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.

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

We currently have no active profit sharing arrangements with Hoffmann-La Roche.

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

	<b>Three Months Ended March 31,</b>			
	<b>2007</b>		<b>2006</b>	
Ex-U.S. product sales to Hoffmann-La Roche	\$	264	\$	58
Royalties earned from Hoffmann-La Roche	\$	255	\$	167
Cost of sales on ex-U.S. product sales to Hoffmann-La Roche	\$	121	\$	49
Contract revenue from Hoffmann-La Roche	\$	30	\$	18

R&D expenses incurred on joint development projects with Hoffmann-La Roche were \$58 million in the first quarter of 2007 and \$43 million in the first quarter of 2006. These expenses are partially reimbursable to us by Hoffmann-La Roche. In addition, these amounts include R&D expenses resulting from the net settlement of amounts owed to Hoffmann-La Roche on R&D development expenses it incurred on joint development projects, less amounts reimbursable by us on these respective projects.

#### **Novartis**

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

We have an agreement with Novartis Pharma AG (a wholly-owned subsidiary of Novartis AG) under which Novartis Pharma AG has the exclusive right to develop and market Lucentis outside of 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 Pharma AG and Tanox, Inc., are co-developing Xolair in the U.S., and we and Novartis are co-promoting Xolair in the U.S. and both make certain joint and individual payments to Tanox; our joint and individual payments are in the form of royalties. We record all sales and cost of sales in the U.S. and Novartis markets the product in and records all sales and cost of sales in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages, and our U.S. and European profit sharing expenses are recorded as collaboration profit sharing expense.

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

	<b>Three Months Ended March 31,</b>			
	<b>2007</b>		<b>2006</b>	
Ex-U.S. product sales to Novartis	\$	2	\$	1
Royalties earned from Novartis	\$	5	\$	-
Cost of sales on ex-U.S. product sales to Novartis	\$	3	\$	1



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Contract revenue from Novartis	\$	40	\$	10
Collaboration profit sharing expense to Novartis	\$	47	\$	43

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

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R&D expenses incurred on joint development projects with Novartis were \$10 million in the first quarters of 2007 and 2006.

## 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 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.

### *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, 2005</b>	83.7	82.8	\$ 46.64
Grants	(17.5)	17.5	79.85
Exercises	-	(9.5)	30.42
Cancellations	2.5	(2.5)	62.09
<b>December 31, 2006</b>	68.7	88.3	\$ 54.53
Grants	(0.3)	0.3	84.72
Exercises	-	(4.8)	30.75
Cancellations	0.6	(0.6)	71.63
<b>March 31, 2007 (Year to date)</b>	69.0	83.2	\$ 55.88

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

As of March 31, 2007	Exercisable		Unexercisable		Total	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
In-the-Money	40	\$ 33.70	25	\$ 68.91	65	\$ 47.42
Out-of-the-Money <sup>(1)</sup>	6	\$ 86.25	12	\$ 86.16	18	\$ 86.19
<b>Total Options Outstanding</b>	<b>46</b>		<b>37</b>		<b>83</b>	

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(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, \$82.12, at the close of business on March 30, 2007.

***Dilutive Effect of Options***

Grants, net of cancellations, as a percentage of outstanding shares, were (0.03)% for the first quarter of 2007, 1.43% for the year ended December 31, 2006 and 1.70% for the year ended December 31, 2005.

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***Equity Compensation Plan Information***

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

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This report contains forward-looking statements regarding our Horizon 2010 strategy of bringing 20 new molecules into clinical development, 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; Avastin, Herceptin, Lucentis and Tarceva sales growth; sales to collaborators; royalty and contract revenue; the effects of the Medicare Prescription Drug Improvement and Modernization Act on our revenues; days of sales outstanding; and the acquisition of Tanox.

These forward-looking statements involve risks and uncertainties, and the cautionary statements set forth below and those contained in "Risk Factors" in this 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, additional time requirements for data analysis; BLA preparation and decision making; FDA actions or delays; failure to obtain FDA approval; difficulty in obtaining materials from suppliers; unexpected safety, efficacy or manufacturing issues for us or our contract/collaborator manufacturers; the ability to supply product; product withdrawals; competition; 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 cost of sales; variations in collaborator sales and expenses; actions by Roche that are adverse to our interests; decreases in third party reimbursement rates; and the extent to which all closing conditions are met for our proposed acquisition of Tanox including the absence of a material adverse effect with respect to the transaction and the expiration of any waiting periods under antitrust laws. We disclaim and do not undertake any obligation to update or revise any forward-looking statement in this Form 10-Q.

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

Our market risks at March 31, 2007 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2006 on file with the Securities and Exchange Commission. See also Note 1, “Summary of Significant Accounting Policies—Derivative Financial Instruments” section in the Notes to Condensed Consolidated Financial Statements in Part I of this Form 10-Q.

**Item 4. Controls and Procedures**

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

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

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

See Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for a description of legal proceedings as well as certain other matters.

See also Item 3 of our report on Form 10-K for the year ended December 31, 2006.

### Item 1A. Risk Factors

This Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements 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 revenues, expenses, net income and earnings per share.

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

Successful development of biotherapeutics 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 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 (or “BLA”) preparation, discussions with the U.S. Food and Drug Administration (or “FDA”), FDA requests for additional preclinical or clinical data, analyses or changes to study design, or unexpected safety, efficacy or manufacturing issues.
- Difficulties formulating the product, scaling the manufacturing process or in getting approval for manufacturing.
- Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being developed or commercialized.
- The contractual rights of our collaborators or others that may prevent the product from being developed or commercialized.

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

Factors affecting our research and development (or “R&D”) productivity and the amount of our R&D expenses include, but are not limited to:

- The number of and the outcome of clinical trials currently being conducted by us and/or our collaborators. For example, our R&D expenses may increase based on the number of late-stage clinical trials being conducted by us and/or our collaborators.
- The number of products entering into development from late-stage research. For example, there is no guarantee that internal research efforts will succeed in generating a sufficient number of candidate products 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 F. Hoffmann-La Roche (or “Hoffmann-La Roche”) whether to exercise its options to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
- 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 upfront fee for the purchase of in-process R&D, which we may record as an R&D expense.
- Participation in a number of collaborative research arrangements. On many of these collaborations, our share of expenses recorded in our financial statements is subject to volatility based on our collaborators’ spending activities as well as the mix and timing of activities between the parties.
- Charges incurred in connection with expanding our product manufacturing capabilities, as described in “Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively affect our financial performance” below.
- Future levels of revenue.

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

We are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA’s requirements covering R&D, testing, manufacturing, quality control, labeling and promotion of drugs for human use. A biotherapeutic cannot be marketed in the United States (or “U.S.”) until it has been approved by the FDA, and then can only be marketed for the indications approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a 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 regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and/or a product recall 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 in “The successful development of biotherapeutics is highly uncertain and requires significant expenditures and time” above.
- Loss of, or changes to, previously obtained approvals, including those resulting from post-approval safety or efficacy issues.
- Failure to comply with existing or future regulatory requirements.

- Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices (or “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, which may affect our ability to obtain or maintain approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

### **We face competition**

We face competition from pharmaceutical companies and biotechnology companies.

The introduction of new competitive products or follow-on biologics, and/or new information about existing products or 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.

*Avastin:* Avastin competes in metastatic colorectal cancer (or “CRC”) with Erbitux® (Imclone/Bristol-Myers Squibb), which is an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic CRC patients and Vectibix™ (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. In addition Avastin competes with: Nexavar® (sorafenib, Bayer Corporation/Onyx Pharmaceuticals, Inc.) and Sutent® (sunitinib malate, Pfizer, Inc.) for the treatment of patients with advanced renal cell carcinoma (or “RCC”) (an unapproved use of Avastin).

Avastin could face competition from products in development that currently do not have regulatory approval. Amgen has stated that it will initiate head-to-head clinical trials comparing AMG 706 and Avastin. There are also head-to-head clinical trials that have recently begun comparing both Sutent and AZD2171 (AstraZeneca) to Avastin. Additionally, there are more than 65 molecules that target VEGF inhibition, and over 130 companies that are developing molecules that, if approved, may compete with Avastin.

*Rituxan:* Rituxan’s current competitors in hematology-oncology include Bexxar® (GlaxoSmithKline (or “GSK”)) and Zevalin® (Biogen Idec), both of which are radioimmunotherapies indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin’s lymphoma (or “NHL”). Other potential competitors include Campath® (Bayer Corporation/Genzyme) in relapsed CLL (an unapproved use of Rituxan), Velcade® (Millennium Pharmaceuticals, Inc.) which is indicated for multiple myeloma and more recently, mantle cell lymphoma (both unapproved uses of Rituxan).

Rituxan’s current biologic competitors in rheumatoid arthritis (or “RA”) include Enbrel® (Amgen/Wyeth), Humira® (Abbott), Remicade® (Johnson & Johnson), Orencia® (Bristol-Myers Squibb), and Kineret® (Amgen). These products are approved for use in a broader RA patient population than the approved population for Rituxan. In addition, molecules in development that, if successful in clinical trials, may compete with Rituxan in RA include: Actemra, an anti-interleukin-6 antibody being developed by Chugai and Roche, certolizumab pegol (Cimzia™), an anti-TNF antibody being developed by UCB, and golimumab (CNTO 148), an anti-TNF antibody being developed by Centocor.

Rituxan may face future competition in both hematology-oncology and rheumatoid arthritis from Ofatumumab (Humax CD20™), an anti-CD20 antibody being co-developed by Genmab and GSK; Ofatumumab is in late-stage development for refractory CLL and NHL. In addition we are aware of other anti-CD20 molecules in development that, if successful in clinical trials, may compete with Rituxan.



*Herceptin*: Herceptin faces competition in the relapsed metastatic setting from lapatinib ditosylate (Tykerb®), manufactured by GlaxoSmithKline (or “GSK”). On March 13, 2007, the FDA approved Tykerb®, in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, or Herceptin.

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*Lucentis:* We are aware that retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration (or “AMD”), an unapproved use for Avastin, which results in significantly less revenue to us per treatment as compared to Lucentis. We expect Avastin use to continue in this setting. Additionally, the National Eye Institute and National Institute of Health announced plans to initiate a head-to-head trial of Avastin and Lucentis in this setting. Lucentis also competes with Macugen® (Pfizer/OSI Pharmaceuticals), and Visudyne® (Novartis) alone, in combination with Lucentis, or in combination with the off-label steroid triamcinolone in wet AMD. In addition, if successful in clinical trials, VEGF-Trap-Eye, a vascular endothelial growth factor blocker being developed by Bayer Corporation and Regeneron, may compete with Lucentis.

*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® (Sanofi-Aventis) and Alimta® (Eli Lilly and Company), both of which are indicated for the treatment of relapsed non-small cell lung cancer (or “NSCLC”). Recent increases in the off-label use of Avastin in combination with chemotherapy in second-line NSCLC have also had an impact in this setting. In front-line pancreatic cancer, Tarceva primarily competes with Gemzar® (Eli Lilly) monotherapy and Gemzar® in combination with other chemotherapeutic agents. Tarceva could also face competition in the future from products in late-phase development, such as Erbitux® (Bristol-Myers Squibb), and Xeloda® (Roche), that currently do not have regulatory approval for use in NSCLC or pancreatic cancer.

*Nutropin:* Nutropin faces competition in the growth hormone market, from other companies currently selling growth hormone products. Nutropin’s current competitors are Genotropin® (Pfizer), Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly and Company), Tev-Tropin® (Teva Pharmaceutical Industries Ltd.), and Saizen® (Serono, Inc.). In addition, follow-on biologics that are not therapeutically equivalent (not substitutable) for current growth hormone products are beginning to enter the market. In May 2006, the FDA approved the first follow-on version of a protein product, Omnitrope® (Sandoz), as a biologic similar to Genotropin® (Pfizer); Omnitrope launched in January of 2007. Cangene received an approvable letter from the FDA for its growth hormone Accretropin in March 2007 as a biologic similar to Humatrope®. Furthermore, as a result of multiple competitors, 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.

*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® (PDL BioPharma Inc.), which engages in competitive price discounting.

*Pulmozyme:* Pulmozyme faces competition from the use of hypertonic saline, an inexpensive approach to clearing the lungs of cystic fibrosis patients.

*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® (Astellas), Enbrel® (Amgen), and Remicade® (Centocor, Inc.). Raptiva also competes with the biologic agent Humira® (Abbott Laboratories), which is currently used off-label in the psoriasis market.

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



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

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

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

Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated for this purpose. It can take longer than five years to design, construct, validate, and license a new biotechnology manufacturing facility. We currently produce our products at our manufacturing facilities located in South San Francisco, 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 cancellations of shipments, loss of product in the process of being manufactured, a shortfall or 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 for manufacture of our products;
- equipment obsolescence, malfunctions or failures;
- product quality or contamination problems;
- damage to a facility, including our warehouses and distribution facilities, due to natural disasters, including, but not limited to, earthquakes as our South San Francisco, Oceanside and Vacaville facilities are located in areas where earthquakes occur;
- changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes;
- action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products we make for others;
- a contract manufacturer going out of business or failing to produce product as contractually required;
- failure to maintain an adequate state of GMP compliance; and
- implementation and integration of our new enterprise resource planning system, including the portions relating to manufacturing and distribution.

In addition, there are inherent uncertainties associated with forecasting future demand, especially for newly introduced products of ours or of those for whom we produce products, and as a consequence we may have inadequate capacity to meet our own actual demands and/or the actual demands of those for whom we produce product. Alternatively, we may have an excess of available capacity which could lead to an idling of a portion of our manufacturing facilities and incurring unabsorbed or idle plant charges, resulting in an increase in our costs of sales.

Furthermore, certain of our raw materials and supplies required for the production of our principal products or products we make for others are available only through sole-source suppliers (the only recognized supplier available to us) or single-source suppliers (the only approved supplier for us among other sources), and we may not be able to obtain such raw materials without significant delay or at all. If such sole-source or single-source suppliers were to limit or terminate production or otherwise fail to supply these materials for any reason, such failures could also have a material adverse 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 could 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 allowed in these companies' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material litigation and other legal proceedings relating to our proprietary rights, such as the Cabilly reexaminations discussed in Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities to third-parties. An adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third-parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

The presence of patents or other proprietary rights belonging to other parties may lead to our termination of the R&D of a particular product, 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 or other legal actions to which we are currently or have been subjected relates 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 or a judgment with significant monetary award, including the possibility of punitive damages, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in these proceedings and such matters could divert management's attention from ongoing business concerns.

Our activities relating to the sale and marketing of our products are subject to regulation under the U.S. Federal Food, Drug and Cosmetic Act and other federal statutes. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). In 1999 we agreed to pay \$50 million to settle a federal investigation relating to our past clinical, sales and marketing activities associated with human growth hormone. We are currently being investigated by the Department of Justice with respect to our promotional practices, and may in the future be investigated for our promotional practices relating to any of our products. If the government were to bring charges against or convict us of violating these laws, or if we were subject to third party litigation relating to the same promotional practices, there could be a material adverse effect on our business, including our financial condition and

results of operations.

We are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase

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

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

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

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

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, (ii) successfully integrate large numbers of new employees into our corporate culture, and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships or that the costs of retaining such personnel or maintaining such relationships will not materially increase.

**Other factors could affect our product sales**

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

- The timing of FDA approval, if any, of competitive products.
- Our pricing decisions, including a decision to increase or decrease the price of a product, 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 of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 milligrams during the remainder of the 12-month period.
- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party could cause the sales of our products to decrease or a product to be recalled 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.
- Efficacy data from clinical studies conducted by any party in the U.S. or internationally, showing or perceived to show, a similar or an improved treatment benefit at a lower dose or shorter duration of therapy could cause the sales of our products to decrease.





- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.
- The increasing use and development of alternate therapies.
- The rate of market penetration by competing products.
- Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers who supply our products.

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

**Our results of operations are affected by our royalty and contract revenues, and sales to collaborators**

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

- Hoffmann-La Roche's decisions whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
- Variations in Hoffmann-La Roche's sales and other licensees' sales of licensed products.
- The expiration or termination of existing arrangements with other companies and Hoffmann-La Roche, which may include development and marketing arrangements for our products in the U.S., Europe and other countries outside the U.S.
- The timing of non-U.S. approvals, if any, for products licensed to Hoffmann-La Roche and to other licensees.
- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Fluctuations in foreign currency exchange rates.
- The initiation of new contractual arrangements with other companies.
- Whether and when contract milestones are achieved.
- The failure of or refusal of a licensee to pay royalties.
- The expiration or invalidation of our patents or licensed intellectual property. For example, patent litigations, interferences, oppositions, and other proceedings involving our patents often include claims by third-parties that such patents are invalid, unenforceable, or unpatentable. If a court, patent office, or other authority were to determine that a patent (including, for example, the Cabilly patent) under which we receive royalties and/or other revenues is invalid, unenforceable, or unpatentable, that determination could cause us to suffer a loss of such royalties and/or revenues, and could cause us to incur other monetary damages.
- Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

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

Our affiliation agreement with Roche provides that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For more information on our stock repurchase program, see discussion in "Liquidity and Capital Resources—Cash Used in Financing Activities." See Note 5, "Relationship with Roche and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for information regarding the Minimum Percentage.

Roche'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 Form 10-Q for information regarding employee stock plans. In order to maintain Roche's Minimum Percentage, we repurchase shares of our Common Stock under the stock repurchase program. While the 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 Roche Holdings, Inc. could limit our ability to make acquisitions**

The affiliation agreement between us and Roche contains provisions that:

- Require the approval of the directors designated by Roche to make any acquisition or any sale or disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues.
- Enable Roche to maintain its percentage ownership interest in our Common Stock.
- Require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For information regarding Minimum Percentage, see Note 5, "Relationship with Roche and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

These provisions may have the effect of limiting our ability to make acquisitions.

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

As of March 31, 2007, Roche owned 587,189,380 shares of our Common Stock, or 55.7% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by Roche in the public market could adversely affect the market price of our Common Stock.

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

As our majority stockholder, Roche 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 Roche, three independent directors nominated by the nomination committee and one Genentech executive officer nominated by the nominations committee. Our bylaws also provide that Roche will have the right to obtain proportional representation on our board until such time that Roche owns less than 5% of our stock. Currently, three of our directors, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles, also serve

as officers and employees of Roche Holding Ltd and its affiliates. As long as Roche owns in excess of 50% of our Common Stock, Roche directors will comprise two of the three members of the nominations committee. Our certificate of incorporation includes provisions relating to competition by Roche affiliates with us, offering of

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corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of specified employees. We cannot assure that Roche will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, persons who are directors and/or officers of Genentech and who are also directors and/or officers of Roche may decline to take action in a manner that might be favorable to us but adverse to Roche.

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

### **We may incur material product liability costs**

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

### **Insurance coverage is increasingly more difficult and costly to obtain or maintain**

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

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

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

We also have acquired, and may continue to acquire in the future, land and buildings as we expand our operations. Some of these properties are “brownfields” for which redevelopment or use is complicated by the presence or potential presence of a hazardous substance, pollutant or contaminant. Certain events which 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:

- The overall competitive environment for our products as described in “We face competition” above.

- The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.

- The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the U.S. and the amount and timing of sales to their respective customers, which directly affects both our product sales and royalty revenues.
- The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of therapy.
- The extent of product discounts extended to customers.
- The 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 use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
- The potential introduction of new products and additional indications for existing products.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.
- Pricing decisions that we or our competitors have adopted or may adopt, as well as our Avastin Patient Assistance Program.

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

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

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

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

The following factors 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 relating to products under development or being commercialized by us or our competitors.
- Concerns about the pricing of our products, or our pricing initiatives (including our Avastin Patient Assistance Program), and the potential effect of such on their utilization or our product sales.
- Developments or outcome of litigation, including litigation regarding proprietary and patent rights.

- Regulatory developments or delays concerning our products in the U.S. and foreign countries.
- Issues concerning the safety of our products or of biotechnology products generally.
- Economic and other external factors or a disaster or crisis.
- Period to period fluctuations in our financial results.

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

Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include but are not limited to changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past and future levels of R&D spending, acquisitions, and changes in overall levels of income before taxes.

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

As of March 31, 2007, we had approximately \$2.0 billion of long-term debt. Our ability to make payments on and to refinance our indebtedness, including our long-term debt obligations, and to fund planned capital expenditures, R&D, as well as stock repurchases and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase our vulnerability to general adverse economic and industry conditions, require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts and other general corporate purposes, and limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

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

Under Financial Accounting Standards Board Interpretation No. 46R (or "FIN 46R"), a revision to Interpretation 46, "*Consolidation of Variable Interest Entities*," we are required to assess new business development collaborations as well as to 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 2007, we are authorized to repurchase up to 100,000,000 shares of our Common Stock for an aggregate price of up to \$8.0 billion through June 30, 2008. 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, 2007, 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 plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage; (ii) to make prudent investments of our cash resources; and (iii) to allow for an effective mechanism to provide stock for our employee stock plans. See above in "Relationship with Roche" for more

information on Roche's minimum ownership percentage.

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We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately four million shares and is effective through June 30, 2007.

Our shares repurchased for the three months ended March 31, 2007 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</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
January 1-31, 2007	3.0	\$ 87.33		
February 1-28, 2007	0.9	86.54		
March 1-31, 2007	0.6	82.33		
Total	4.5	\$ 86.47	67	33

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

## Item 6. Exhibits

### Exhibit

<u>No.</u>	<u>Description</u>	<u>Location</u>
10.1	Fourth Amendment to the Manufacturing and Supply Agreement between Genentech and Lonza Biologics PLC, dated as of 2 February 2007.*	Filed herewith
10.2	Amendment No. 1 to the Genentech, Inc. Tax Reduction Investment Plan, as amended and restated.	Filed herewith
10.3	Amendment No. 2 to the Genentech, Inc. Tax Reduction Investment Plan, as amended and restated.	Filed herewith
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.	Furnished herewith

Section 1350, as adopted pursuant to Section  
906 of the Sarbanes-Oxley Act of 2002

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\* Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

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**SIGNATURES**

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

GENENTECH, INC.

Date: May 3, 2007

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

Date: May 3, 2007

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

Date: May 3, 2007

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