

GENENTECH INC  
Form 10-Q  
November 02, 2007

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

**FORM 10-Q**

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**(Mark  
One)**

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

**For the quarterly period ended September 30, 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):

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	1,053,091,492 Outstanding at October 26, 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. (RHI) on June 30, 1999.

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Activase® (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; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva® (efalizumab) anti-CD11a antibody; and TNKase® (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva® (erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks, and trade names of other companies.

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

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

	<b>Three Months</b>		<b>Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Revenue</b>				
Product sales (including amounts from related parties: three months—2007—\$137; 2006—\$87; nine months—2007—\$659; 2006—\$220)	\$ 2,321	\$ 1,941	\$ 7,094	\$ 5,395
Royalties (including amounts from related parties: three months—2007—\$357; 2006—\$230; nine months—2007—\$914; 2006—\$603)	524	364	1,427	966
Contract revenue (including amounts from related parties: three months—2007—\$30; 2006—\$52; nine months—2007—\$134; 2006—\$114)	63	79	234	208
<b>Total operating revenue</b>	<b>2,908</b>	<b>2,384</b>	<b>8,755</b>	<b>6,569</b>
<b>Costs and expenses</b>				
Cost of sales (including amounts for related parties: three months—2007—\$100; 2006—\$63; nine months—2007—\$365; 2006—\$178)	406	297	1,227	843
Research and development (associated with related party collaborations: three months—2007—\$75; 2006—\$62; nine months—2007—\$222; 2006—\$179) (including amounts where reimbursement was recorded as contract revenue: three months—2007—\$49; 2006—\$48; nine months—2007—\$154; 2006—\$135)	615	454	1,828	1,218
Marketing, general and administrative	541	501	1,564	1,414
Collaboration profit sharing (including related party amounts: three months—2007—\$47; 2006—\$46; nine months—2007—\$143; 2006—\$137)	276	250	805	735
Write-off of in-process research and development related to acquisition	77	—	77	—
Gain on acquisition	(121)	—	(121)	—
Recurring charges related to redemption and acquisition	38	26	90	79
Special items: litigation related	14	13	41	40
<b>Total costs and expenses</b>	<b>1,846</b>	<b>1,541</b>	<b>5,511</b>	<b>4,329</b>
Operating income	1,062	843	3,244	2,240
Other income (expense):				
Interest and other income, net	84	74	233	249
Interest expense	(18)	(19)	(53)	(56)
Total other income, net	66	55	180	193

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Income before taxes	1,128	898	3,424	2,433
Income tax provision	443	330	1,286	914
<b>Net income</b>	\$ 685	\$ 568	\$ 2,138	\$ 1,519
<b>Earnings per share</b>				
Basic	\$ 0.65	\$ 0.54	\$ 2.03	\$ 1.44
Diluted	\$ 0.64	\$ 0.53	\$ 2.00	\$ 1.41
Shares used to compute basic earnings per share	1,053	1,053	1,053	1,053
Shares used to compute diluted earnings per share	1,069	1,072	1,070	1,074

*See Notes to Condensed Consolidated Financial Statements.*

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

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 2,138	\$ 1,519
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	345	298
Employee stock-based compensation	300	225
In-process research and development	77	–
Gain on acquisition	(121)	–
Deferred income taxes	(116)	(86)
Deferred revenue	(50)	(13)
Litigation-related liabilities	39	39
Excess tax benefit from stock-based compensation arrangements	(160)	(142)
Gain on sales of securities available-for-sale and other, net	(15)	(76)
Write-down of securities available-for-sale and other	4	1
Loss on property and equipment dispositions	30	–
Changes in assets and liabilities:		
Receivables and other current assets	(236)	(423)
Inventories	(238)	(311)
Investments in trading securities	(140)	(26)
Accounts payable, other accrued liabilities, and other long-term liabilities	216	311
<b>Net cash provided by operating activities</b>	<b>2,073</b>	<b>1,316</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(622)	(1,078)
Proceeds from sales of securities available-for-sale	482	366
Proceeds from maturities of securities available-for-sale	358	297
Capital expenditures	(692)	(888)
Change in other intangible and long-term assets	(39)	24
Transfer to restricted cash	–	(53)
Acquisition and related costs, net	(833)	–
<b>Net cash used in investing activities</b>	<b>(1,346)</b>	<b>(1,332)</b>
<b>Cash flows from financing activities</b>		
Stock issuances	381	286
Stock repurchases	(815)	(758)
Excess tax benefit from stock-based compensation arrangements	160	142
<b>Net cash used in financing activities</b>	<b>(274)</b>	<b>(330)</b>
Net increase (decrease) in cash and cash equivalents	453	(346)
Cash and cash equivalents at beginning of period	1,250	1,225
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,703</b>	<b>\$ 879</b>

**Supplemental cash flow data**

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Cash paid during the period for:			
Interest	\$	71	\$ 77
Income taxes		1,277	851
Non-cash investing and financing activities			
Capitalization of construction in progress related to financing lease transactions		156	84
Deferral of royalty revenue associated with the acquisition of Tanox, Inc.		(185)	—

*See Notes to Condensed Consolidated Financial Statements.*



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

	September 30, 2007	December 31, 2006
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 1,703	\$ 1,250
Short-term investments	1,217	1,243
Accounts receivable—product sales (net of allowances of: 2007—\$109; 2006—\$92; including amounts from related parties: 2007—\$42; 2006—\$57)	1,012	965
Accounts receivable—royalties (including amounts from related parties: 2007—\$581; 2006—\$316)	716	453
Accounts receivable—other (including amounts from related parties: 2007—\$123; 2006—\$150)	185	248
Inventories	1,425	1,178
Deferred tax assets	292	278
Prepaid expenses and other current assets	121	89
<b>Total current assets</b>	<b>6,671</b>	<b>5,704</b>
Long-term marketable debt and equity securities	1,952	1,832
Property, plant and equipment, net	4,758	4,173
Goodwill	1,574	1,315
Other intangible assets	1,208	476
Restricted cash and investments	788	788
Other long-term assets	493	554
<b>Total assets</b>	<b>\$ 17,444</b>	<b>\$ 14,842</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable (including amounts to related parties: 2007—\$8; 2006—\$7)	\$ 283	\$ 346
Deferred revenue	44	62
Taxes payable	67	111
Other accrued liabilities (including amounts to related parties: 2007—\$220; 2006—\$136)	1,662	1,491
<b>Total current liabilities</b>	<b>2,056</b>	<b>2,010</b>
Long-term debt	2,346	2,204
Deferred revenue	353	199
Litigation-related and other long-term liabilities	1,057	951
<b>Total liabilities</b>	<b>5,812</b>	<b>5,364</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock	21	21
Additional paid-in capital	10,842	10,091
Accumulated other comprehensive income	212	204
Retained earnings (accumulated deficit) since June 30, 1999	557	(838)
<b>Total stockholders' equity</b>	<b>11,632</b>	<b>9,478</b>

<b>Total liabilities and stockholders' equity</b>	\$	17,444	\$	14,842
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*See Notes to Condensed Consolidated Financial Statements.*

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

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

***Basis of Presentation***

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

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

***Principles of Consolidation***

The consolidated financial statements include the accounts of Genentech and all wholly owned subsidiaries. Following the completion of our acquisition of Tanox, Inc. on August 2, 2007, the financial results of Tanox's operations have been included in the consolidated financial results of Genentech. 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 (EITF) Issue No. 06-2, "Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43, Accounting for Compensated Absences" (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 retained earnings (accumulated deficit) of \$26 million, net of tax, as a cumulative effect of a change in accounting principle.

We adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48), on January 1, 2007. Implementation of FIN 48 did not result in a cumulative

adjustment to retained earnings (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 any future period. As a result of the implementation of FIN 48, we reclassified \$147 million of unrecognized tax benefits from current liabilities to long-term liabilities as of December 31, 2006 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 international jurisdictions. The Internal Revenue Service (IRS) is examining our U.S. federal income tax returns for 2002 through 2004. As of September 30, 2007, the IRS has not proposed any adjustments. We are also under examination by several state jurisdictions. As of September 30, 2007, no material adjustments related to these audits have been proposed.

We accrue tax-related interest and penalties and include such expenses with income tax expense in the Condensed Consolidated Statements of Income. We recognized approximately \$2 million and \$6 million in tax-related interest expense during the third quarter and first nine months of 2007, respectively, 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, 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 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 those estimates, we defer a portion of Avastin revenue on product vials sold through normal commercial channels. The deferred revenue is recognized when free Avastin vials are delivered or after the associated patient eligibility period has passed.

### **Earnings Per Share**

Basic earnings per share (EPS) are computed based on the weighted-average number of shares of our Common Stock outstanding. Diluted 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</b>		<b>Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Numerator:</b>				
Net income	\$ 685	\$ 568	\$ 2,138	\$ 1,519
<b>Denominator:</b>				
Weighted-average shares outstanding used to compute basic earnings per share	1,053	1,053	1,053	1,053
Effect of dilutive stock options	16	19	17	21
	1,069	1,072	1,070	1,074

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

Outstanding employee stock options to purchase approximately 36 million and 35 million shares of our Common Stock were excluded from the computation of diluted EPS for the third quarter and first nine months of 2007, respectively, because the effect would have been anti-dilutive.

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**Comprehensive Income**

Comprehensive income comprises net income and other comprehensive income (OCI). OCI includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in OCI changes in the estimated fair value of derivatives designated as effective cash flow hedges, and unrealized gains and losses on our securities available-for-sale. In accordance with our adoption of Statement of Financial Accounting Standards (FAS) No. 158, "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans – an amendment of FASB Statements No. 87, 88, 106, and 132(R)," 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>September 30, 2007</b>	<b>December 31, 2006</b>
Net unrealized gains on securities available-for-sale	\$ 224	\$ 214
Net unrealized losses on cash flow hedges	(6)	(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 September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net income	\$ 685	\$ 568	\$ 2,138	\$ 1,519
Increase (decrease) in unrealized gains on securities available-for-sale	19	16	10	(24)
(Decrease) increase in unrealized gains on cash flow hedges	(13)	1	(2)	(19)
Comprehensive income, net of income taxes	\$ 691	\$ 585	\$ 2,146	\$ 1,476

**Derivative Instruments**

Our derivative instruments, designated as cash flow hedges, consist of foreign currency exchange options and marketable equity collars. At September 30, 2007, estimated net losses expected to be reclassified from accumulated OCI to "other income, net" within the next 12 months are \$6 million.

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

Employee stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS No. 123(R), "Share-Based Payment" (FAS 123R), requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Employee stock-based compensation expense recognized under FAS 123R was as follows (*in millions*):

<b>Three Months</b>	<b>Nine Months</b>
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	Ended September 30,		Ended September 30,	
	2007	2006	2007	2006
Cost of sales	\$ 16	\$ -	\$ 49	\$ -
Research and development	37	35	114	101
Marketing, general and administrative	44	41	137	124
Total employee stock-based compensation expense	\$ 97	\$ 76	\$ 300	\$ 225

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As of September 30, 2007, total compensation cost related to unvested stock options not yet recognized was \$934 million, which is expected to be allocated to expense and production costs over a weighted-average period of 36 months.

The carrying value of inventory on our Condensed Consolidated Balance Sheets as of September 30, 2007 and 2006 includes employee stock-based compensation costs of \$77 million and \$49 million, respectively. During the third quarter and first nine months of 2007, \$16 million and \$49 million, respectively, of previously capitalized employee stock-based compensation costs were recognized in cost of sales. Substantially all of the products sold during the first nine months 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 were as follows:

	<b>Three Months</b>		<b>Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Risk-free interest rate	4.3%	4.6%	4.3%	4.6%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	25.0%	27.0%	25.0%	27.0%
Expected term (years)	5.0	4.6	5.0	4.6

Due to the redemption of our Special Common Stock in June 1999 by Roche Holdings, Inc. (RHI), there is limited historical information available to support our estimate of certain assumptions required to value our employee stock options 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 on 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>September 30, 2007</b>		<b>December 31, 2006</b>	
Raw materials and supplies	\$	131	\$	116
Work in process		933		818
Finished goods		361		244
Total	\$	1,425	\$	1,178

### **Note 4. Contingencies**

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

On October 4, 2004, we received a subpoena from the U.S. Department of Justice, requesting documents related to the promotion of Rituxan, a prescription treatment now approved for five indications. We are cooperating with the associated investigation, which is both civil and criminal in nature, and through counsel we are having continuing

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discussions with government representatives about the status of their investigation and Genentech's views on this matter. 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 Inc., alleging violations of the False Claims Act and retaliatory discharge of employment. On December 20, 2005, the United States 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. On July 24, 2007, the District Court Judge affirmed the dismissal of both claims related to the False Claims Act but denied Genentech's motion to dismiss plaintiff's federal retaliatory discharge claim and granted plaintiff's motion for leave to file a Second Amended Complaint asserting an additional state law employment claim. The outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (COH) are parties to a 1976 agreement related to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, we have entered into license agreements with various companies to manufacture, use, and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, 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 September 30, 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 accrued interest and bond costs related to the COH trial judgment of \$14 million for the third quarter of 2007 and \$13 million for the third quarter of 2006, and \$41 million for the first nine months of 2007 and \$40 million for the first nine months of 2006. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of \$788 million at September 30, 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.

On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415

(the Cabilly patent) that we co-own with COH and under which MedImmune and other companies have been licensed and are paying royalties to us. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking a ruling that the Cabilly patent is invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the Cabilly patent on sales of its Synagis® antibody product, an injunction to prevent us from enforcing the Cabilly patent, an award of actual and exemplary damages,

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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 U.S. Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune's petition, and the oral argument of this case before the Supreme Court occurred on October 4, 2006. On January 9, 2007, the Supreme Court issued a decision reversing the Federal Circuit's decision and remanding the case to the lower courts for further proceedings in connection with the patent and contract claims. On August 16, 2007, the U.S. District Court entered a Claim Construction Order defining several terms used in the '415 patent. Discovery and motion practice are ongoing and the trial of this matter has been scheduled for June 23, 2008. The outcome of this matter cannot be determined at this time.

On May 13, 2005, a request was filed by a third party for reexamination of the Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent and Trademark Office (Patent Office) ordered reexamination of the Cabilly patent. On September 13, 2005, the Patent Office mailed an initial non-final Patent Office action rejecting the claims of the Cabilly patent. We filed our response to the Patent Office action on November 25, 2005. On December 23, 2005, a second request for reexamination of the Cabilly patent was filed by another third party, and on January 23, 2006, the Patent Office granted that request. On June 6, 2006, the two reexaminations were merged into one proceeding. On August 16, 2006, the Patent Office mailed a non-final Patent Office action in the merged proceeding, rejecting the claims of the Cabilly patent based on issues raised in the two reexamination requests. We filed our response to the Patent Office action on October 30, 2006. On February 16, 2007, the Patent Office mailed a final Patent Office action rejecting all 36 claims of the Cabilly patent. We responded to the final Patent Office action on May 21, 2007 and requested continued reexamination. On May 31, 2007, the Patent Office granted the request for continued reexamination, and in doing so withdrew the finality of the February 2007 Patent Office action and agreed to treat our May 21, 2007 filing as a response to a first Patent Office action. The Cabilly patent, which expires in 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. We have licensed the Cabilly patent to other companies and derive significant royalties from those licenses. The claims of the Cabilly patent remain valid and enforceable throughout the reexamination and appeals processes. Because the above-described proceeding is ongoing, the outcome of this matter cannot be determined at this time.

In 2006, we made development decisions involving our humanized anti-CD20 program, and our collaborator, Biogen Idec, disagreed with certain of our development decisions related to humanized anti-CD20 products. Under our 2003 collaboration agreement with Biogen Idec, we believe that we are permitted under the agreement to proceed with further trials of certain humanized anti-CD20 antibodies, and Biogen Idec disagreed with our position. The disputed issues have been submitted to arbitration. In the arbitration, Biogen Idec filed motions for a preliminary injunction and summary judgment seeking to stop us from proceeding with certain development activities, including planned clinical trials. On April 20, 2007, the arbitration panel denied 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 hearing of this matter is scheduled to begin in June 2008. We expect a final decision by the arbitrators by approximately the end of 2008, unless the parties are able to resolve the matter earlier through settlement discussions or otherwise. The outcome of this matter cannot be determined at this time.

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

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

We issue shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with RHI provides, among other things, that with

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respect to any issuance of our Common Stock in the future, we will repurchase a sufficient number of shares so that immediately after such issuance, the percentage of our Common Stock owned by RHI will be no lower than 2% below the “Minimum Percentage” (subject to certain conditions). The Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by RHI since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech Common Stock by RHI as well as for stock splits or stock combinations) divided by 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech Common Stock outstanding at the time of the July 1999 offering, adjusted for stock splits. We have repurchased shares of our Common Stock since 2001. The affiliation agreement also provides that upon RHI’s request, we will repurchase shares of our Common Stock to increase RHI’s ownership to the Minimum Percentage. In addition, RHI will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. Under the terms of the affiliation agreement, RHI’s Minimum Percentage is 57.7%, and RHI’s ownership percentage is to be no lower than 55.7%. At September 30, 2007, RHI’s ownership percentage was 55.8%.

### Related Party Transactions

We enter into transactions with our related parties, Roche Holding AG and affiliates (Roche) and Novartis AG and affiliates (Novartis). The accounting policies that we apply to our transactions with our related parties are consistent with those applied in transactions with independent third parties.

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” (EITF 99-19), because we bear the manufacturing risk, general inventory risk, and the risk to defend our intellectual property. For circumstances in which we are the principal in the transaction, we record the transaction on a gross basis in accordance with EITF 99-19. Otherwise, our transactions are recorded on a net basis.

#### Roche

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Product sales to Roche	\$ 135	\$ 86	\$ 651	\$ 217
Royalties earned from Roche	\$ 317	\$ 230	\$ 855	\$ 602
Contract revenue from Roche	\$ 21	\$ 37	\$ 81	\$ 76
Cost of sales on product sales to Roche	\$ 98	\$ 60	\$ 356	\$ 173
Research and development (R&D) expenses incurred on joint development projects with Roche	\$ 64	\$ 52	\$ 192	\$ 147

Certain R&D expenses are partially reimbursable to us by Roche. In addition, R&D expenses may include the net settlement of amounts we owed to Roche on R&D expenses that Roche incurred on joint development projects, less amounts reimbursable to us by Roche on these projects.

#### Novartis

Based on information available to us at the time of filing this Form 10-Q, we believe that Novartis holds approximately 33.3 percent 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 percent of our voting stock.

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We have an agreement with Novartis under which Novartis has the exclusive right to develop and market Lucentis outside the U.S. for indications related to diseases or disorders of the eye. As part of this agreement, the parties will share the cost of certain of our ongoing development expenses for Lucentis. Novartis makes royalty payments to us on sales of Lucentis outside the U.S.

We, along with Novartis, are co-developing and co-promoting Xolair in the U.S. 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. Effective with our acquisition of Tanox on August 2, 2007, Novartis also makes royalty payments to us on sales of Xolair worldwide and also pays us a manufacturing fee related to Xolair. See Note 6, "Acquisition of Tanox, Inc." for more information on the acquisition.

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

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2007	2006	2007	2006
Product sales to Novartis	\$ 2	\$ 1	\$ 8	\$ 3
Royalties earned from Novartis	\$ 40	\$ -	\$ 59	\$ 1
Contract revenue from Novartis	\$ 9	\$ 15	\$ 53	\$ 38
Cost of sales on product sales to Novartis	\$ 2	\$ 3	\$ 9	\$ 5
R&D expenses incurred on joint development projects with Novartis	\$ 11	\$ 10	\$ 30	\$ 32
Collaboration profit sharing expense to Novartis	\$ 47	\$ 46	\$ 143	\$ 137

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

Certain R&D expenses are partially reimbursable to us by Novartis. In addition, R&D expenses may include the net settlement of amounts we owed to Novartis on R&D expenses that Novartis incurred on joint development projects, less amounts reimbursable to us by Novartis on these projects.

See Note 6, "Acquisition of Tanox, Inc." for information on Novartis proceeds resulting from our acquisition of Tanox.

#### **Note 6. Acquisition of Tanox, Inc.**

On August 2, 2007, we completed our acquisition of 100% of the outstanding shares of Tanox, a biotechnology company specializing in the discovery and development of biotherapeutics based on monoclonal antibody technology, for \$925 million in cash, plus \$8 million in transaction costs. The preliminary purchase price allocation is as follows, and we may make further adjustments as we continue to evaluate the purchase price allocation within the next year.



*(In millions)***Assets**

Cash	\$	100
Investments		102
Working capital and other, net		56
In-process research and development (IPR&D)		77
Developed product technology		780
Core technology		34
Goodwill		259
Deferred revenue		(185)
Deferred tax liability, net		(217)
Total acquisition consideration and gain	\$	1,006

**Consideration and Gain**

Consideration	\$	925
Transaction costs		8
Gain on settlement of preexisting relationship, net of tax		73
	\$	1,006

In accordance with FAS No. 141, “*Business Combinations*” (FAS 141), assets and liabilities acquired were valued at their fair values at the date of acquisition. We recorded deferred revenue associated with Tanox’s intellectual property license with Novartis related to Xolair of \$185 million, which will be recognized as additional royalty revenue over the duration of the estimated remaining patent lives of approximately 12 years.

In connection with our acquisition of Tanox, we terminated certain officers and employees of Tanox. The total amount of the severance packages offered to these officers and employees was approximately \$4 million. Tanox also leased a plant in San Diego, California that has been certified by the U.S. Food and Drug Administration (FDA) for clinical use. Our current estimate of the present value of the future lease payments we owe, less the expected sublease income if we are able to sublease the facility, is approximately \$5 million. We expect these restructuring programs to be substantially complete within the next six months.

We recorded a \$77 million charge for in-process research and development. This charge primarily represents acquired R&D for label extensions for Xolair that have not yet been approved by the FDA and require significant further development.

Under FAS 141, acquired identifiable intangible assets are measured and recognized apart from goodwill even if it would not be practical to sell or exchange the acquired intangible assets and any related license agreements apart from one another. In our accounting for our acquisition of Tanox’s developed product technology and core technology in accordance with FAS No. 142, “*Goodwill and Other Intangible Assets*,” the fair value assigned to those intangible assets was based on valuations using a present value technique referred to as the income approach, with estimates and assumptions determined by management, including valuing Tanox’s intellectual property and rights thereon at assumed current fair values, which, for developed product technology, were in excess of existing contractual rates. The developed product technology we valued relates to intellectual property and rights thereon primarily related to the Xolair molecule. The core technology asset we valued represents the value of Tanox’s intellectual property and rights thereon expected to be leveraged in the design and development of future products and indications. The developed product technology and core technology, which totaled \$814 million, are being amortized over 12 years. The excess of purchase price over tangible assets, identifiable intangible assets, and assumed liabilities represents goodwill.

The intangible assets and goodwill acquired are not deductible for income tax purposes. As a result, we recorded a net deferred tax liability of \$262 million, based on the tax effect of the amount of the acquired intangible assets other than goodwill with no tax basis. We also recorded a net deferred tax asset of approximately \$45 million, primarily related to net operating loss carryforwards acquired in the transaction.

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Under EITF 04-1, “*Accounting for Preexisting Relationships between the Parties to a Business Combination*” (EITF 04-1), a business combination between parties with a preexisting relationship should be evaluated to determine if a settlement of a preexisting relationship exists. The acquisition of Tanox is considered to include the settlement of our 1996 license of certain intellectual property and rights thereon from Tanox. We measured the amount that the preexisting license arrangement is favorable, from our perspective, by comparing it to estimated pricing for current market transactions for intellectual property rights similar to Tanox’s intellectual property rights related to Xolair. In connection with the settlement of this license arrangement, we recorded a gain of \$121 million, or \$73 million net of tax, in accordance with EITF 04-1.

On August 2, 2007, we understand that Novartis owned approximately 14% of the outstanding shares of Tanox, representing approximately \$127 million of the total cash paid to acquire the outstanding shares of Tanox.

Assuming that the Tanox acquisition was consummated as of January 1, 2006, pro forma consolidated financial results of the company for the three and nine months ended September 30, 2007 and 2006 would not have been materially different from the amounts reported.

#### **Note 7. Income Taxes**

The effective income tax rate was 39% in the third quarter of 2007 compared to 37% in the third quarter of 2006. The increase was primarily due to the non-deductible IPR&D charge in the third quarter of 2007 resulting from our acquisition of Tanox. The effective income tax rate was 38% in the first nine months of 2007 and 2006.

#### **Note 8. Subsequent Event**

On October 11, 2007, we entered into a five-year, \$1 billion revolving credit facility with various financial institutions. The credit facility is expected to be used for general corporate and working capital purposes, including providing support for our new \$1 billion commercial paper program. As of October 26, 2007, we had no borrowings under the credit facility and had \$600 million outstanding in commercial paper.

**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 September 30, 2007, and the related condensed consolidated statements of income for the three-month and nine-month periods ended September 30, 2007 and 2006, and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 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 including an explanatory paragraph relating to the change in method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-based Payment." In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 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  
October 29, 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 Third Quarter of 2007*

We primarily earn revenue and income and generate cash from product sales and royalty revenue. In the third quarter of 2007, our total operating revenue was \$2,908 million, an increase of 22% from \$2,384 million in the third quarter of 2006. Our net income for the third quarter of 2007 was \$685 million, an increase of 21% from \$568 million in the third quarter of 2006. In the first nine months of 2007, our total operating revenue was \$8,755 million, an increase of 33% from \$6,569 million in the first nine months of 2006. Our net income for the first nine months of 2007 was \$2,138 million, an increase of 41% from \$1,519 million in the first nine months of 2006.

On August 2, 2007, we acquired 100% of the outstanding shares of Tanox, Inc. for \$925 million, including \$8 million in transaction costs. The acquired assets include \$202 million of Tanox's cash and investments, resulting in a net cash and investment outlay of \$731 million. Included in our operating results for the third quarter and first nine months of 2007 are items related to our acquisition of Tanox, including a non-recurring in-process research and development (IPR&D) charge of \$77 million; a non-recurring gain of \$121 million on a pretax basis pursuant to the Emerging Issues Task Force (EITF) Issue 04-1, "Accounting for Preexisting Relationships between the Parties to a Business Combination" (EITF 04-1); the recognition of deferred royalty revenue; and amortization of intangible assets. Tanox's post-acquisition operating results were not material to our consolidated results for the third quarter of 2007. See "Write-off of In-process Research and Development Related to Acquisition" and "Gain on Acquisition" in the "Results of Operations" section for more information on these items.

On August 24, 2007, we resubmitted a supplemental Biologics License Application (sBLA) to the United States (U.S.) Food and Drug Administration (FDA) for Avastin, in combination with paclitaxel chemotherapy, for patients who have not received chemotherapy for their locally recurrent or metastatic breast cancer (BC). We have been informed that an Oncologic Drugs Advisory Committee meeting will be held in December 2007, and the FDA action date is February 23, 2008.

#### *Our Strategy and Goals*

As announced in 2006, our business objectives for the years 2006 through 2010 include bringing at least 20 new molecules into clinical development, bringing at least 15 major new products or indications onto the market, becoming the number one U.S. oncology company in sales, and achieving certain financial growth measures. These

objectives are reflected in our revised Horizon 2010 strategy and goals summarized on our website at [www.gene.com/gene/about/corporate/growthstrategy](http://www.gene.com/gene/about/corporate/growthstrategy).

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***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, and/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 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 research and development (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.
- 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 (AMD) and Avastin for the treatment of non-small cell lung cancer, and to successfully obtain FDA approvals for potential new indications for our existing products such as Avastin for the treatment of metastatic BC and anti-CD20 molecules for the treatment of immunological disorders.
- Our business model requires appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. The pricing and distribution of our products have 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 reimbursement environment for our products may change in the future and become more challenging.
- As the Medicare and Medicaid programs are the largest payers for our products, rules related to coverage and reimbursement continue to represent an important issue for our business. New regulations related to hospital and physician payment continue to be implemented annually. To date, we have not seen any detectable effects of the new rules on our product sales. As a result of the Deficit Reduction Act, new regulations will take effect in the fourth quarter of 2007 that will impact the discounted price for our products paid by Medicaid and government-affiliated customers. While pricing continues to be an important area of focus, we anticipate minimal impact on our revenue for the remainder of 2007.
- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection could result in lost sales to competing products and may negatively affect our sales, royalty revenue, and operating results. We are often involved in disputes over contracts and intellectual property, and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.

- Manufacturing 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. Additionally, 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, or other excess capacity charges, resulting in an increase in our cost of sales.
- Our ability to attract and retain highly qualified and talented people in all areas of the company, and our ability to maintain our unique culture, will be critical to our success over the long-term. We are working diligently across the company to make sure that we successfully hire, train, and integrate new employees into the Genentech culture and environment.

### Marketed Products

We commercialize the biotechnology products listed below in the U.S.:

*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 that we commercialize with Biogen Idec, Inc. It is approved for first-line treatment of patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy regimens or following CVP chemotherapy in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy. Rituxan is also approved for use in the follicular setting for treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, including retreatment and bulky diseases. Rituxan is indicated for first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy. Rituxan is also indicated for use in combination with methotrexate for reducing 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.

*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 (HER2) protein. It is also approved for use as a first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy for patients with HER2-positive metastatic BC.

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

*Xolair* (omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis Pharma AG (a wholly owned subsidiary of Novartis AG; Novartis AG and affiliates are collectively referred to herein as Novartis). Xolair is approved for adults and adolescents (age 12 or older) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

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

patients with locally advanced or metastatic 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.

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*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 (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 (Roche) on sales of:

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

See Note 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-related legal proceedings.

### **Available Information**

The following information is found on our website at [www.gene.com](http://www.gene.com), or can be obtained free of charge by contacting our Investor Relations Department at (650) 225-1599 or 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 U.S. Securities and Exchange Commission;
- Our policies related to corporate governance, including our Principles of Corporate Governance, Good Operating Principles, and Code of Ethics, which apply to our Chief Executive Officer, Chief Financial Officer, and senior financial officials; and
- The charters of the Audit Committee and the Compensation Committee of our Board of Directors.

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

The accompanying discussion and analysis of our financial condition and results of operations are based on our Condensed Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles (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 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. See Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for more information on these matters. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. We record an estimated loss as a charge to income if we determine that, based on information available at the time, the loss is probable and the amount of loss can be reasonably estimated. Included in "litigation-related and other long-term liabilities" in the accompanying Condensed Consolidated Balance Sheet at September 30, 2007 is \$764 million, which represents our estimate of the costs for the current resolution of the City of Hope National Medical Center (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. The outcomes of such matters that are different from our current estimates 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 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 when free Avastin vials are delivered. Enrollment in the program was lower than expected in the first nine months of 2007, and we recorded net decreases in deferred revenue, and

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corresponding net increases to product sales, of \$5 million in the third quarter of 2007 and \$2 million in the first nine months of 2007 for Avastin U.S. product sales, resulting in a remaining deferred revenue liability in connection with the Avastin Patient Assistance Program of \$7 million in our Condensed Consolidated Balance Sheet at September 30, 2007. As we continue to evaluate the amount of revenue to defer related to the Avastin Patient Assistance Program, we may recognize previously deferred revenue in Avastin U.S. product sales in future periods or we may increase the amount of revenue deferred.

### *Product Sales Allowances*

Revenue from U.S. product sales is recorded net of allowances and accruals for rebates, healthcare provider contractual chargebacks, prompt-pay sales discounts, product returns, and wholesaler inventory management allowances, all of which are established at the time of sale. Sales allowances and accruals are based on estimates of the amounts earned or to be claimed on the related sales. The amounts reflected in our Condensed Consolidated Statements of Income as product sales allowances have been relatively consistent at approximately 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 include both direct and indirect rebates. Direct rebates are contractual price adjustments payable to direct customers, mainly to wholesalers and specialty pharmacies that purchase products directly from us. Indirect rebates are contractual price adjustments payable to healthcare providers and organizations such as clinics, hospitals, pharmacies, Medicaid, and group purchasing organizations that do not purchase products directly from us;
- 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 on the historical levels of credits and allowances as a percentage of product sales. We believe that our estimates related to healthcare provider contractual chargebacks and prompt-pay sales discounts do not have a high degree of estimation complexity or uncertainty, as the related amounts are settled within a short period of time. We consider rebate allowances and accruals to be the only estimations that involve material amounts and require a higher degree of subjectivity and judgment necessary. 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 on definitive agreements or legal requirements (such as Medicaid). These rebates are primarily estimated using historical and other data, including patient usage, customer buying patterns, applicable contractual rebate rates, and contract performance by the benefit providers. Direct rebates are accrued at the time of sale and recorded as allowances against trade accounts receivable; indirect (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,

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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 that 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 that we reasonably expect to observe for rebates) would have an approximate \$18 million effect on our income before taxes (or approximately \$0.01 per share after taxes). The total rebate allowances and accruals recorded in our Condensed Consolidated Balance Sheet were \$63 million as of September 30, 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 may need to adjust our estimates in future periods. As of September 30, 2007, our Condensed Consolidated Balance Sheet reflected estimated product sales allowance reserves and accruals totaling approximately \$166 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 estimates of royalty revenue and receivables in those instances are based on communication with some licensees, historical information, forecasted sales trends, and collectibility. Differences between actual royalty revenue and estimated royalty revenue are adjusted for in the period in which they become known, typically the following quarter. If the collectibility of a royalty amount is doubtful, royalty revenue is not recorded. In the case of a receivable related to previously recognized royalty revenue that 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 (the Cabilly patent), under which we receive royalty revenue on sales of products that are covered by the patent. The Cabilly patent, which expires in 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in those methods. The U.S. Patent and Trademark Office (Patent Office) is performing a reexamination of the patent and on February 16, 2007 issued a final Patent Office action rejecting all 36 claims of the Cabilly patent. We responded to the final Patent Office action on May 21, 2007 and requested continued reexamination. On May 31, 2007, the Patent Office granted the request for continued reexamination, and in so doing withdrew the finality of the February 2007 Patent Office action and agreed to treat our May 21, 2007 filing as a response to a first Patent Office action. The claims of the patent remain valid and enforceable throughout the reexamination and appeals processes. In addition, MedImmune, Inc. has filed a lawsuit against us challenging the Cabilly patent. See also Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for more information on our Cabilly patent reexamination and the MedImmune lawsuit.

Cabilly patent royalties are generally due 60 days after the end of the quarter. Additionally, we pay COH a percentage of our Cabilly patent royalty revenue 60 days after the quarter in which we receive payments from our licensees. As of September 30, 2007, our Condensed Consolidated Balance Sheet included Cabilly patent receivables totaling approximately \$57 million and the related COH payable totaling approximately \$23 million.

### ***Income Taxes***

Income tax provision 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

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

On January 1, 2007, we adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes*" (FIN 48). As a result of the implementation of FIN 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 may include currently marketed products manufactured under a new process or at facilities awaiting regulatory licensure. These inventories are capitalized based on management's judgment of probable near-term regulatory licensure. Excess or idle capacity costs, based on estimated plant capabilities, are expensed in the period in which they are incurred. The valuation of inventory requires us to estimate the value of inventory that may expire prior to use or that may fail to be released for commercial sale. The determination of obsolete inventory requires us to estimate the future demands for our products, and in the case of pre-approval inventories, to estimate the regulatory approval date for the product or for the licensure of either the manufacturing facility or the new manufacturing process. We may be required to expense previously capitalized inventory costs upon a change in our estimate, due to, among other potential factors, the denial or delay of approval of a product or the licensure of either a manufacturing facility or a new manufacturing process by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable.

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

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

We believe that the fair values assigned to the intangible assets acquired are based on reasonable estimates and assumptions, given the available facts and circumstances as of the acquisition date. However, we may record adjustments to goodwill resulting from our acquisition of Tanox for the resolution of preacquisition contingencies, our restructuring activities, tax matters, and other estimates related to the acquisition. Further, we will have to continuously evaluate whether any or all intangible assets valued have been impaired.

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

Under the provisions of Statement of Financial Accounting Standards (FAS) No. 123(R), "*Share-Based Payment*" (FAS 123R), employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the

requisite service period in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Due to the redemption of our Special Common Stock in June 1999 (Redemption) by Roche Holdings, Inc. (RHI), there is limited historical information available to support our estimate of certain assumptions required to value our stock options. When establishing an estimate of the expected term of an award, we consider the vesting period for the

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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 more information.

## Results of Operations

(In millions, except per share amounts)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	% Change	2007	2006	% Change
Product sales	\$ 2,321	\$ 1,941	20%	\$ 7,094	\$ 5,395	31%
Royalties	524	364	44	1,427	966	48
Contract revenue	63	79	(20)	234	208	13
Total operating revenue	2,908	2,384	22	8,755	6,569	33
Cost of sales	406	297	37	1,227	843	46
Research and development	615	454	35	1,828	1,218	50
Marketing, general and administrative	541	501	8	1,564	1,414	11
Collaboration profit sharing	276	250	10	805	735	10
Write-off of in-process research and development related to acquisition	77	–	–	77	–	–
Gain on acquisition	(121)	–	–	(121)	–	–
Recurring charges related to redemption and acquisition	38	26	46	90	79	14
Special items: litigation-related	14	13	8	41	40	3
Total costs and expenses	1,846	1,541	20	5,511	4,329	27
Operating income	1,062	843	26	3,244	2,240	45
Other income (expense):						
Interest and other income, net	84	74	14	233	249	(6)
Interest expense	(18)	(19)	(5)	(53)	(56)	(5)
Total other income, net	66	55	20	180	193	(7)
Income before taxes	1,128	898	26	3,424	2,433	41
Income tax provision	443	330	34	1,286	914	41
Net income	\$ 685	\$ 568	21	\$ 2,138	\$ 1,519	41
Earnings per share:						
Basic	\$ 0.65	\$ 0.54	20	\$ 2.03	\$ 1.44	41
Diluted	\$ 0.64	\$ 0.53	21%	\$ 2.00	\$ 1.41	42%
Cost of sales as a % of product sales	17%	15%		17%	16%	

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Research and development as a % of operating revenue	21	19	21	19
Marketing, general and administrative as a % of operating revenue	19	21	18	22
Pretax operating margin	37	35	37	34
Effective income tax rate	39%	37%	38%	38%

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

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**Total Operating Revenue**

Total operating revenue increased 22% in the third quarter of 2007 and 33% in the first nine months of 2007 from the comparable periods in 2006. These increases were primarily due to higher product sales and royalty revenue, and are further discussed below.

**Total Product Sales**

(In millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	% Change	2007	2006	% Change
Net U.S. product sales						
Avastin	\$ 597	\$ 435	37%	\$ 1,694	\$ 1,256	35%
Rituxan	572	509	12	1,689	1,511	12
Herceptin	320	302	6	960	912	5
Lucentis	198	153	29	618	163	279
Xolair	121	107	13	352	307	15
Tarceva	101	100	1	304	296	3
Nutropin products	93	92	1	278	277	0
Thrombolytics	67	60	12	202	181	12
Pulmozyme	57	50	14	164	146	12
Raptiva	29	23	26	80	66	21
Total U.S. product sales <sup>(1)</sup>	2,155	1,830	18	6,341	5,116	24
Net product sales to collaborators	166	111	50	753	280	169
Total product sales	\$ 2,321	\$ 1,941	20%	\$ 7,094	\$ 5,395	31%

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

Total product sales increased 20% in the third quarter and 31% in the first nine months of 2007 from the comparable periods in 2006. Total U.S. product sales increased 18% to \$2,155 million in the third quarter and 24% to \$6,341 million in the first nine months of 2007 from the comparable periods in 2006. This increase in U.S. sales over the comparable periods was due to higher sales across most products, in particular higher sales of our oncology products and resulting from the approval of Lucentis on June 30, 2006. Increased U.S. sales volume accounted for 82%, or \$266 million, of the increase in U.S. net product sales in the third quarter of 2007, and 85%, or \$1,041 million, of the increase in the first nine months 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 third quarter and first nine months of 2007.

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

Avastin

Net U.S. sales of Avastin increased 37% to \$597 million in the third quarter and 35% to \$1,694 million in the first nine months of 2007 from the comparable periods in 2006. Net U.S. sales in the third quarter and in the first nine months of 2007 included the net recognition of \$5 million and \$2 million, respectively, of previously deferred revenue due to lower than expected enrollment in our Avastin Patient Assistance Program. There have been no price increases on Avastin.

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The increases in sales were primarily a result of increased use of Avastin in metastatic non-small cell lung cancer (NSCLC), approved on October 11, 2006, and, to a lesser extent, in metastatic colorectal cancer (CRC) and in metastatic BC, an unapproved use of Avastin. Among all first-line metastatic NSCLC patients, we estimate that Avastin penetration was approximately 30% in the third quarter of 2007, an increase from the adoption rate in the third quarter of 2006, but remained flat compared to the second quarter of 2007. We estimate that approximately 55% of first-line lung cancer patients are eligible for treatment with Avastin. With respect to dose, use of the 15mg/kg/every-three-weeks dose decreased from approximately 75% in the second quarter of 2007 to approximately 60% in the third quarter of 2007. This decrease reflects physician adoption of a lower dose of Avastin following the presentation of the results from the Roche-sponsored Phase III BO17704 study at the American Society of Clinical Oncology in June 2007. The BO17704 study evaluated two different doses of Avastin in combination with gemcitabine and cisplatin chemotherapy compared to chemotherapy alone in patients with previously untreated, advanced NSCLC. The study evaluated a 15mg/kg/every-three-weeks dose of Avastin (the dose approved in the U.S. for use in combination with carboplatin and paclitaxel) and a 7.5mg/kg/every-three-weeks dose of Avastin (a dose not approved for use in the U.S.). Both doses met the primary endpoint of prolonging progression-free survival (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. We expect greater adoption by physicians of the lower Avastin dose of 7.5mg/kg/every-three-weeks. Efficacy data from other clinical studies conducted by any party in the U.S. or internationally (such as AVADO, Roche's study evaluating two doses of Avastin in first-line metastatic BC), showing or perceived to be showing a similar or an improved treatment benefit at a lower dose, could further negatively affect future sales of Avastin.

In first-line metastatic CRC, we estimate that penetration remained flat in the third quarter of 2007 compared to the third quarter of 2006 and the second quarter of 2007. Growth in metastatic CRC during this period resulted primarily from a slight increase in treatment duration. In combined second- and third-line CRC, we estimate that Avastin penetration decreased in the third quarter of 2007 compared to the third quarter of 2006, due to increased competition, and was flat compared to the second quarter of 2007. In metastatic BC, we estimate that Avastin adoption increased in the third quarter of 2007 compared to the third quarter of 2006 and the second quarter of 2007. We believe that Avastin sales growth for the remainder of 2007 will depend on increased penetration in the first-line treatment of metastatic NSCLC and the extent to which physicians prescribe Avastin at its approved dose.

#### *Rituxan*

Net U.S. sales of Rituxan increased 12% to \$572 million in the third quarter and 12% to \$1,689 million in the first nine months of 2007 from the comparable periods in 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. However, based on our market research, we believe that the sales growth resulted from the increased use of Rituxan in treating rheumatoid arthritis (RA), an indication that was approved on February 28, 2006. The increase in market share was driven by both current and new prescribing physicians. Rituxan in RA continued its market share growth in the patient population with an inadequate response to anti-TNF inhibitors, with an estimated market share of more than 10% in the third quarter of 2007. We believe that sales growth also resulted from the increased use of Rituxan following first-line therapy in indolent non-Hodgkin's lymphoma (NHL), and from increased adoption in front-line chronic lymphocytic leukemia (CLL), an unapproved use. Rituxan's overall adoption rate in other areas of NHL and CLL remained flat in the first nine months of 2007 and throughout 2006. Also contributing to the increase in product sales were price increases in 2006 and 2007.

#### *Herceptin*

Net U.S. sales of Herceptin increased 6% to \$320 million in the third quarter and 5% to \$960 million in the first nine months of 2007 from the comparable periods in 2006. The increases in product sales resulted primarily from price

increases in 2006 and 2007. Also contributing to the growth in sales was increased use of Herceptin in the treatment of adjuvant (early-stage) HER2-positive breast cancer, approved on November 16, 2006. We estimate that Herceptin's penetration in adjuvant HER2-positive breast cancer patients was approximately 70% in the third quarter of 2007, an increase from the adoption rate in the third quarter of 2006. We believe that due to the significant adoption in the adjuvant population, further volume growth opportunities for Herceptin may be limited.

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*Lucentis*

Lucentis was approved by the FDA for the treatment of neovascular (wet) AMD on June 30, 2006. Net U.S. sales of Lucentis increased 29% to \$198 million in the third quarter and 279% to \$618 million in the first nine months of 2007 from the comparable periods in 2006, and decreased 5% from \$209 million in the second quarter of 2007. New patient share in the third quarter of 2007 was approximately 50%, a decrease from 55% in the second quarter of 2007. We believe that the main factors affecting Lucentis sales are the continued off-label use of Avastin by some retinal specialists and reimbursement concerns from retinal specialists. We believe that some of the reimbursement concerns may be addressed when Lucentis receives a permanent J-code classification from the Centers for Medicare and Medicaid Services, expected in January 2008, which will allow for automated processing of claims. Sales in the third quarter of 2007 also may have been affected by some patients not returning for repeat treatments during the summer months. We expect that Lucentis sales for the remainder of 2007 will be affected by the continued off-label use of Avastin, reimbursement concerns, the extent to which patients return for treatment after the first year of therapy and the frequency with which those patients receive treatment, and reactions by physicians to our decision regarding compounding pharmacies discussed below.

Given the FDA approval of Lucentis; concerns related to the sterility and repackaging of Avastin for ocular use; and the fact that Avastin is not designed, manufactured, tested in rigorous clinical trials, or approved for ocular use, in October 2007 we announced that we would no longer allow compounding pharmacies the ability to purchase Avastin directly from wholesale distributors. We expect this change in distribution to be effective as of January 1, 2008. However, compounding pharmacies and retinal specialists may continue to obtain Avastin through other established channels.

*Xolair*

Net U.S. sales of Xolair increased 13% to \$121 million in the third quarter and 15% to \$352 million in the first nine months of 2007 from the comparable periods in 2006. The sales growth was primarily driven by increased penetration in the asthma market and, to a lesser extent, price increases in 2006 and 2007. We believe that the FDA's request that we strengthen the existing warning of 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 (RiskMAP), including providing a medication guide for patients, had a modest negative effect on sales in the first nine months of 2007. We and Novartis, our co-promotion collaborator, agreed on a new U.S. label and are working with the FDA to produce a RiskMAP that emphasizes the incidence of anaphylaxis and instruct physicians that patients should be closely observed for an appropriate period of time after Xolair administration. We believe that this update to the label and RiskMAP will not have a significant effect on the way physicians prescribe Xolair.

*Tarceva*

Net U.S. sales of Tarceva increased 1% to \$101 million in the third quarter and 3% to \$304 million in the first nine months of 2007 from the comparable periods in 2006. Sales results were positively affected by price increases in 2006 and 2007, but these increases were substantially offset by product returns and return reserve requirements, which were higher than expected in the second and third quarters of 2007, and by modest decreases in volume. In second-line NSCLC, Tarceva's overall penetration decreased in the first nine months of 2007 relative to the same period in 2006. However, duration of therapy in second-line NSCLC increased in the third quarter and first nine months of 2007 compared to the same periods in 2006. Future sales growth in NSCLC will depend on increases in duration of therapy and penetration, particularly against chemotherapy within select second-line NSCLC patient subsets. In first-line pancreatic cancer, Tarceva's penetration decreased in the first nine months of 2007 compared to the first nine months of 2006 and was flat in the third quarter of 2007 compared to third quarter of 2006.

*Nutropin Products*

Combined net U.S. sales of our Nutropin products increased 1% to \$93 million in the third quarter and remained flat at \$278 million in the first nine months of 2007 from the comparable periods in 2006. Sales in the third quarter and first nine months of 2007 were positively affected by price increases in 2007, but these increases were substantially offset by lower sales volume, partially resulting from the loss of managed care product placement due to pricing.

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### *Thrombolytics*

Combined net U.S. sales of our three thrombolytic products—Activase, Cathflo Activase, and TNKase—increased 12% to \$67 million in the third quarter and 12% to \$202 million in the first nine months of 2007 from the comparable periods in 2006. The increases were 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 increases in product sales were price increases in 2006 and 2007.

### *Pulmozyme*

Net U.S. sales of Pulmozyme increased 14% to \$57 million in the third quarter and 12% to \$164 million in the first nine months of 2007 from the comparable periods in 2006. The increases reflected price increases in 2006 and 2007, and, to a lesser extent, increased penetration in certain patient segments.

### *Raptiva*

Net U.S. sales of Raptiva increased 26% to \$29 million in the third quarter and 21% to \$80 million in the first nine months of 2007 from the comparable periods in 2006. Contributing to the growth in sales were price increases in 2006 and 2007 and increased use of Raptiva in certain patient sub-populations.

### *Sales to Collaborators*

Product sales to collaborators, for use in non-U.S. markets, increased 50% to \$166 million in the third quarter and 169% to \$753 million in the first nine months of 2007 from the comparable periods in 2006. The increases were primarily due to more favorable Herceptin pricing terms to Genentech that were part of the supply agreement with Roche signed in the third quarter of 2006 and higher sales volumes of Herceptin, Avastin, and Rituxan to Roche. The favorable Roche Herceptin pricing terms will continue through the end of 2008.

For the full year 2007, we expect sales to collaborators to be approximately 90% higher than the 2006 level; however, sales to collaborators vary depending on contractual purchase obligations, production schedules and actual demand by collaborators. Therefore, our quarterly sales to collaborators do not directly predict our collaborators' sales to end users outside the U.S., nor are they always an indicator of the extent and timing of royalties expected to be received from the sales of our products in non-U.S. markets.

### *Royalties*

Royalty revenue increased 44% to \$524 million in the third quarter and 48% to \$1,427 million in the first nine months of 2007 from the comparable periods in 2006. The increases were primarily due to higher sales by Roche of our Herceptin, Rituxan, and Avastin products and sales of our Lucentis product by Novartis. The increase from the first nine months of 2006 was also due to an acceleration of royalties in the second quarter of 2007, as discussed below. Of the overall royalties received, royalties from Roche represented approximately 60% in the third quarter and first nine months of 2007 compared to approximately 63% in the third quarter and 62% in the first nine months of 2006. Royalties from other licensees included royalty revenue on our patent licenses, including our Cabilly patent, as discussed below.

In June 2007, we entered into a transaction with an existing licensee to license from them the right to co-develop and commercialize certain molecules. In exchange, we released the licensee from its obligation to make certain royalty payments to us that would have otherwise been owed over the three-and-a-half-year period ending June 2010, and that period may be extended contingent upon certain events as defined in the agreement. We estimate that the fair value of

the royalty revenue owed to us over the three-and-a-half-year period, less any amount recognized in the first quarter of 2007, was approximately \$65 million, and this amount was recognized as royalty revenue in the second quarter of 2007. We also recognized a similar amount as R&D expense for the purchase of the new license, and thus the net earnings per share (EPS) effect of entering into this new collaboration was not significant.

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We have confidential licensing agreements with a number of companies on the Cabilly patent, under which we receive royalty revenue on sales of products covered by the patent. The Cabilly patent expires in December 2018. The net pretax contributions related to the Cabilly patent were as follows (*in millions*):

	<b>Three Months Ended September 30, 2007</b>	<b>Nine Months Ended September 30, 2007</b>
Royalty revenue	\$ 75	\$ 183
Gross expenses <sup>(1)</sup>	\$ 30	\$ 87
Net of tax effect of Cabilly patent on diluted EPS	\$ 0.03	\$ 0.06

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

See also Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for more information on our Cabilly patent reexamination and the MedImmune lawsuit relating to the Cabilly patent.

Cash flows from royalty income include revenue denominated in foreign currencies. We currently enter into foreign currency option contracts (options) and forwards to hedge these foreign currency cash flows. These options and forwards are due to expire between 2007 and 2009.

For the full year 2007, we expect royalty revenue to increase approximately 40% over the 2006 level 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 Revenue***

Contract revenue decreased 20% to \$63 million in the third quarter and increased 13% to \$234 million in the first nine months of 2007 from the comparable periods in 2006. The decrease in the third quarter of 2007 was mainly due to the receipt of a Herceptin milestone payment in the third quarter of 2006 and fewer projects in 2007 on which we received reimbursements. The increase in the first nine months of 2007 was primarily due to recognition of a \$30 million milestone payment from Novartis for European Union approval of Lucentis for the treatment of patients with AMD, higher reimbursements from Roche related to R&D efforts on Avastin and higher reimbursements from Biogen Idec related to R&D efforts on Rituxan. See "Related Party Transactions" below for more information on contract revenue from Roche and Novartis.

Contract revenue varies each quarter and is dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones, and opt-in payments received, and new contract arrangements. For the full year 2007, we expect contract revenue to be approximately 90% of the 2006 level; however, contract revenue is difficult to forecast because it can vary based on the mix of spending by us and our collaborators and the related reimbursements that we will receive.

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

Cost of sales as a percentage of product sales was 17% in the third quarter and first nine months of 2007 compared to 15% in the third quarter and 16% in the first nine months of 2006. Cost of sales in the third quarter and first nine

months of 2007 included a non-recurring charge of approximately \$53 million resulting from our decision to cancel and buy out a future manufacturing obligation. The increases in cost of sales as a percentage of product sales were also due to the recognition of employee stock-based compensation expense of \$16 million in the third quarter and \$49 million in the first nine months of 2007, related to products sold for which employee stock-based compensation expense was previously capitalized as part of inventory costs in 2006, and higher volume of lower margin sales to collaborators. However, cost of sales as a percentage of product sales was favorably affected by the U.S. product sales mix (increased sales of our higher margin products, primarily Lucentis, Avastin, and Herceptin in the first nine months of 2007) and a price increase on sales of Herceptin to Roche, which started in the third quarter of 2006.

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### Research and Development

Research and development (R&D) expenses increased 35% to \$615 million in the third quarter and 50% to \$1,828 million in the first nine months of 2007 from the comparable periods in 2006. The higher levels of expenses in the third quarter and first nine months of 2007 reflected increased development activity across our entire product portfolio, including increased spending on clinical trials, post-marketing studies, clinical manufacturing expenses (notably for Rituxan, Avastin, Xolair, and Lucentis), early-stage projects, and higher research expenses. The increase in the first nine months of 2007 was also due to an increase in up-front, in-licensing expense for new collaborations.

R&D as a percentage of operating revenue was 21% in the third quarter and first nine months of 2007 compared to 19% in the third quarter and first nine months of 2006.

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

<b>Research and Development</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>% Change</b>	<b>2007</b>	<b>2006</b>	<b>% Change</b>
Product development (including post-marketing)	\$ 479	\$ 316	52%	\$ 1,277	\$ 900	42%
Research	109	83	31	304	232	31
In-licensing (up-front and ongoing fees)	27	55	(51)	247	86	187
Total R&D	\$ 615	\$ 454	35%	\$ 1,828	\$ 1,218	50%

### Marketing, General and Administrative

Marketing, general and administrative (MG&A) expenses increased 8% to \$541 million in the third quarter and 11% to \$1,564 million in the first nine months of 2007 from the comparable periods in 2006. The increase from the third quarter of 2006 was primarily due to (i) an increase in royalty expense, primarily to Biogen Idec, resulting from higher Roche sales of Rituxan and (ii) an increase in marketing and sales expenses primarily in support of commercial activities for Lucentis and Rituxan (RA setting). The increase from the first nine months of 2006 was primarily due to: (i) an increase in royalty expense, primarily to Biogen Idec resulting from higher Roche sales of Rituxan, (ii) an increase in general and administrative expenses, including charitable donations and losses on property and equipment disposals, and (iii) an increase in marketing and sales expense, primarily in support of Herceptin (adjuvant setting) and commercial activities related to Lucentis and Rituxan (RA setting).

MG&A as a percentage of operating revenue was 19% in the third quarter and 18% in the first nine months of 2007 compared to 21% in the third quarter and 22% in the first nine months of 2006.

### Collaboration Profit Sharing

Collaboration profit sharing expenses increased 10% to \$276 million in the third quarter and 10% to \$805 million in the first nine months of 2007 from the comparable periods in 2006 primarily due to higher sales of Rituxan and Xolair.

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

#### Three Months

#### Nine Months

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	Ended September 30,			Ended September 30,		
	2007	2006	% Change	2007	2006	% Change
U.S. Rituxan profit sharing expense	\$ 187	\$ 165	13%	\$ 541	\$ 490	10%
U.S. Tarceva profit sharing expense	42	39	8	121	108	12
Total Xolair profit sharing expense	47	46	2	143	137	4
Total collaboration profit sharing expense	\$ 276	\$ 250	10%	\$ 805	\$ 735	10%

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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 R&D expenses, related to Biogen Idec for the periods ended September 30, 2007 and 2006 consisted of the following (*in millions*):

	Three Months			Nine Months		
	Ended September 30,		% Change	Ended September 30,		% Change
	2007	2006		2007	2006	
Product sales, net	\$ 572	\$ 509	12%	\$ 1,689	\$ 1,511	12%
Combined commercial and manufacturing costs and expenses	129	120	8	405	351	15
Combined co-promotion profits	\$ 443	\$ 389	14	\$ 1,284	\$ 1,160	11
Amount due to Biogen Idec for their share of co-promotion profits – included in collaboration profit sharing expense	\$ 187	\$ 165	13%	\$ 541	\$ 490	10%

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

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

	Three Months			Nine Months		
	Ended September 30,		% Change	Ended September 30,		% Change
	2007	2006		2007	2006	
Contract revenue from Biogen Idec (R&D reimbursement)	\$ 27	\$ 20	35%	\$ 83	\$ 59	41%
Royalty expense on sales of Rituxan by Roche and to Zenyaku, and other patent costs – included in MG&A expense	\$ 69	\$ 46	50%	\$ 175	\$ 126	39%

***Write-off of In-process Research and Development Related to Acquisition***

In connection with the acquisition of Tanox in the third quarter of 2007, we recorded a \$77 million charge for in-process research and development. This charge primarily represents acquired R&D for label extensions for Xolair that have not yet been approved by the FDA and require significant further development. We expect to continue further developing these label extensions until a decision is made to file for a label extension or to discontinue development efforts. We expect these development efforts to be completed from 2009 to 2013, if not abandoned sooner.

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### ***Gain on Acquisition***

Under EITF 04-1, a business combination between parties with a preexisting relationship should be evaluated to determine if a settlement of that preexisting relationship exists. The acquisition of Tanox is considered to include the settlement of our 1996 license arrangement of certain intellectual property and rights thereon from Tanox. We measured the amount that the license arrangement is favorable, from our perspective, by comparing it to estimated pricing for current market transactions for intellectual property rights similar to Tanox's intellectual property rights related to Xolair. In connection with the settlement of this license arrangement, we recorded a gain of \$121 million on a pretax basis, in accordance with EITF 04-1.

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

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

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

We recorded recurring charges related to the amortization of intangibles associated with the Redemption and push-down accounting and our acquisition of Tanox in the third quarter of 2007. These charges were \$38 million in the third quarter of 2007 and \$26 million in the third quarter of 2006, and \$90 million in the first nine months of 2007 and \$79 million in the first nine months of 2006.

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

We recorded accrued interest and bond costs related to the COH trial judgment of \$14 million for the third quarter of 2007 and \$13 million for the third quarter of 2006, and \$41 million for the first nine months of 2007 and \$40 million for the first nine months of 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. 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 more information regarding our litigation.

### ***Operating Income***

Operating income was \$1,062 million in the third quarter of 2007, a 26% increase from the third quarter of 2006, and \$3,244 million in the first nine months of 2007, a 45% increase from the first nine months of 2006. Our operating income as a percentage of operating revenue (pretax operating margin) was 37% in the third quarter of 2007 and 35% in the third quarter of 2006, and was 37% in the first nine months of 2007 and 34% in the first nine months of 2006.

**Other Income (Expense)**

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

<b>Other Income, Net</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>% Change</b>	<b>2007</b>	<b>2006</b>	<b>% Change</b>
Gains on sales of biotechnology equity securities, net	\$ 5	\$ 11	(55)%	\$ 17	\$ 81	(79)%
Write-downs of biotechnology debt and equity securities	–	(1)	(100)	(4)	(1)	300
Interest income	80	64	25	219	166	32
Interest expense	(18)	(19)	(5)	(53)	(56)	(5)
Other miscellaneous income (expense)	(1)	–	–	1	3	(67)
Total other income, net	\$ 66	\$ 55	20%	\$ 180	\$ 193	(7)%

Other income, net increased 20% to \$66 million in the third quarter of 2007 and decreased 7% to \$180 million in the first nine months of 2007 over the comparable periods in 2006. Gains on sales of biotechnology equity securities, net were lower, resulting from approximately \$70 million in gains from sales of certain of our biotechnology equity investments in the first nine months of 2006. Interest income increased, primarily due to higher yields and higher average cash balances in the third quarter and first nine months of 2007 from the comparable periods in 2006. For the full year 2007, we expect other income, net to be approximately 90% of 2006 levels, although this may vary with fluctuations in interest rates and unexpected gains or losses from our biotechnology equity and investment portfolio.

**Income Tax Provision**

The effective income tax rate was 39% in the third quarter of 2007 and 37% in the third quarter of 2006. The increase was primarily due to the non-deductible IPR&D charge in the third quarter of 2007 resulting from our acquisition of Tanox. The effective income tax rate was 38% in the first nine months of 2007 and 2006.

We adopted the provisions of FIN 48 on January 1, 2007. Implementation of FIN 48 did not result in any adjustment to our Condensed Consolidated Statements of Income or a cumulative adjustment to retained earnings (accumulated deficit). As a result of the implementation of FIN 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 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*)

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Unrestricted cash, cash equivalents, short-term investments, and long-term marketable debt and equity securities	\$ 4,872	\$ 4,325
Net receivable equity hedge instruments	4	50
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge	\$ 4,876	\$ 4,375

instruments				
Working capital	\$	4,615	\$	3,694
Current ratio		3.2:1		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, was \$4,876 million at September 30, 2007, an increase of \$501 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 our acquisition of Tanox in the third quarter of 2007,

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 4, "Investment Securities and Financial Instruments," in the Notes to the Consolidated Financial Statements of Part II, Item 8 of our Form 10-K for the year ended December 31, 2006 for more 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 Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for factors that could negatively affect our cash position.

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

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

Our "accounts receivable—product sales" was \$1,012 million at September 30, 2007, an increase of \$47 million from December 31, 2006. The increase was primarily due to higher product sales of Avastin. The average collection period of our "accounts receivable—product sales" as measured in days' sales outstanding (DSO) was 40 days for both the third quarter and second quarter of 2007 compared to 37 days for the third quarter of 2006. The increase from the third quarter of 2006 was primarily due to the extended payment terms of approximately 100 days in addition to our customary terms that we offered certain wholesalers in conjunction with the launch of Lucentis on June 30, 2006. This program ended on June 30, 2007 and was revised to an extended payment term of approximately 60 days in addition to our customary terms. We expect the revised payment term to continue into the first quarter of 2008.

Our inventory balance was \$1,425 million at September 30, 2007, an increase of \$247 million from December 31, 2006. The increase was primarily due to finished goods of our Herceptin and Avastin products, as well as bulk campaign production of our Avastin product. In the first nine months of 2007, we capitalized into inventory \$59 million of non-cash employee stock-based compensation costs pursuant to FAS 123R, and recognized \$49 million of previously capitalized employee stock-based compensation costs in cost of sales.

Accounts payable, other accrued liabilities, and other long-term liabilities increased \$215 million in the first nine months of 2007. This increase was mainly due to increases in accrued clinical expenses, accrued royalties, accrued marketing expenses, and other liabilities, which were mainly due to the growth in the business, partially offset by decreases in taxes payable due to payments made during the first nine months of 2007.

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

Cash used in investing activities was primarily related to our acquisition of Tanox, capital expenditures and purchases, sales, and maturities of investments. Our net cash and cash equivalent outlay to acquire Tanox in the third quarter of 2007 was \$833 million, which represents the \$933 million cash consideration, less approximately \$100 million of Tanox's cash and cash equivalents that we acquired. Capital expenditures were \$692 million during the first nine months of 2007 compared to \$888 million during the first nine months of 2006. Capital expenditures in the first nine months of 2007 included ongoing construction of our second manufacturing facility in Vacaville, California, leasehold improvements for newly constructed buildings on our South San Francisco, California campus, construction of our fill/finish facility in Hillsboro, Oregon, and purchases of equipment and information systems.

### ***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 \$815 million during the first nine months of 2007 and \$758 million during the first nine months of 2006 pursuant to our stock repurchase program approved by our Board of Directors. We also received \$381 million during the first nine months of 2007 and \$286 million during the first

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nine months 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 \$160 million in the first nine months of 2007 and \$142 million in the first nine months of 2006.

On October 11, 2007, we entered into a five-year, \$1 billion revolving credit facility with various financial institutions. The credit facility is expected to be used for general corporate and working capital purposes, including providing support for our new \$1 billion commercial paper program. As of October 26, 2007, we had no borrowings under the credit facility and had \$600 million outstanding in commercial paper.

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 million 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, though as of September 30, 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 RHI related to maintaining RHI'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 "Relationship with Roche Holdings, Inc." for more information on RHI's minimum ownership percentage.

We enter into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The most recent trading plan covered approximately one million shares and expired on October 16, 2007.

Our shares repurchased during the first nine months 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
April 1–30, 2007	0.8	82.14
May 1–31, 2007	1.4	79.65
June 1–30, 2007	1.3	75.84
August 1–31, 2007	0.8	73.66
September 1–30, 2007	1.2	78.67
Total	10.0	\$ 81.90

As of September 30, 2007, 72 million cumulative shares had been purchased under our stock repurchase program for \$5.2 billion, and a maximum of 28 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 that there have been no significant changes in the off-balance sheet arrangements disclosed in our Annual Report on Form 10-K for the year ended December 31, 2006 that have or are

reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources.

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### ***Contractual Obligations***

During the first nine months of 2007, we believe that there have been no significant changes in our payments due under contractual obligations, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 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 I, Item 1 of this Form 10-Q for more information.

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

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

We issue shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with RHI provides, among other things, that with respect to any issuance of our Common Stock in the future, we will repurchase a sufficient number of shares so that immediately after such issuance, the percentage of our Common Stock owned by RHI will be no lower than 2% below the "Minimum Percentage" (subject to certain conditions). The Minimum Percentage equals the lowest number of shares of Genentech Common Stock owned by RHI since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech Common Stock by RHI as well as for stock splits or stock combinations) divided by 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech Common Stock outstanding at the time of the July 1999 offering, as adjusted for stock splits. We have repurchased shares of our Common Stock since 2001 (see discussion above in "Liquidity and Capital Resources"). The affiliation agreement also provides that, upon RHI's request, we will repurchase shares of our Common Stock to increase RHI's ownership to the Minimum Percentage. In addition, RHI will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. Under the terms of the affiliation agreement, RHI's Minimum Percentage is 57.7% and RHI's ownership percentage is to be no lower than 55.7%. At September 30, 2007, RHI's ownership percentage was 55.8%.

### **Related Party Transactions**

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

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

**Roche**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Product sales to Roche	\$ 135	\$ 86	\$ 651	\$ 217
Royalties earned from Roche	\$ 317	\$ 230	\$ 855	\$ 602
Contract revenue from Roche	\$ 21	\$ 37	\$ 81	\$ 76
Cost of sales on product sales to Roche	\$ 98	\$ 60	\$ 356	\$ 173
R&D expenses incurred on joint development projects with Roche	\$ 64	\$ 52	\$ 192	\$ 147

Certain R&D expenses are partially reimbursable to us by Roche. In addition, R&D expenses may include the net settlement of amounts that we owed to Roche for R&D expenses that Roche incurred on joint development projects, less amounts reimbursable to us by Roche on these projects.

**Novartis**

Based on information available to us at the time of filing this Form 10-Q, we believe that Novartis holds approximately 33.3 percent 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 percent of our voting stock.

We have an agreement with Novartis under which Novartis has the exclusive right to develop and market Lucentis outside the U.S. for indications related to diseases or disorders of the eye. As part of this agreement, the parties will share the cost of certain of our ongoing development expenses for Lucentis. Novartis makes royalty payments to us on sales of Lucentis outside the U.S.

We, along with Novartis, are co-developing and co-promoting Xolair in the U.S. 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 according to prescribed profit sharing percentages, and our U.S. and European profit sharing expenses are recorded as collaboration profit sharing expense. Effective with our acquisition of Tanox on August 2, 2007, Novartis also makes royalty payments to us on sales of Xolair worldwide and also pays us a manufacturing fee related to Xolair. See Note 6, "Acquisition of Tanox, Inc." in Part I, Item 1 of this Form 10-Q for more information on the acquisition.

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

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2007	2006	2007	2006
Product sales to Novartis	\$ 2	\$ 1	\$ 8	\$ 3
Royalties earned from Novartis	\$ 40	\$ –	\$ 59	\$ 1
Contract revenue from Novartis	\$ 9	\$ 15	\$ 53	\$ 38
Cost of sales on product sales to Novartis	\$ 2	\$ 3	\$ 9	\$ 5
R&D expenses incurred on joint development projects with Novartis	\$ 11	\$ 10	\$ 30	\$ 32
Collaboration profit sharing expense to Novartis	\$ 47	\$ 46	\$ 143	\$ 137

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

Certain R&D expenses are partially reimbursable to us by Novartis. In addition, R&D expenses may include the net settlement of amounts that we owed to Novartis for R&D expenses that Novartis incurred on joint development projects, less amounts reimbursable to us by Novartis on these projects.

See Note 6, “Acquisition of Tanox, Inc.” in Part I, Item 1 of this Form 10-Q for information on Novartis proceeds resulting from our acquisition of Tanox.

## 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	(17.4)	17.4	79.55
Exercises	–	(8.9)	32.31
Cancellations	2.5	(2.5)	75.51
<b>September 30, 2007 (Year to Date)</b>	53.8	94.3	\$ 60.69

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

As of September 30, 2007	Exercisable		Unexercisable		Total	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
In-the-Money	40	\$ 34.85	5	\$ 55.55	45	\$ 37.20
Out-of-the-Money <sup>(1)</sup>	12	83.97	37	81.09	49	81.81
Total Options Outstanding	52		42		94	

(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, \$78.02, at the close of business on September 28, 2007.

**Dilutive Effect of Options**

Grants, net of cancellations, as a percentage of outstanding shares were 1.42% for the first nine months of 2007, 1.43% for the year ended December 31, 2006, and 1.70% for the year ended December 31, 2005.

**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; the impact of new regulations related to coverage and reimbursement; Avastin, Lucentis and Tarceva sales growth; the effect of a new

label and RiskMAP on the use of Xolair; sales to collaborators; royalty and contract revenue; other income, net; days of sales outstanding; revised payment terms for Lucentis; purchase price allocation for and the completion of restructuring programs related to the acquisition of Tanox; further development of label extensions for Xolair; and our credit facility.

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

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limited to, difficulty in enrolling patients in clinical trials; additional time requirements for data analysis; efficacy data concerning any of our products which shows or is perceived to show similar or improved treatment benefit at a lower dose or shorter duration of therapy; BLA preparation and decision making; FDA actions or delays; failure to obtain or maintain FDA approval; the need for additional data or clinical studies; difficulty in obtaining materials from suppliers; unexpected safety, efficacy or manufacturing issues for us or our contractors/collaborators; the ability to supply product and meet demand for our products; 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, R&D, MG&A and stock based compensation expenses; variations in collaborator sales and expenses; actions by Roche Holdings, Inc. that are adverse to our interests; decreases in third party reimbursement rates; the ability to repay our indebtedness; and new accounting pronouncements or guidance. We disclaim and do not undertake any obligation to update or revise any forward-looking statement in this Form 10-Q.

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

Our market risks at September 30, 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 U.S. Securities and Exchange Commission.

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

**Item 4. Controls and Procedures**

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

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

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

See Note 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 Annual Report on Form 10-K for the year ended December 31, 2006 and Part II, Item 1 of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2007 and June 30, 2007.

### 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 that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, royalties, contract revenue, expenses, net income, and earnings per share.

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

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit, or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing

approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. If our large-scale clinical trials are not successful, we will not recover our substantial investments in the product.

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

- The number of and the outcome of clinical trials currently being conducted by us and/or our collaborators. For example, our R&D expenses may increase based on the number of late-stage clinical trials being conducted by us and/or our collaborators.
- The number of products entering into development from late-stage research. For example, there is no guarantee that internal research efforts will succeed in generating a sufficient number of product candidates that are ready to move into development or that will be available for in-licensing on terms acceptable to us and permitted under the anti-trust laws.
- Decisions by Roche Holding AG and affiliates (Roche) whether to exercise its options to develop and sell our future products in non-U.S. markets, and the timing and amount of any related development cost reimbursements.
- Our ability to in-license projects of interest to us, and the timing and amount of related development funding or milestone payments for such licenses. For example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process R&D, which we may record as an R&D expense.
- Participation in a number of collaborative research arrangements. On many of these collaborations, our share of expenses recorded in our financial statements is subject to volatility based on our collaborators' spending activities as well as the mix and timing of activities between the parties.
- Charges incurred in connection with expanding our product manufacturing capabilities, as described below in "Difficulties or delays in product manufacturing or in obtaining materials from our suppliers, or difficulties in accurately forecasting manufacturing capacity needs, could harm our business and/or negatively affect our financial performance."
- Future levels of revenue.

#### **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 U.S. until it has been approved by the FDA, and then can be marketed for only 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 New Drug Application are substantial and can require a number of years. In addition, even if our products receive regulatory approval, they remain subject to ongoing FDA regulations, including, for example, obligations to conduct additional clinical trials or other testing, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

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

- Significant delays in obtaining or failing to obtain approvals, as described above in "The successful development of biotherapeutics is highly uncertain and requires significant expenditures and time."



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

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

*Rituxan:* Rituxan's current competitors in hematology-oncology include Bexxar® (GlaxoSmithKline [GSK]) and Zevalin® (Biogen Idec Inc.), both of which are radioimmunotherapies indicated for the treatment of patients with relapsed or refractory low-grade, follicular or transformed B-cell non-Hodgkin's lymphoma (NHL). Other potential competitors include Campath® (Bayer Corporation/Genzyme) in relapsed chronic lymphocytic leukemia (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); and Revlimid® (Celgene), which is indicated for multiple myeloma and myelodysplastic syndromes (both unapproved uses of Rituxan).

Rituxan's current competitors in rheumatoid arthritis (RA) include Enbrel® (Amgen/Wyeth), Humira® (Abbott Laboratories), 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 receptor being developed by Chugai and Roche; Cimzia™ (certolizumab pegol), an anti-TNF antibody being developed by UCB; and CNTO 148 (golimumab), an anti-TNF antibody being developed by Centocor, Inc. (a wholly owned subsidiary of Johnson & Johnson).

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Rituxan may face future competition in both hematology-oncology and RA from Humax CD20™ (Ofatumumab), an anti-CD20 antibody being co-developed by Genmab and GSK. Genmab and GSK announced their plans to file for approval and launch of Humax™ in the fourth quarter of 2008 for monotherapy use in refractory CLL and monotherapy use in Rituxan refractory NHL. In addition, we are aware of other anti-CD20 molecules in development that, if successful in clinical trials, may compete with Rituxan. Rituxan could also face competition from Treanda® (Cephalon, Inc.), a non-Hodgkin's lymphoma treatment candidate that showed positive results in a Phase III clinical trial involving indolent NHL patients who no longer responded to Rituxan. Full results of the trial are expected to be released in December 2007.

*Herceptin:* Herceptin faces competition in the relapsed metastatic setting from Tykerb® (lapatinib ditosylate), manufactured by GSK. On March 13, 2007, the FDA approved Tykerb®, in combination with capecitabine, for the treatment of patients with advanced or metastatic BC whose tumors overexpress HER2 and who have received prior therapy, including an anthracycline, a taxane, or Herceptin. Market research indicates that lapatinib use in the third quarter is primarily within the later lines of metastatic BC. We will continue to monitor the clinical development of lapatinib in early lines of metastatic and adjuvant breast cancer.

*Lucentis:* We are aware that retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration (AMD), an unapproved use for Avastin, which results in significantly less revenue to us per treatment compared to Lucentis. Although we will no longer allow compounding pharmacies the ability to purchase Avastin from wholesale distributors as of January 1, 2008, we expect ocular use of Avastin to continue. Additionally, an independent head-to-head trial of Avastin and Lucentis in wet AMD, partially funded by the National Eye Institute, is expected to begin enrollment in the next few months. Lucentis also competes with Macugen® (Pfizer/OSI Pharmaceuticals), and with Visudyne® (Novartis) alone, in combination with Lucentis, in combination with Avastin, or in combination with the off-label steroid triamcinolone in wet AMD. In addition, if successful in recently initiated Phase III 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 NSCLC. Astra Zeneca recently announced equivalent survival data when comparing the use of Iressa® versus the use of Taxotere® for the treatment of relapsed NSCLC in an international study. The results of this study have not yet been published, and it is unclear whether a re-filing with U.S. regulatory authorities is pending. Eli Lilly and BMS/ImClone/Merck KGaA recently announced positive data on the use of Alimta® and Erbitux® (Bristol-Myers Squibb), respectively, in combination with chemotherapy for the treatment of front-line NSCLC (an unapproved use of Tarceva). This may have a material impact on the landscape of treatment options for the management of patients with relapsed NSCLC. 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 Zactima® (Astra Zeneca) and Erbitux® in the treatment of relapsed NSCLC and Xeloda® (Roche), in the treatment of pancreatic cancer; none of these products currently 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. Omnitrope® (Sandoz), a biologic similar to Genotropin®, launched in January 2007. In March 2007, Cangene received an approvable letter from the FDA for its growth hormone Accretropin™ as a biologic similar to Humatrope®. Valtropin® (LG Life Sciences along with its partner Biopartners) also received FDA approval in April 2007 as a biologic similar to Humatrope® for three indications: short stature associated with growth hormone deficiency and Turner Syndrome in pediatrics, and growth hormone deficiency in adults. Furthermore, as a result of multiple competitors, we have experienced, and may continue to

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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.).

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

*Raptiva:* Raptiva competes with established therapies for moderate-to-severe psoriasis, including oral systemics such as methotrexate and cyclosporin as well as ultraviolet light therapies. In addition, Raptiva competes with biologic agents Amevive® (Astellas), Enbrel® (Amgen), and Remicade® (Centocor). Raptiva also competes with the biologic agent Humira® (Abbott), which is currently used off-label in the psoriasis market. Abbott is expecting FDA approval of Humira® for the treatment of psoriasis in the first quarter of 2008.

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

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

Sales of our products will depend significantly on the extent to which reimbursement for the cost of our products and related treatments will be available to physicians and patients from government health administration authorities, private health insurers, and other organizations. Third-party payers and government health administration authorities increasingly attempt to limit and/or regulate the reimbursement of medical products and services, including branded prescription drugs. Changes in government legislation or regulation, such as the Medicare Prescription Drug Improvement and Modernization Act of 2003, the Deficit Reduction Act of 2005 and the Food and Drug Administration Amendments Act of 2007, 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 products and may have a material adverse effect on our product sales, results of operations, and financial condition.

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

Manufacturing 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

cancellation of shipments; loss of product in the process of being manufactured; a shortfall, stock-out, or recall of available product inventory; or unplanned increases in production costs, any of which could have a material adverse effect on our business. A number of factors could cause significant production problems or interruptions, including:

- The inability of a supplier to provide raw materials used for manufacture of our products;

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- Equipment obsolescence, malfunctions, or failures;
- Product quality or contamination problems;
- Damage to a facility, including our warehouses and distribution facilities, due to events such as fires or earthquakes, as our South San Francisco, Vacaville, and Oceanside facilities are located in areas where earthquakes and/or fires have occurred;
- Changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes;
- Action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products that we make for others;
- A contract manufacturer going out of business or failing to produce product as contractually required;
- Failure to maintain an adequate state of GMP compliance; and
- Implementation and integration of our new enterprise resource planning system, including the portions related to manufacturing and distribution.

In addition, there are inherent uncertainties associated with forecasting future demand, 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 products. 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, or other excess capacity charges, resulting in an increase in our cost of sales.

Furthermore, certain of our raw materials and supplies required for the production of our principal products, or products that we make for others, are available only through sole-source suppliers (the only recognized supplier available to us) or single-source suppliers (the only approved supplier for us among other sources), 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 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 companies' patents. Patent disputes are frequent and may ultimately preclude the commercialization of products. We have in the past been, are currently, and may in the future be involved in material litigation and other legal proceedings related to our proprietary rights, such as the Cabilly reexamination (discussed in Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q) and disputes in connection with licenses granted to or obtained from third parties. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities with third parties, including the payment of significant royalty expenses, the loss of significant royalty income, or other expenses or losses. Furthermore, an adverse decision or ruling could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision or ruling with respect to



one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

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

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

Litigation and other legal actions to which we are currently or have been subjected relate to, among other things, our patent and other intellectual property rights, licensing arrangements and other contracts with third parties, and product liability. We cannot predict with certainty the eventual outcome of pending proceedings, which may include an injunction against the development, manufacture, or sale of a product or potential product; a judgment with a significant monetary award including the possibility of punitive damages; or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in these proceedings, and such matters could divert management's attention from ongoing business concerns.

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

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

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

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

- 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.
- Our decision to no longer allow compounding pharmacies the ability to purchase Avastin directly from wholesale distributors, which could have a negative impact on Lucentis sales as a result of negative reaction by retinal specialists to our decision.
- Product returns and allowances greater than expected or historically experienced.

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 revenue, and sales to collaborators.**

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

- Roche's decisions about whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets, and the timing and amount of any related development cost reimbursements.
- Variations in Roche's sales and other licensees' sales of licensed products.
- The expiration or termination of existing arrangements with other companies and Roche, which may include development and marketing arrangements for our products in the U.S., Europe, and other countries.
- The timing of non-U.S. approvals, if any, for products licensed to Roche and other licensees.
- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- The initiation of new contractual arrangements with other companies.



- Whether and when contract milestones are achieved.
- The failure or refusal of a licensee to pay royalties.
- The 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 revenue is invalid, unenforceable, or unpatentable, that determination could cause us to suffer a loss of such royalties and/or revenue, 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.
- Fluctuations in foreign currency exchange rates.

**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 subject to public and regulatory scrutiny because of the perceived risk of contamination with the infectious agent that causes bovine spongiform encephalopathy (BSE). Should such BSE contamination occur, it would likely negatively affect our ability to manufacture certain products for an indefinite period of time (or at least until an alternative process is approved), negatively affect our reputation, and could result in a material adverse effect on our product sales, financial condition, and results of operations.

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

The success of our business depends, in large part, on our continued ability to (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.

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

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

RHI's ownership percentage is diluted by the exercise of stock options to purchase shares of our Common Stock by our employees and the purchase of shares of our Common Stock through our employee stock purchase plan. See Note 2, "Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for information regarding employee stock plans. In order to maintain RHI's Minimum Percentage, we repurchase shares of our Common Stock under the stock repurchase program. 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.**

Our affiliation agreement with RHI contains provisions that:

- Require the approval of the directors designated by RHI to make any acquisition or any sale or disposal of all or a portion of our business representing 10 percent or more of our assets, net income, or revenue.
- Enable RHI to maintain its percentage ownership interest in our Common Stock.
- Require us to establish a stock repurchase program designed to maintain RHI's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For information regarding the Minimum Percentage, see Note 5, "Relationship with Roche Holdings, Inc. 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 Holdings, Inc. could cause the price of our Common Stock to decline.**

As of September 30, 2007, RHI owned 587,189,380 shares of our Common Stock, or 55.8 percent of our outstanding shares. All of our shares owned by RHI are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon RHI's request, we will file one or more registration statements under the Securities Act of 1933 in order to permit RHI to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by RHI in the public market could adversely affect the market price of our Common Stock.

**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 Holdings, Inc.**

As our majority stockholder, RHI controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our Board of Directors shall consist of at least three directors designated by RHI, three independent directors nominated by the Nominations Committee, and one Genentech executive officer nominated by the Nominations Committee. Our bylaws also provide that RHI will have the right to obtain proportional representation on our Board until such time that RHI owns less than five percent of our stock. Currently, three of our directors—Mr. William Burns, Dr. Erich Hunziker, and Dr. Jonathan K. C. Knowles—also serve as officers and employees of Roche Holding Ltd and its affiliates. As long as RHI owns in excess of 50 percent of our Common Stock, RHI directors will be two of the three members of the Nominations Committee. Our certificate of incorporation includes provisions related to competition by RHI affiliates with Genentech, offering of corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of specified employees. We cannot assure that RHI will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, persons who are directors and/or officers of Genentech and who are also directors and/or officers of RHI may decline to take action in a manner that might be favorable to us but adverse to RHI.

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



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

The testing and marketing of medical products 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 may be 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, we may be exposed to an increase in premiums and a narrowing of scope of coverage. 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 that such hazardous materials are stored, handled, or released into the environment in violation of law or any permit, we could be subject to loss of our permits, government fines, or penalties and/or other adverse governmental or private actions. The levy of a substantial fine or penalty, the payment of significant environmental remediation costs, or the loss of a permit or other authorization to operate or engage in our ordinary course of business could materially adversely affect our business.

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

**Fluctuations in our operating results could affect the price of our Common Stock.**

Our operating results may vary from period to period for several reasons, including, but not limited to, the following:

- The overall competitive environment for our products, as described in “We face competition” above.
- The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns, or sales initiatives that we may undertake from time to time.
- The amount and timing of our sales to Roche and our other collaborators of products for sale outside the U.S. and the amount and timing of sales to their respective customers, which directly affect both our product sales and royalty revenue.
- The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of 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 the use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and the use of our products may be affected by the results of clinical studies reporting on the benefits or risks of a product.
- The potential introduction of new products and additional indications for existing products.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.
- Pricing decisions that we or our competitors have adopted or may adopt, as well as our Avastin Patient Assistance Program.
- Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers who supply our products.

**Our integration of new information systems could disrupt our internal operations, which could decrease our revenue 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, 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 related to products under development or being commercialized by us or our competitors.
- Concerns about our pricing initiatives and distribution strategy, and the potential effect of such initiatives and strategy on the utilization of our products or our product sales.
- Developments or outcomes of litigation, including litigation regarding proprietary and patent rights.
- Regulatory developments or delays concerning our products in the U.S. and other countries.
- Issues concerning the efficacy or safety of our products or of biotechnology products generally.
- Economic and other external factors or a disaster or crisis.

- 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; the results of any tax examinations; changing interpretations of existing tax laws or regulations; changes in estimates of prior years' items; past and future levels of R&D spending; acquisitions; changes in our corporate structure; and changes in overall levels of income before taxes.

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

As of October 26, 2007, we had approximately \$2.0 billion of long-term debt and \$600 million of commercial paper 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 risk, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory, and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase our vulnerability to general adverse economic and industry conditions, and require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts, and other general corporate purposes, and limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

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

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

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

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2007, we are authorized to repurchase up to 100 million 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 September 30, 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 we do not currently have 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 Holdings, Inc. (RHI) related to maintaining RHI'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 Note 5, "Relationship

with Roche Holdings, Inc. and Related Party Transactions,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for more information on RHI’s minimum ownership percentage.

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We enter 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 most recent trading plan covered approximately one million shares and expired on October 16, 2007.

Our shares repurchased during the third quarter of 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>
August 1–31, 2007	0.8	73.66		
September 1–30, 2007	1.2	78.67		
Total	2.0	\$ 76.69	72	28

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

<b>Exhibit No.</b>	<b>Description</b>	<b>Location</b>
15.1	Letter regarding Unaudited Interim Financial Information.	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended	Filed herewith
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

**SIGNATURES**

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

GENENTECH, INC.

Date: November 2, 2007

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

Date: November 2, 2007

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

Date: November 2, 2007

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