

GENENTECH INC  
Form 10-Q  
November 04, 2008

---

---

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

---

FORM 10-Q

---

(Mark  
One)

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

For the quarterly period ended September 30, 2008

or

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

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

Commission File Number: 1-9813

GENENTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware 94-2347624  
(State or other jurisdiction of incorporation or (I.R.S. Employer Identification Number)  
organization)

1 DNA Way, South San Francisco, California 94080-4990  
(Address of principal executive offices and Zip Code)

(650) 225-1000  
(Registrant's telephone number, including area code)

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

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

Edgar Filing: GENENTECH INC - Form 10-Q

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

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

Class	Number of Shares Outstanding
Common Stock \$0.02 par value	1,052,033,529 Outstanding at October 31, 2008

GENENTECH, INC.  
TABLE OF CONTENTS

		Page No.
<b>PART I—FINANCIAL INFORMATION</b>		
Item 1.	Financial Statements (unaudited)	3
	Condensed Consolidated Statements of Income— for the three months and nine months ended September 30, 2008 and 2007	3
	Condensed Consolidated Statements of Cash Flows— for the nine months ended September 30, 2008 and 2007	4
	Condensed Consolidated Balance Sheets— September 30, 2008 and December 31, 2007	5
	Notes to Condensed Consolidated Financial Statements	6-19
	Report of Independent Registered Public Accounting Firm	20
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	21-51
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	52
Item 4.	Controls and Procedures	52
<b>PART II—OTHER INFORMATION</b>		
Item 1.	Legal Proceedings	53
Item 1A.	Risk Factors	53-67
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	67
Item 6.	Exhibits	68
<b>SIGNATURES</b>		<b>69</b>

In this report, “Genentech,” “we,” “us,” and “our” refer to Genentech, Inc. and its consolidated subsidiaries. “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); Genentech®; Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis® (ranibizumab) 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 registered trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a registered trademark of Novartis AG. This report also includes other trademarks, service marks, and trade names of other companies.

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenue				
Product sales (including amounts from related parties: three months—2008—\$148; 2007—\$137; nine months—2008—\$435; 2007—\$659)	\$ 2,634	\$ 2,321	\$ 7,549	\$ 7,094
Royalties (including amounts from related parties: three months—2008—\$459; 2007—\$357; nine months—2008—\$1,333; 2007—\$914)	687	524	1,932	1,427
Contract revenue (including amounts from related parties: three months—2008—\$53; 2007—\$30; nine months—2008—\$119; 2007—\$134)	91	63	230	234
Total operating revenue	3,412	2,908	9,711	8,755
Costs and expenses				
Cost of sales (including amounts for related parties: three months—2008—\$94; 2007—\$100; nine months—2008—\$251; 2007—\$365)	409	406	1,240	1,227
Research and development (including amounts from programs where related parties share costs: three months—2008—\$95; 2007—\$75; nine months—2008—\$264; 2007—\$222) (including amounts for which reimbursement was recorded as contract revenue: three months—2008—\$57; 2007—\$49; nine months—2008—\$154; 2007—\$154)	777	615	2,043	1,828
Marketing, general and administrative	611	541	1,687	1,564
Collaboration profit sharing (including related party amounts: three months—2008—\$49; 2007—\$47; nine months—2008—\$138; 2007—\$143)	315	276	907	805
Write-off of in-process research and development related to acquisition	—	77	—	77
Gain on acquisition	—	(121)	—	(121)
Recurring amortization charges related to redemption and acquisition	43	38	129	90
Special items: litigation-related	40	14	(260)	41
Total costs and expenses	2,195	1,846	5,746	5,511
Operating income	1,217	1,062	3,965	3,244

Edgar Filing: GENENTECH INC - Form 10-Q

Other income (expense):

Interest and other income (expense), net	(33)	84	133	233
Interest expense	(25)	(18)	(57)	(53)
Total other income (expense), net	(58)	66	76	180
Income before taxes	1,159	1,128	4,041	3,424
Income tax provision	428	443	1,546	1,286
Net income	\$ 731	\$ 685	\$ 2,495	\$ 2,138
Earnings per share				
Basic	\$ 0.69	\$ 0.65	\$ 2.37	\$ 2.03
Diluted	\$ 0.68	\$ 0.64	\$ 2.34	\$ 2.00
Shares used to compute basic earnings per share	1,055	1,053	1,053	1,053
Shares used to compute diluted earnings per share	1,071	1,069	1,067	1,070

See Notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2008	2007
Cash flows from operating activities		
Net income	\$ 2,495	\$ 2,138
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	433	345
Employee stock-based compensation	311	300
Excess tax benefit from stock-based compensation arrangements	(119)	(160)
In-process research and development	–	77
Gain on acquisition	–	(121)
Deferred income taxes	207	(116)
Deferred revenue	(15)	(50)
Litigation-related special items	(260)	39
Gain on sales of securities available-for-sale and other	(76)	(15)
Impairment of preferred securities	67	–
Write-downs of and losses on securities available-for-sale and other	48	4
Loss on property and equipment dispositions and other	24	30
Changes in assets and liabilities:		
Receivables and other current assets	(31)	(236)
Inventories	88	(238)
Investments in trading securities	(2)	(140)
Accounts payable, other accrued liabilities, and other long-term liabilities	(214)	216
Accrued litigation	(476)	–
Net cash provided by operating activities	2,480	2,073
Cash flows from investing activities		
Purchases of securities available-for-sale	(1,314)	(622)
Proceeds from sales of securities available-for-sale	1,018	482
Proceeds from maturities of securities available-for-sale	192	358
Capital expenditures	(569)	(692)
Change in other intangible and long-term assets	22	(39)
Acquisition and related costs, net	–	(833)
Net cash used in investing activities	(651)	(1,346)
Cash flows from financing activities		
Stock issuances	632	381
Stock repurchases	(756)	(815)
Excess tax benefit from stock-based compensation arrangements	119	160
Maturities of commercial paper	(63)	–
Net cash used in financing activities	(68)	(274)
Net increase in cash and cash equivalents	1,761	453
Cash and cash equivalents at beginning of period	2,514	1,250

Edgar Filing: GENENTECH INC - Form 10-Q

Cash and cash equivalents at end of period	\$	4,275	\$	1,703
Supplemental cash flow data				
Cash paid during the period for:				
Income taxes	\$	1,337	\$	1,277
Interest		77		71
Non-cash investing and financing activities				
Capitalization of construction in progress related to financing lease transactions		104		156
Transfer of restricted cash to short-term investments		788		—

See Notes to Condensed Consolidated Financial Statements.



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

	September 30, 2008	December 31, 2007
Assets		
Current assets		
Cash and cash equivalents	\$ 4,275	\$ 2,514
Short-term investments	1,657	1,461
Restricted cash and investments	–	788
Accounts receivable—product sales (net of allowances of: 2008—\$158; 2007—\$116; including amounts from related parties: 2008—\$53; 2007—\$2)	862	847
Accounts receivable—royalties (including amounts from related parties: 2008—\$541; 2007—\$463)	734	620
Accounts receivable—other (including amounts from related parties: 2008—\$115; 2007—\$233)	232	299
Inventories	1,408	1,493
Deferred tax assets	395	614
Prepaid expenses	94	100
Other current assets	34	17
Total current assets	9,691	8,753
Long-term marketable debt and equity securities	2,606	2,090
Property, plant and equipment, net	5,320	4,986
Goodwill	1,590	1,577
Other intangible assets	1,046	1,168
Other long-term assets	358	366
Total assets	\$ 20,611	\$ 18,940
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable (including amounts to related parties: 2008—\$5; 2007—\$2)	\$ 235	\$ 420
Commercial paper	536	599
Deferred revenue (including amounts from related parties: 2008—\$70; 2007—\$63)	81	73
Taxes payable	79	173
Accrued litigation	–	776
Other accrued liabilities (including amounts to related parties: 2008—\$285; 2007—\$230)	1,905	1,877
Total current liabilities	2,836	3,918
Long-term debt	2,504	2,402
Deferred revenue (including amounts from related parties: 2008—\$367; 2007—\$384)	397	418
Other long-term liabilities	248	297

Edgar Filing: GENENTECH INC - Form 10-Q

Total liabilities	5,985	7,035
Commitments and contingencies		
Stockholders' equity		
Common stock	21	21
Additional paid-in capital	11,897	10,695
Accumulated other comprehensive income	137	197
Retained earnings	2,571	992
Total stockholders' equity	14,626	11,905
Total liabilities and stockholders' equity	\$ 20,611	\$ 18,940

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 normally required by U.S. generally accepted accounting principles (GAAP) can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2007. In the opinion of management, the financial statements include all adjustments, consisting only of normal and recurring adjustments, considered necessary for the fair presentation of our financial position and operating results.

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

Principles of Consolidation

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

Use of Estimates

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

Recent Accounting Pronouncements

In February 2008, the Financial Accounting Standards Board (FASB) issued Statement of Financial Position (FSP) No. 157-2, which delays the effective date of FASB Statement of Financial Accounting Standards (FAS) No. 157, "Fair Value Measurements" (FAS 157) for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value on a recurring basis (items that are remeasured at least annually). The FSP defers the effective date of FAS 157 for non-financial assets and non-financial liabilities until our fiscal year beginning on January 1, 2009. We do not expect the adoption of FAS 157 for non-financial assets and non-financial liabilities to have an effect on our consolidated financial statements.

In March 2008, the FASB issued FAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133" (FAS 161). FAS 161 requires us to provide greater transparency about how and why we use derivative instruments, how the instruments and related hedged items are accounted for under FAS 133, and how the instruments and related hedged items affect our financial position, results of operations, and cash flows. FAS 161 is effective for us beginning on January 1, 2009. We do not expect the adoption of FAS 161 to have an effect on our consolidated financial statements, but we will be required to expand our disclosure regarding our

derivative instruments.

#### Revenue Recognition

We recognize revenue from the sale of our products, royalties earned, and contract arrangements. Certain of our revenue arrangements that contain multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has standalone value to the customer and whether there is objective

-6-

---

and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

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

#### Earnings Per Share

Basic earnings per share (EPS) are computed based on the weighted-average number of shares of our Common Stock outstanding. Diluted EPS are computed based on the weighted-average number of shares of our Common Stock and dilutive stock options.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Numerator:				
Net income	\$ 731	\$ 685	\$ 2,495	\$ 2,138
Denominator:				
Weighted-average shares outstanding used to compute basic earnings per share	1,055	1,053	1,053	1,053
Effect of dilutive stock options	16	16	14	17
Weighted-average shares outstanding and dilutive securities used to compute diluted earnings per share	1,071	1,069	1,067	1,070

Outstanding employee stock options to purchase 17 million and 48 million shares of our Common Stock were excluded from the computation of diluted EPS for the third quarter and first nine months of 2008, respectively, because the effect would have been anti-dilutive.

#### Comprehensive Income

Comprehensive income comprises net income and other comprehensive income (OCI). OCI includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in OCI changes in the estimated fair value of derivatives designated as effective cash flow hedges, net unrealized gains and losses on our securities available-for-sale, and gains or losses and prior service costs or credits related to our post-retirement benefit plan that

arise during the period but are not recognized as components of net periodic benefit cost.

-7-

---

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

	September 30, 2008		December 31, 2007	
Net unrealized gains on securities available-for-sale	\$	136	\$	219
Net unrealized gains (losses) on cash flow hedges		9		(14)
Accumulated changes in post-retirement benefit obligation		(8)		(8)
Accumulated other comprehensive income	\$	137	\$	197

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

	Three Months		Nine Months					
	Ended September 30,		Ended September 30,					
	2008	2007	2008	2007				
Net income	\$	731	\$	685	\$	2,495	\$	2,138
(Decrease) increase in unrealized gains on securities available-for-sale		(20)		19		(83)		10
Increase (decrease) in unrealized gains on cash flow hedges		52		(13)		23		(2)
Comprehensive income, net of income taxes	\$	763	\$	691	\$	2,435	\$	2,146

The increase in net unrealized gains on cash flow hedges during the third quarter and first nine months of 2008 was primarily due to the strengthening of the U.S. dollar during these periods compared to the same periods in 2007. In the periods in which the hedged transaction affects earnings, any gains or losses on cash flow hedges will be offset by revenue denominated in the underlying foreign currency.

#### Fair Value of Financial Instruments

The fair value of our financial instruments reflects the amounts that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value estimates presented in this report reflect the information available to us as of September 30, 2008 and December 31, 2007. See Note 4, "Fair Value Measurements."

#### Derivative Instruments

Our derivative instruments consist of cash flow and fair value hedges. Our cash flow hedges consist of foreign currency exchange options and forwards. As of September 30, 2008, unrealized net losses of approximately \$12 million were expected to be reclassified from accumulated OCI to earnings within the next 12 months. If realized, these amounts are expected to be offset by increases in the underlying foreign-currency-denominated royalty revenue over this same 12-month period. Our fair value hedges consist of interest rate swap instruments and equity hedges which are recorded against the assets and liabilities being hedged.

#### Note 2. Retention Plans and Employee Stock-Based Compensation

##### Retention Plan Costs

On July 21, 2008, we announced that we received an unsolicited proposal from Roche to acquire all of the outstanding shares of our Common Stock not owned by Roche at a price of \$89 in cash per share (the Roche Proposal). See also Note 6, "Relationship with Roche Holdings, Inc. and Related Party Transactions," for more information on the Roche

Proposal. On August 18, 2008, we announced that a special committee of our Board of Directors composed of our independent directors (the Special Committee) approved the implementation of two retention plans that together cover substantially all employees of the company. The plans are estimated to cost approximately \$375 million, payable in cash, and are being implemented in lieu of our 2008 annual stock option grant. The timing of the payments related to these plans will depend on the outcome of the Roche Proposal. If a merger of Genentech with Roche or an affiliate of Roche has not occurred on or before June 30, 2009, we will pay the retention bonus at that time in accordance with the terms of the



plans. We are currently recognizing the retention plan costs in our financial statements ratably over the period from August 18, 2008 to June 30, 2009. If a merger of Genentech with Roche or an affiliate of Roche has occurred on or before June 30, 2009, the timing of the payments and the recognition of the expense will depend on the terms of the merger. During the third quarter and first nine months of 2008, total costs for the retention plans were \$53 million, of which \$44 million was expensed and \$9 million was capitalized into inventory, which will be recognized as cost of sales (COS) as products that were manufactured after the initiation of the retention plans are estimated to be sold.

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

The components of employee stock-based compensation expense recognized under FAS No. 123(R), "Share-Based Payment" (FAS 123R), were as follows (in millions):

	Three Months		Nine Months	
	Ended September 30, 2008	2007	Ended September 30, 2008	2007
Cost of sales	\$ 20	\$ 16	\$ 62	\$ 49
Research and development	39	37	119	114
Marketing, general and administrative	44	44	130	137
Total employee stock-based compensation expense	\$ 103	\$ 97	\$ 311	\$ 300

As of September 30, 2008, total compensation costs related to unvested stock options not yet recognized was \$573 million, which is expected to be allocated to expense and production costs over a weighted-average period of 29 months. The portion allocated to production costs will be recognized as COS when the related products are estimated to be sold.

#### 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:

	Three Months		Nine Months	
	Ended September 30, 2008	2007	Ended September 30, 2008	2007
Risk-free interest rate	3.1%	4.3%	3.0%	4.3%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	23.0%	25.0%	24.0%	25.0%
Expected term (years)	5.0	5.0	5.0	5.0

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



## Note 3. Condensed Consolidated Financial Statement Detail

## Inventories

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

	September 30, 2008	December 31, 2007
Raw materials and supplies	\$ 116	\$ 119
Work-in-process	1,096	1,062
Finished goods	196	312
Total	\$ 1,408	\$ 1,493

Included in work-in-process as of September 30, 2008 were approximately \$77 million of inventories using a manufacturing process that is awaiting regulatory licensure.

The carrying value of inventory on our Condensed Consolidated Balance Sheets as of September 30, 2008 and December 31, 2007 included employee stock-based compensation costs of \$67 million and \$72 million, respectively. The carrying value of inventory on our Condensed Consolidated Balance Sheet as of September 30, 2008 also included retention plan costs of \$9 million.

## Note 4. Fair Value Measurements

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

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

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

Level 3—unobservable inputs

The adoption of FAS 157 did not have an effect on our financial condition or results of operations, but FAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure focuses on the inputs used to measure fair value, particularly in instances in which the measurement uses significant unobservable (Level 3) inputs. A substantial majority of our financial instruments are Level 1 and Level 2 assets.

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

(In millions)	September 30, 2008		December 31, 2007	
	Assets	Liabilities	Assets	Liabilities
Cash and cash equivalents	\$ 4,275	\$ –	\$ 2,514	\$ –
Restricted cash	–	–	788	–
Short-term investments	1,657	–	1,461	–
Long-term marketable debt securities	2,266	–	1,674	–
Total fixed income investment portfolio	8,198	–	6,437	–
Long-term marketable equity securities	340	–	416	–
Total derivative financial instruments	72	12	30	19
Total	\$ 8,610	\$ 12	\$ 6,883	\$ 19

The following table sets forth the fair value of our financial assets and liabilities, allocated into Level 1, Level 2, and Level 3 that were measured on a recurring basis as of September 30, 2008 (in millions).

	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Cash and cash equivalents	\$ 2,158	\$ 2,117	\$ –	\$ 4,275
Trading securities	88	914	1	1,003
Securities available-for-sale	159	2,607	154	2,920
Equity securities	340	–	–	340
Derivative financial instruments	33	39	–	72
Total	\$ 2,778	\$ 5,677	\$ 155	\$ 8,610
<b>Liabilities</b>				
Derivative financial instruments(1)	\$ –	\$ 12	\$ –	\$ 12

(1) Our Level 2 liabilities consisted of derivative financial instruments including currency forward contracts and currency option contracts.

As of September 30, 2008, the fair value of our Level 1 assets was \$2.8 billion, consisting primarily of cash, money market instruments, marketable equity securities in biotechnology companies with which we have collaboration agreements, and U.S. Treasury securities. Included in this amount were gross unrecognized gains and losses of approximately \$320 million and \$20 million, respectively, primarily related to marketable equity securities.

As of September 30, 2008, the fair value of our Level 2 assets was \$5.7 billion consisting primarily of commercial paper, corporate bonds, and government and agency securities. Asset-backed securities and preferred securities represent less than 5% of the total value of Level 2 assets. Included in the total amount were gross unrecognized losses of approximately \$60 million related to corporate bonds, government and agency securities and preferred securities, partially offset by approximately \$10 million of gross unrecognized gains on various fixed income investments. In addition, the fair value of our Level 2 assets included approximately \$40 million in gross unrecognized gains primarily related to foreign exchange derivative contracts which serve as hedge instruments against anticipated foreign-currency denominated royalty revenue. During the third quarter of 2008, the U.S. Treasury announced actions that significantly reduced the value of U.S. government agency preferred securities that we hold as investments. As a

result, we recorded an impairment charge of \$46 million during the third quarter of 2008. Furthermore, since we intend to hold these investments, we reclassified them from short-term Level 2 assets to long-term Level 2 assets.

Our Level 3 assets included student loan auction-rate securities, structured investment vehicle securities, and the preferred securities of an insolvent company. As of September 30, 2008, we held \$155 million of investments, which were measured using unobservable (Level 3) inputs, representing approximately 2% of our total fair value investment portfolio. Student loan auction-rate securities of \$154 million and structured investment vehicle

securities of \$1 million were valued based on broker-provided valuation models. In addition, our Level 3 assets included preferred securities in a financial institution that declared bankruptcy during the third quarter of 2008. We recorded the full carrying amount of \$21 million as an impairment charge, because we do not expect to recover the value of these assets during the bankruptcy proceedings. We also transferred the financial institution preferred securities to Level 3 assets from Level 2 assets, since we recorded the investment at zero value rather than a value based on an observable input.

The following table sets forth a summary of the changes in the fair value of our Level 3 financial assets, which were measured at fair value on a recurring basis for the third quarter and first nine months of 2008 (in millions).

	Three Months Ended September 30, 2008			Nine Months Ended September 30, 2008		
	Structured Investment Vehicle Securities	Auction-Rate Securities	Preferred Securities	Structured Investment Vehicle Securities	Auction-Rate Securities	Preferred Securities
Beginning balance	\$ 2	\$ 155	\$ –	\$ 7	\$ –	\$ –
Transfer into Level 3(1)	–	–	21	–	174	21
Impairment charges	–	–	(21)	–	–	(21)
Unrealized losses(2)	–	–	–	(1)	(16)	–
Purchases, issuances, settlement	(1)	(1)	–	(5)	(4)	–
Ending balance	\$ 1	\$ 154	\$ –	\$ 1	\$ 154	\$ –

(1) In the third quarter of 2008, we transferred \$21 million of preferred securities into Level 3 assets. In the first nine months of 2008, we transferred \$195 million of auction-rate securities and preferred securities into Level 3 assets.

(2) The unrealized losses of \$17 million in the first nine months of 2008 were included in OCI as of September 30, 2008.

#### Note 5. Contingencies

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

On October 4, 2004, we received a subpoena from the U.S. Department of Justice requesting documents related to the promotion of Rituxan, a prescription treatment now approved for five indications. We are cooperating with the associated investigation. Through counsel we are having discussions with government representatives about the status of their investigation and Genentech's views on this matter, including potential resolution. Previously, the investigation had been both criminal and civil in nature. We have been informed by the criminal prosecutor handling this matter that the government has declined to prosecute the company criminally in connection with this investigation. The civil matter is still ongoing. 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 that are referred to as the "Riggs/Itakura Patents." Since that time, we have entered into license agreements with various companies to manufacture, use, and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses

under the Riggs/Itakura Patents. On June 10, 2002, a jury voted to award COH approximately \$300 million in compensatory damages. On June 24, 2002, a jury voted to award COH an additional \$200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002. Included within current liabilities in "Accrued litigation" in the accompanying Condensed Consolidated Balance Sheet at December 31, 2007 was \$776 million, which represented our estimate of the costs for the resolution of the COH matter as of that reporting date. We filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. On October 21, 2004, the California Court of Appeal affirmed the verdict and damages awards in all respects. On November 22, 2004, the California Court of Appeal modified its opinion without changing the verdict and denied Genentech's request for rehearing. On November 24, 2004, we filed a petition seeking review by the California Supreme Court. On February 2, 2005, the California Supreme Court granted that petition. The California Supreme

Court heard our appeal on this matter on February 5, 2008, and on April 24, 2008 overturned the award of \$200 million in punitive damages to COH but upheld the award of \$300 million in compensatory damages. We paid \$476 million to COH in the second quarter of 2008, reflecting the amount of compensatory damages awarded plus interest thereon from the date of the original decision, June 10, 2002.

As a result of the April 24, 2008 California Supreme Court decision, we reversed a \$300 million net litigation accrual related to the punitive damages and accrued interest, which we recorded as "Special items: litigation-related" in our Condensed Consolidated Statements of Income for the first quarter and first nine months of 2008. In the third quarter and first nine months of 2007, we recorded accrued interest and bond costs on both compensatory and punitive damages totaling \$14 million and \$41 million, respectively. In conjunction with the COH judgment in 2002, we posted a surety bond and were required to pledge cash and investments of \$788 million to secure the bond, and this balance was reflected in "Restricted cash and investments" in the accompanying Condensed Consolidated Balance Sheet as of December 31, 2007. During the third quarter of 2008, the court completed certain administrative procedures to dismiss the case. As a result, the restrictions were lifted from the restricted cash and investments accounts, which consisted of available-for-sale investments, and the funds became available for use in our operations. We and COH have had discussions, but have not reached agreement, regarding additional royalties and other amounts that Genentech owes COH under the 1976 agreement for third-party product sales and settlement of a third-party patent litigation that occurred after the 2002 judgment. Discussions are ongoing. We recorded additional costs of \$40 million as "Special items: litigation-related" in the third quarter of 2008 based on our estimate of our range of liability in connection with the resolution of these issues.

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 related 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 included claims for violation of anti-trust, patent, and unfair competition laws. MedImmune sought a ruling that the Cabilly patent was invalid and/or unenforceable, a determination that MedImmune did 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, and other relief. On June 11, 2008, we announced that we settled this litigation with MedImmune. Pursuant to the settlement agreement, the U.S. District Court dismissed all of the claims against us in the lawsuit. The litigation has been fully resolved and dismissed, and the settlement did not have a material effect on our operating results for the third quarter and first nine months of 2008.

On May 13, 2005, a request was filed by a third party for reexamination of the Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent and Trademark Office (Patent Office) ordered reexamination of the Cabilly patent. On September 13, 2005, the Patent Office mailed an initial non-final Patent Office action rejecting all 36 claims of the Cabilly patent. We filed our response to the Patent Office action on November 25, 2005. On December 23, 2005, a second request for reexamination of the Cabilly patent was filed by another third party, and on January 23, 2006, the Patent Office granted that request. On June 6, 2006, the two reexaminations were merged into one proceeding. On August 16, 2006, the Patent Office mailed a non-final Patent Office action in the merged proceeding rejecting all the claims of the Cabilly patent based on issues raised in the two reexamination requests. We filed our response to the Patent Office action on October 30, 2006. On February 16, 2007, the Patent Office mailed a final Patent Office action rejecting all the claims of the Cabilly patent. We responded to the final Patent Office action on May 21, 2007 and requested continued reexamination. On May 31, 2007, the Patent Office granted the request for continued reexamination, and in doing so withdrew the finality of the February 2007 Patent Office action and agreed to treat our May 21, 2007 filing as a response to a first Patent Office action. On February 25, 2008, the Patent Office mailed a final Patent Office action rejecting all the claims of the Cabilly patent. We filed our response to that final Patent Office action on June 6, 2008. On July 19, 2008, the Patent Office mailed an advisory action replying to our response and confirming the



rejection of all claims of the Cabilly patent. We filed a notice of appeal challenging the rejection on August 22, 2008. Our opening appeal brief is due to be filed by December 10, 2008. The Cabilly patent, which expires in 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and deoxyribonucleic acid (DNA) used in these methods. We have licensed the Cabilly patent to other companies and derive significant royalties from those licenses. The Cabilly patent licenses contributed royalty revenue of \$106 million and \$265 million in the third quarter and first nine months of 2008, respectively. The claims

of the Cabilly patent remain valid and enforceable throughout the reexamination and appeals processes. The outcome of this matter cannot be determined at this time.

In 2006, we made development decisions involving our humanized anti-CD20 program, and our collaborator, Biogen Idec Inc., disagreed with certain of our development decisions related to humanized anti-CD20 products. Under our 2003 collaboration agreement with Biogen Idec, we believe that we are permitted to proceed with further trials of certain humanized anti-CD20 antibodies, but Biogen Idec disagreed with our position. The disputed issues have been submitted to arbitration. In the arbitration, Biogen Idec filed motions for a preliminary injunction and summary judgment seeking to stop us from proceeding with certain development activities, including planned clinical trials. On April 20, 2007, the arbitration panel denied Biogen Idec's motion for a preliminary injunction and Biogen Idec's motion for summary judgment. Resolution of the arbitration could require that both parties agree to certain development decisions before moving forward with humanized anti-CD20 antibody clinical trials (and possibly clinical trials of other collaboration products, including Rituxan), in which case we may have to alter or cancel planned clinical trials in order to obtain Biogen Idec's approval. Each party is also seeking monetary damages from the other. The arbitrators held hearings on this matter over several days in September 2008, and an additional day of hearing is scheduled for December 9, 2008. We expect a final decision from the arbitrators by approximately June 2009, unless the parties are able to resolve the matter earlier through settlement discussions or otherwise. The outcome of this matter cannot be determined at this time.

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

On May 30, 2008, Centocor, Inc. filed a patent lawsuit against Genentech and COH in the U.S. District Court for the Central District of California. The lawsuit relates to the Cabilly patent that we co-own with COH and under which Centocor and other companies have been licensed and are paying royalties to us. The lawsuit seeks a declaratory judgment of patent invalidity and unenforceability with regard to the Cabilly patent and of patent non-infringement with regard to Centocor's marketed product ReoPro® (Abciximab) and its unapproved product CNTO 1275 (Ustekinumab). Centocor originally sought to recover the royalties that it has paid to Genentech for ReoPro® and the monies it alleges that Celltech has paid to Genentech for Remicade® (infliximab), a product marketed by Centocor (a wholly owned subsidiary of Johnson & Johnson) under an agreement between Centocor and Celltech, but Centocor withdrew those claims in connection with its first amended complaint filed on September 3, 2008. Genentech answered the complaint on September 19, 2008 and also filed counterclaims against Centocor alleging that four Centocor products infringe certain Genentech patents. Genentech filed an amendment to those counterclaims on October 10, 2008. The outcome of this matter cannot be determined at this time.

On May 8, June 11, August 8, and September 29 of 2008, Genentech was named as a defendant, along with InterMune, Inc. and its former chief executive officer, W. Scott Harkonen, in four separate class-action complaints filed in the U.S. District Court for the Northern District of California on behalf of plaintiffs who allegedly paid part or

all of the purchase price for Actimmune® for the treatment of idiopathic pulmonary fibrosis. Actimmune® is an interferon-gamma product that was licensed by Genentech to Connectics Corporation and was subsequently assigned to InterMune. InterMune currently sells Actimmune® in the U.S. The complaints are related in part to royalties that we received in connection with the Actimmune® product. The May 8, June 11, and August 8 complaints have been consolidated into a single amended complaint that claims and seeks damages for violations of federal racketeering laws, unfair competition laws, and consumer protection laws, and for unjust enrichment. The

September 29 complaint includes six claims, but only names Genentech as a defendant in one claim for damages for unjust enrichment. The outcome of these matters cannot be determined at this time.

Subsequent to the Roche Proposal, more than thirty shareholder lawsuits have been filed against Genentech and/or the members of its Board of Directors, and various Roche entities, including RHI, Roche Holding AG, and Roche Holding Ltd. The lawsuits are currently pending in various state courts, including the Delaware Court of Chancery, San Francisco County Superior Court, and San Mateo County Superior Court, as well as in the United States District Court for the Northern District of California. The lawsuits generally assert class-action claims for breach of fiduciary duty and aiding and abetting breaches of fiduciary duty based in part on allegations that, in connection with Roche's offer to purchase the remaining shares, some or all of the defendants failed to properly value Genentech, failed to solicit other potential acquirers, and are engaged in improper self-dealing. Several of the suits also seek the invalidation, in whole or in part, of the July 1999 Affiliation Agreement between Genentech and RHI (Affiliation Agreement), and an order deeming Articles 8 and 9 of the company's Amended and Restated Certificate of Incorporation invalid or inapplicable to a potential transaction with Roche. The outcome of these matters cannot be determined at this time.

On October 27, 2008, Genentech and Biogen Idec Inc. filed a complaint against Sanofi-Aventis Deutschland GmbH (Sanofi), Sanofi-Aventis U.S. LLC, and Sanofi-Aventis U.S. Inc. in the Northern District of California, seeking a declaratory judgment that certain Genentech products, including Rituxan (which is co-marketed with Biogen Idec) do not infringe U.S. Patents 5,849,522 ('522 patent) and 6,218,140 ('140 patent) and a declaratory judgment that the '522 and '140 patents are invalid. Also on October 27, 2008, Sanofi filed suit against Genentech and Biogen Idec in the Eastern District of Texas, Lufkin Division, claiming that Rituxan and at least eight other Genentech products infringe the '522 and '140 patents. Sanofi is seeking preliminary and permanent injunctions, compensatory and exemplary damages, and other relief. In addition, on October 24, 2008, Hoechst GmbH filed with the ICC International Court of Arbitration (Paris) a request for arbitration against Genentech, relating to a terminated agreement between Hoechst's predecessor and Genentech that pertained to the above-referenced patents and related patents outside the U.S. Hoechst is seeking payment of royalties on sales of Genentech products, damages for breach of contract, and other relief. Genentech intends to vigorously defend itself. The outcome of these matters can not be determined at this time.

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

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

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

outstanding shares was 55.8% as of September 30, 2008. Future share repurchases under our share repurchase program may increase Roche's ownership percentage. However, significant option exercises and stock purchases by employees could result in further dilution, and limitations in our ability to enter into new share repurchase arrangements could negatively affect our ability to offset dilution.

#### The Roche Proposal

We announced on July 21, 2008 that we received the Roche Proposal, and on July 24, 2008 we announced that the Special Committee was formed to review, evaluate, and, in the Special Committee's discretion, negotiate and recommend or not recommend the Roche Proposal. On August 13, 2008, we announced that the Special Committee

unanimously concluded that the Roche Proposal substantially undervalues the company, but that the Special Committee would consider a proposal that recognizes the value of the company and reflects the significant benefits that would accrue to Roche as a result of full ownership. On August 18, 2008, we also announced that the Special Committee adopted two retention plans being implemented in lieu of our 2008 annual stock option grant. See also Note 2, “Retention Plans and Employee Stock-Based Compensation,” for more information on the retention plans. In addition, the Special Committee and the company have incurred and will continue to incur third-party legal and advisory costs in connection with the Roche Proposal that are included in the “Marketing, general and administrative” expenses line of our Condensed Consolidated Statements of Income.

The retention plan and third-party legal and advisory costs were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Retention plan costs(1)				
Research and development	\$ 22	\$ —	\$ 22	\$ —
Marketing, general and administrative	22	—	22	—
Total retention plan costs	44	—	44	—
Third-party legal and advisory costs incurred by us on behalf of the Special Committee	6	—	6	—
Other third-party legal and advisory costs	3	—	3	—
Total retention plan costs and legal and advisory costs	\$ 53	\$ —	\$ 53	\$ —

(1) During the third quarter of 2008, \$9 million of retention plan costs were capitalized into inventory, which will be recognized as COS as products that were manufactured after the initiation of the retention plans are estimated to be sold.

#### Related Party Transactions

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

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

#### Roche

We signed two product supply agreements with Roche in July 2006, each of which was amended in November 2007. The Umbrella Manufacturing Supply Agreement (Umbrella Agreement) supersedes our previous product supply agreements with Roche. The Short-Term Supply Agreement (Short-Term Agreement) supplements the terms of the Umbrella Agreement. Under the Short-Term Agreement, Roche agreed to purchase specified amounts of Herceptin, Avastin, and Rituxan through 2008. Under the Umbrella Agreement, Roche agreed to purchase specified amounts of Herceptin and Avastin through 2012, and on a perpetual basis, either party may order other collaboration products from the other party, including Herceptin and Avastin after 2012, pursuant to certain forecasted terms. The Umbrella

Agreement also provides that either party can terminate its obligation to purchase and/or supply Avastin and/or Herceptin with six years' notice on or after December 31, 2007. To date, we have not received a notice of termination from Roche.

Under the July 1999 amended and restated licensing and commercialization agreement, Roche has the right to opt in to development programs that we undertake on our products at certain pre-defined stages of development. Previously, Roche also had the right to develop certain products under the July 1998 licensing and commercialization agreement related to anti-HER2 antibodies (including Herceptin, pertuzumab, and trastuzumab-DM1). When Roche opts in to a program, we record the opt-in payments that we receive as deferred revenue, which

we recognize over the expected development periods or product life, as appropriate. As of September 30, 2008, the amounts in short-term and long-term deferred revenue related to opt-in payments received from Roche were \$51 million and \$191 million, respectively. For the third quarter and first nine months of 2008, we recognized \$19 million and \$43 million, respectively, as contract revenue related to opt-in payments previously received from Roche. For the third quarter and first nine months of 2007, we recognized \$10 million and \$33 million, respectively, as contract revenue related to opt-in payments previously received from Roche.

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

In May 2008, Roche acquired Piramed Limited, a privately held entity based in the United Kingdom, and as a result of the transaction, Piramed is considered a related party. Previous to the Roche acquisition of Piramed, we had entered into a licensing agreement with Piramed related to a molecule in our development pipeline.

In June 2008, we entered into a licensing agreement with Roche under which we obtained rights to a preclinical small-molecule drug development program. We recorded \$35 million in research and development (R&D) expense in the second quarter of 2008 related to this agreement. The future R&D costs incurred under the agreement and any profit and loss from global commercialization will be shared equally with Roche.

In July 2008, we signed an agreement with Chugai-Pharmaceutical Co., Ltd., a Japan-based entity and part of Roche, under which we agreed to manufacture Actemra, a product of Chugai, at our Vacaville, California facility. After an initial term of five years, the agreement may be terminated subject to certain terms and conditions under the contract.

In September 2008, we entered into a collaboration agreement with Roche and GlycArt Biotechnology AG (wholly owned by Roche) for the joint development and commercialization of GA101, a humanized anti-CD20 monoclonal antibody for the potential treatment of hematological malignancies and other oncology-related B-cell disorders such as non-Hodgkin's lymphoma (NHL). We recorded \$105 million in R&D expense in the third quarter and first nine months of 2008 related to this collaboration. The future global R&D costs incurred under the agreement will be shared equally with Roche. We received commercialization rights in the U.S. and have the right to manufacture our own commercial requirements for the U.S. On October 28, 2008, Biogen Idec exercised the right under our collaboration agreement with them to opt in to this agreement and paid us an upfront fee of \$32 million as part of the opt-in, which we will recognize ratably as contract revenue over future periods.

We currently have no commercialized products subject to profit sharing arrangements with Roche.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Product sales to Roche	\$ 144	\$ 135	\$ 425	\$ 651
Royalties earned from Roche	\$ 381	\$ 317	\$ 1,142	\$ 855
Contract revenue from Roche	\$ 35	\$ 21	\$ 75	\$ 81
Cost of sales on product sales to Roche	\$ 90	\$ 98	\$ 242	\$ 356



Research and development expenses incurred on joint development projects with Roche	\$	84	\$	64	\$	232	\$	192
In-licensing expenses to Roche	\$	105	\$	–	\$	140	\$	–

-17-

---

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

#### Novartis

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

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

We and Novartis are co-promoting Xolair in the U.S and co-developing Xolair in both the U.S. and Europe. We record sales, COS, and marketing and sales expenses in the U.S.; Novartis markets the product in and records sales, COS, and marketing and sales expenses in Europe and also records marketing and sales expenses in the U.S. We and Novartis share the resulting U.S. and European operating profits according to prescribed profit sharing percentages. Generally, we evaluate whether we are a net recipient or payer of funds on an annual basis in our cost and profit sharing arrangements. Net amounts received on an annual basis under such arrangements are classified as contract revenue, and net amounts paid on an annual basis are classified as collaboration profit sharing expense. With respect to the U.S. operating results, for the full year in 2007 we were a net payer to Novartis, and we anticipate that for the full year in 2008 we will be a net payer to Novartis. As a result, for the third quarters and first nine months of 2008 and 2007, the portion of the U.S. operating results that we owed to Novartis was recorded as collaboration profit sharing expense. With respect to the European operating results, for the full year in 2007 we were a net payer to Novartis, and we anticipate that for the full year in 2008 we will be a net recipient from Novartis. As a result, for the third quarter and first nine months of 2008, the portion of the European operating results that Novartis owed us was recorded as contract revenue. For the same periods in 2007, however, our portion of the European operating results was recorded as collaboration profit sharing expense. Effective with our acquisition of Tanox, Inc. on August 2, 2007, Novartis also makes: (1) additional profit sharing payments to us on U.S. sales of Xolair, which reduces our profit sharing expense; (2) royalty payments to us on sales of Xolair worldwide, which we record as royalty revenue; and (3) manufacturing service payments related to Xolair, which we record as contract revenue.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Product sales to Novartis	\$ 4	\$ 2	\$ 10	\$ 8
Royalties earned from Novartis	\$ 78	\$ 40	\$ 191	\$ 59
Contract revenue from Novartis	\$ 18	\$ 9	\$ 44	\$ 53
Cost of sales on product sales to Novartis	\$ 4	\$ 2	\$ 9	\$ 9

Edgar Filing: GENENTECH INC - Form 10-Q

Research and development expenses incurred on joint development projects with Novartis	\$	11	\$	11	\$	32	\$	30
Collaboration profit sharing expense to Novartis	\$	49	\$	47	\$	138	\$	143

-18-

---

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 (AMD).

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

#### Note 7. Income Taxes

Our effective income tax rate was 37% in the third quarter of 2008 compared to 39% in the third quarter of 2007. The decrease was mainly due to the non-deductible in-process research and development charge in the third quarter of 2007 resulting from our acquisition of Tanox. Our effective income tax rate was 38% in the first nine months of 2008, which included a settlement with the Internal Revenue Service (IRS) in the second quarter of 2008 for an item related to prior years. Our effective income tax rate was 38% in the first nine months of 2007, which included the non-deductible in-process research and development charge resulting from our acquisition of Tanox.

The IRS continues to examine our U.S. income tax returns for 2002 through 2004, and has proposed adjustments related to research credits and other items, including the settlement reached in the second quarter of 2008. We believe it is reasonably possible, that the unrecognized tax benefits, as of September 30, 2008, related to these items could decrease (by payment, release, or combination of both) in the next twelve months by approximately \$100 million.

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, 2008, and the related condensed consolidated statements of income for the three-month and nine-month periods ended September 30, 2008 and 2007 and cash flows for the nine-month periods ended September 30, 2008 and 2007. These financial statements are the responsibility of the company's management.

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

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

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Genentech, Inc. as of December 31, 2007, and the related consolidated statements of income, stockholders' equity, and cash flows for the year then ended, not presented herein, and in our report dated February 5, 2008, we expressed an unqualified opinion on those consolidated financial statements and included an explanatory paragraph relating to the change in method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-based Payment." In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2007, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Ernst & Young LLP

Palo Alto, California  
October 27, 2008

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

### GENENTECH, INC. FINANCIAL REVIEW

#### Overview

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Consolidated Financial Statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2007.

#### The Company

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

#### Recent Major Developments

We primarily earn revenue and income and generate cash from product sales and royalty revenue. In the third quarter of 2008, our total operating revenue was \$3,412 million, an increase of 17% from \$2,908 million in the third quarter of 2007. Our net income for the third quarter of 2008 was \$731 million, an increase of 7% from \$685 million in the third quarter of 2007. In the first nine months of 2008, our total operating revenue was \$9,711 million, an increase of 11% from \$8,755 million in the first nine months of 2007. Our net income for the first nine months of 2008 was \$2,495 million, an increase of 17% from \$2,138 million in the first nine months of 2007.

We announced on July 21, 2008 that we received an unsolicited proposal from Roche to acquire all of the outstanding shares of our Common Stock not owned by Roche at a price of \$89 in cash per share (the Roche Proposal) and on July 24, 2008 we announced that a special committee of our Board of Directors composed of our independent directors (the Special Committee) was formed to review, evaluate, and, in the Special Committee's discretion, negotiate and recommend or not recommend the Roche Proposal. On August 13, 2008, we announced that the Special Committee unanimously concluded that the Roche Proposal substantially undervalues the company, but that the Special Committee would consider a proposal that recognizes the value of the company and reflects the significant benefits that would accrue to Roche as a result of full ownership.

On August 18, 2008, the Special Committee adopted two retention plans and two severance plans that together cover substantially all employees of the company, including our executive officers. The two retention plans are being implemented in lieu of our 2008 annual stock option grant, and the aggregate cost is currently estimated to be approximately \$375 million payable in cash.

On October 2, 2008, we announced that we entered into a collaboration agreement with Roche and GlycArt in September for the joint development and commercialization of GA101, a humanized anti-CD20 monoclonal antibody for the potential treatment of hematological malignancies and other oncology-related B-cell disorders such as NHL. GA101 is currently in Phase I/II clinical trials for CD20-positive B-cell malignancies, such as NHL and chronic lymphocytic leukemia (CLL). On October 28, 2008, Biogen Idec exercised the right under our collaboration agreement with them to opt in to this agreement and paid us an upfront fee as part of the opt-in.

On October 2, 2008, we announced that we issued a Dear Healthcare Provider letter to inform potential prescribers of a case of progressive multifocal leukoencephalopathy (PML) in a 70-year-old patient who had received Raptiva for more than four years for treatment of chronic plaque psoriasis. The patient subsequently died. On October 16, 2008, revised prescribing information for Raptiva was approved by the FDA. A boxed warning was added that includes the recently reported case of PML and updated information on the risk of serious infections leading to hospitalizations and death in patients receiving Raptiva. The updated label also includes a warning about certain

neurologic events as well as precautions regarding immunizations and pediatric use. A Dear Healthcare Provider letter was issued to communicate this updated prescribing information to healthcare professionals.

On October 5, 2008, we and OSI Pharmaceuticals, Inc. announced that a randomized Phase III study (BeTa Lung) evaluating Avastin in combination with Tarceva in patients with advanced non-small cell lung cancer (NSCLC) whose disease had progressed following platinum-based chemotherapy did not meet its primary endpoint of improving overall survival compared to Tarceva in combination with a placebo. However, there was clear evidence of clinical activity with improvements in the secondary endpoints of progression-free survival (PFS) and response rate when Avastin was added to Tarceva compared to Tarceva alone. No new or unexpected safety signals for either Avastin or Tarceva were observed in the study, and adverse events were consistent with those observed in previous NSCLC clinical trials evaluating the agents.

On October 6, 2008, we and Biogen Idec announced that a global Phase III study of Rituxan in combination with fludarabine and cyclophosphamide chemotherapy met its primary endpoint of improving PFS, as assessed by investigators, in patients with previously treated CD20-positive CLL compared to chemotherapy alone. There were no new or unexpected safety signals reported in the study. An independent review of the primary endpoint is being conducted for U.S. regulatory purposes. Earlier this year, Roche announced that another Phase III study of Rituxan, CLL-8, showed that a similar treatment combination improved PFS in patients with CLL who had not previously received treatment.

On October 19, 2008, we announced that the National Surgical Adjuvant Breast and Bowel Project (NSABP) informed us that an ongoing Phase III study (NSABP C-08) of Avastin plus chemotherapy in patients with early-stage colon cancer will continue as planned. The NSABP's decision to continue the trial was based on a recommendation from an independent data monitoring committee after a planned interim analysis. We anticipate final results from NSABP C-08 in mid-2009.

#### Our Strategy and Goals

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

#### Economic and Industry-wide Factors

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

• We face significant competition in the diseases of interest to us from pharmaceutical and biotechnology companies. The introduction of new competitive products or follow-on biologics, new information about existing products, and pricing and distribution 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. We monitor the competitive landscape and develop strategies in response to new information.

• Our long-term business growth depends upon our ability to continue to successfully develop and commercialize important novel therapeutics to treat unmet medical needs. We recognize that the successful development of pharmaceutical products is highly difficult and uncertain, and that it will be challenging for us to continue to



discover and develop innovative treatments. Our business requires significant investment in R&D over many years, often for products that fail during the R&D process. Once a product receives FDA approval, it remains subject to ongoing FDA regulation, including changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisement to physicians, and product recalls or withdrawals.

• Our business model requires appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. Some of the pricing and distribution of our products have received negative press coverage and public and governmental scrutiny. We will continue to meet with patient groups, payers, and other stakeholders in the healthcare system to understand their issues and concerns. The pricing and reimbursement environment for our products may change in the future and become more challenging due to, among other reasons, new policies of the next presidential administration or new healthcare legislation passed by Congress.

• As the Medicare and Medicaid programs are the largest payers for our products, rules related to the programs' coverage and reimbursement continue to represent an important issue for our business. New regulations related to hospital and physician payment continue to be implemented annually. As a result of the Deficit Reduction Act of 2005, regulations became effective in the fourth quarter of 2007 that have affected and will continue to affect the reimbursement for our products paid by Medicare, Medicaid, and other public payers. We consider these rules as we plan our business and as we work to present our point of view to the legislators and payers.

• Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection could result in lost sales to competing products and loss of royalty payments (for example, royalty income associated with the Cabilly patent) from licensees, and may negatively affect our sales, royalty revenue, and operating results. We are often involved in disputes over contracts and intellectual property, and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.

• Manufacturing pharmaceutical products is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. Difficulties or delays in product manufacturing or in obtaining materials from our suppliers, or difficulties in accurately forecasting manufacturing capacity needs or complying with regulatory requirements, could negatively affect our business. Additionally, we have had, and may continue to have, an excess of available capacity, which could lead to idling of a portion of our manufacturing facilities, during which time we would incur unabsorbed or idle plant charges or other excess capacity charges, resulting in an increase in our COS. We use integrated demand management and manufacturing processes to optimize our production processes.

• 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, particularly in light of the Roche Proposal, 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.

• During the months of September and October 2008, the financial markets experienced high volatility and significant price declines and the availability of credit decreased significantly, making it more difficult for businesses to access capital. Various macroeconomic factors impacted by the financial markets could affect our business and the results of our operations. Interest rates and the ability to access credit markets could affect the ability of our customers/distributors to purchase, pay for, and effectively distribute our products. Similarly, these macroeconomic factors could also affect the ability of our sole-source or single-source suppliers to remain in business or otherwise supply product; failure by any of them to remain a going concern could affect our ability to manufacture products. In addition, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass significant price increases on to our customers due to the process by which physicians are reimbursed for our products by the government.

#### Marketed Products

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

Avastin (bevacizumab) is an anti-VEGF (vascular endothelial growth factor) humanized antibody approved for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first- or second-

-23-

---

line metastatic cancer of the colon or rectum. It is also approved for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC. On February 22, 2008, we received accelerated approval from the FDA to market Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not received prior chemotherapy for metastatic HER2-negative breast cancer (BC).

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

Herceptin (trastuzumab) is a humanized anti-HER2 antibody approved for treatment of patients with node-positive or node-negative early-stage BC, whose tumors overexpress the HER2 protein, as part of an adjuvant treatment regimen containing 1) doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; 2) docetaxel and carboplatin and as a single agent following multi-modality anthracycline-based therapy. It is also approved for use as a first-line metastatic therapy in combination with paclitaxel and as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease.

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

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

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

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

Activase (alteplase) 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.

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

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

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

#### Licensed Products

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

• Herceptin, Pulmozyme, and Avastin outside the U.S.;

• Rituxan outside the U.S., excluding Japan; and

• Nutropin products, Activase, and TNKase in Canada.

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

#### Available Information

The following information can be found on our website at [www.gene.com](http://www.gene.com), or can be obtained free of charge by contacting our Investor Relations Department at (650) 225-4150 or by sending an e-mail message to [investor.relations@gene.com](mailto:investor.relations@gene.com):

• Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as is reasonably practicable after such material is electronically filed with the U.S. Securities and Exchange Commission;

• Our policies related to corporate governance, including our Principles of Corporate Governance, Good Operating Principles, and Code of Ethics, which apply to our Chief Executive Officer, Chief Financial Officer, and senior financial officials; and

• The charters of the Audit Committee and the Compensation Committee of our Board of Directors.

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

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

We believe the following policies to be critical to understanding our financial condition, results of operations, and expectations for 2008, because these policies require management to make significant estimates, assumptions, and judgments about matters that are inherently uncertain.

#### Loss Contingencies

We are currently, and have been, involved in certain legal proceedings, including licensing and contract disputes, stockholder lawsuits, and other matters. See Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on these matters. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. We record an estimated loss as a charge to income if we determine that, based on information available at the time, the loss is probable and the amount of loss can be reasonably estimated. If only a range of the

probable loss can be reasonably estimated, we accrue a liability at the low end of that range. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters that differs from our current estimates could have a material effect on our financial position or our results of operations in any one quarter.

#### Product Sales Allowances

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

Definitions for product sales allowance types are as follows:

- ÿ 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.
- ÿ Product returns 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.
- ÿ Prompt-pay sales discounts are credits granted to wholesalers for remitting payment on their purchases within established cash payment incentive periods.
- ÿ 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.
- ÿ Healthcare provider contractual chargebacks are the result of our contractual commitments to provide products to healthcare providers at specified prices or discounts.

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



Our rebates are based on definitive agreements or legal requirements (such as Medicaid). Direct rebates are accrued at the time of sale and recorded as allowances against trade accounts receivable; indirect rebates (including Medicaid) are accrued at the time of sale and recorded as liabilities. Rebate estimates are evaluated quarterly and may require changes to better align our estimates with actual results. These rebates are primarily estimated and evaluated using historical and other data, including patient usage, customer buying patterns, applicable contractual rebate rates, contract performance by the benefit providers, changes to Medicaid legislation and state rebate contracts, changes in the level of discounts, and significant changes in product sales trends. Although rebates are

accrued at the time of sale, rebates are typically paid out, on average, up to six months after the sale. We believe that our rebate allowances and accruals estimation process provides a high degree of confidence in the annual allowance amounts established. Based on our estimation, the changes in rebate allowances and accruals estimates related to prior years have not exceeded 3%. To further illustrate our sensitivity to changes in the rebate allowances and accruals process, a 10% change in our annualized rebate allowances and accruals provision experienced to date in 2008 (which is in excess of three times the level of variability that we reasonably expect to observe for rebates) would have an approximate \$20 million unfavorable effect on our results (or approximately \$0.01 per share). The total rebate allowances and accruals recorded in our Condensed Consolidated Balance Sheets were \$82 million as of September 30, 2008 and \$70 million as of December 31, 2007.

At the time of sale, we record product returns allowances based on our best estimate of the portion of sales that will be returned by our customers in the future. Product returns allowances are established in accordance with our returns policy, which allows buyers to return our products with two months or less remaining prior to product expiration and up to six months following product expiration. As part of the estimation process, we compare historical returns data to the related sales on a production lot basis. Historical rates of return are then determined by product and may be adjusted for known or expected changes in the marketplace. Actual annual product returns processed were less than 0.5% of gross product sales in all periods between 2005 and 2007, while annual provisions for expected future product returns were less than 1% of gross product sales in all such periods. Although product returns allowances are recorded at the time of sale, the majority of the returns are expected to occur within two years of sale. Therefore, our provisions for product returns allowances may include changes in the estimate for a prior period due to the lag time. However, to date such changes have not been material. For example, in 2007, changes in estimates related to prior years were approximately 0.3% of 2007 gross product sales. To illustrate our sensitivity to changes in the product returns allowances, if we were to experience an adjustment rate of 0.5% of 2007 gross product sales, which is nearly twice the level of annual variability that we have historically observed for product returns, that change in estimate would likely have an unfavorable effect of approximately \$50 million (or approximately \$0.03 per share) on our results of operations. We estimate that for the first nine months of 2008, our changes in estimates for product returns allowances related to prior years were approximately \$25 million, or 0.4% of gross product sales, during this period. Product returns allowances recorded in our Condensed Consolidated Balance Sheets were \$97 million as of September 30, 2008 and \$60 million as of December 31, 2007.

All of the aforementioned categories of allowances and accruals are evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could materially affect our results of operations or financial position; however, to date they have not been material. It is possible that we may need to adjust our estimates in future periods. Our Condensed Consolidated Balance Sheets reflect estimated product sales allowance reserves and accruals totaling \$234 million as of September 30, 2008 and \$176 million as of December 31, 2007.

### Royalties

For substantially all of our agreements with licensees, we estimate royalty revenue and royalty receivables in the period that the royalties are earned, which is in advance of collection. Royalties from Roche, which are approximately 60% of our total royalty revenue, are reported using actual sales reports from Roche. Our royalty revenue and receivables from non-Roche licensees are determined primarily based on communication with some licensees, historical information, forecasted sales trends, and our assessment of collectibility. As all of these factors represent an estimation process, there is inherent uncertainty and variability in our recorded royalty revenue. Differences between actual royalty revenue and estimated royalty revenue are adjusted for in the period in which they become known, typically the following quarter. Since 2005, the changes in estimates for our royalty revenue related to prior periods arising from this estimation process has not exceeded 1% of total annual royalty revenue. However, on a quarterly basis, changes in estimates related to prior quarters have been higher than 1% of total royalty revenue for the

respective quarter. For example, in the third quarter of 2008, royalty revenue benefited from approximately \$25 million of changes in estimates related to the second quarter, which represents approximately 4% of royalty revenue for the third quarter of 2008. To further illustrate our sensitivity to the royalty estimation process, a 1% adjustment to total annual royalty revenue, which is at the upper end of the range of our historic experience, would result in an adjustment to total 2007 annual royalty revenue of approximately \$25 million (or approximately \$0.01 to \$0.02 per share, net of any related royalty expenses).

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

We have confidential licensing agreements with a number of companies under which we receive royalty revenue on sales of products that are covered by the Cabilly patent. The Cabilly patent, which expires in December 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in those methods. The Patent Office has been performing a reexamination of the patent, and we are in the process of appealing the Patent Office's decision. See also Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on our Cabilly patent litigation and reexamination.

Cabilly patent royalties are generally due 60 days after the end of the quarter in which they are earned and recorded by us as royalty revenue. Additionally, we pay COH a percentage of our Cabilly patent royalty revenue 60 days after the quarter in which we receive payments from our licensees. As of September 30, 2008, our Condensed Consolidated Balance Sheet included Cabilly patent receivables totaling approximately \$81 million and related COH payables totaling approximately \$39 million.

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

In February 2007, we launched the Avastin Patient Assistance Program, which is a voluntary program that enables eligible patients who have received 10,000 mg of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 mg during the remainder of the 12-month period. Based on the current wholesale acquisition cost, the 10,000 mg is valued at \$55,000 in gross revenue. Eligible patients include those who are being treated for an FDA-approved indication and who meet the financial eligibility requirements for this program. The program is available for eligible patients who enroll, regardless of whether they are insured. We defer a portion of our gross Avastin product sales revenue that is sold through normal commercial channels to reflect our estimate of the commitment to supply free Avastin to eligible patients who elect to enroll in the program.

In order to estimate the amount of free Avastin to be provided to patients under the Avastin Patient Assistance Program, we need to estimate several factors, most notably: the number of patients who are currently being treated for FDA-approved indications and the start date for their treatment regimen, the extent to which patients may elect to enroll in the program, the number of patients who will meet the financial eligibility requirements of the program, and the duration and extent of treatment for the FDA-approved indications, among other factors. We have based our enrollment assumptions on physician surveys and other information that we consider relevant. We will continue to update our estimates in each reporting period as new information becomes available. If the actual results underlying this deferred revenue accounting vary significantly from our estimates, we will need to adjust these estimates. The deferred revenue will be recognized when free Avastin vials are delivered. In the third quarter and first nine months of 2008, we deferred \$1 million and \$3 million, respectively, of Avastin product sales, resulting in a total deferred revenue liability in connection with the Avastin Patient Assistance Program of \$5 million in our Condensed Consolidated Balance Sheet as of September 30, 2008. In the third quarter and first nine months of 2007, we recorded net decreases in deferred revenue, and corresponding net increases to product sales of \$5 million and \$2 million, respectively, of Avastin product sales in connection with the Avastin Patient Assistance Program. As we continue to evaluate the amount of revenue to defer related to the Avastin Patient Assistance Program, we may recognize previously deferred revenue in Avastin U.S. product sales in future periods or increase the amount of revenue

deferred.

#### Income Taxes

Our income tax provision is based on income before taxes and is computed using the liability method in accordance with FAS No. 109, "Accounting for Income Taxes." Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in

-28-

---

effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations, or the findings or expected results from any tax examinations. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations, and/or rates; the results of any tax examinations; changing interpretations of existing tax laws or regulations; changes in estimates of prior years' items; past and future levels of R&D spending; acquisitions; changes in our corporate structure; and changes in overall levels of income before taxes—all of which may result in periodic revisions to our effective income tax rate. For example, the effective income tax rate in the first nine months of 2008 was unfavorably affected by a \$33 million settlement with the IRS for an item related to prior years. Uncertain tax positions are accounted for in accordance with FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes." We accrue tax-related interest and penalties related to uncertain tax positions, and include these items with income tax expense in the Condensed Consolidated Statements of Income.

#### Inventories

Inventories may include currently marketed products manufactured under a new process or at facilities awaiting regulatory licensure. These inventories are capitalized if in our judgment at the time of manufacture, there is a high probability of near-term regulatory licensure. Excess or idle capacity costs, resulting from utilization below a plant's normal capacity, 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. For example, in the first nine months of 2008, we recognized charges of \$83 million related to unexpected failed lots and delays in manufacturing start-up campaigns and excess capacity. The determination of obsolete inventory requires us to estimate the future demands for our products. In the case of inventories of products not yet approved, we determine whether to capitalize inventory based on the probability and expected date of regulatory approval of 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 salable.

#### 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 determine the fair value of the assets as of the acquisition date, using valuation techniques such as discounted cash flow models. These models require the use of significant estimates and assumptions, including, but not limited to, determining the timing and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed products and in-process projects, and developing appropriate discount rates and probability rates by project.

In the third quarter of 2008, we adjusted the purchase price allocation related to our 2007 acquisition of Tanox by recording a net increase to goodwill of \$13 million, due to revised estimates of certain restructuring liabilities and deferred tax assets. We will continue to evaluate whether the fair value of any or all of our intangible assets have been impaired. If we determine that the fair value of an intangible asset has been impaired, we will record an impairment charge in that period. As of September 30, 2008, we did not believe that there was any impairment of the intangible assets related to the Tanox acquisition.

#### Employee Stock-Based Compensation

Under the provisions of FAS 123R, employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these

-29-

---

assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Due to the redemption of our Special Common Stock in June 1999 (Redemption) by RHI, there is limited historical information available to support our estimate of certain assumptions required to value our stock options. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under GAAP, we review our valuation assumptions at each grant date, and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. See Note 2, "Retention Plans and Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.



## Results of Operations

(In millions, except per share amounts)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
Product sales	\$ 2,634	\$ 2,321	13%	\$ 7,549	\$ 7,094	6%
Royalties	687	524	31	1,932	1,427	35
Contract revenue	91	63	44	230	234	(2)
Total operating revenue	3,412	2,908	17	9,711	8,755	11
Cost of sales	409	406	1	1,240	1,227	1
Research and development	777	615	26	2,043	1,828	12
Marketing, general and administrative	611	541	13	1,687	1,564	8
Collaboration profit sharing	315	276	14	907	805	13
Write-off of in-process research and development related to acquisition	–	77	–	–	77	–
Gain on acquisition	–	(121)	–	–	(121)	–
Recurring amortization charges related to redemption and acquisition	43	38	13	129	90	43
Special items: litigation-related	40	14	186	(260)	41	(734)
Total costs and expenses	2,195	1,846	19	5,746	5,511	4
Operating income	1,217	1,062	15	3,965	3,244	22
Other income (expense):						
Interest and other income (expense), net	(33)	84	(139)	133	233	(43)
Interest expense	(25)	(18)	39	(57)	(53)	8
Total other income (expense), net	(58)	66	(188)	76	180	(58)
Income before taxes	1,159	1,128	3	4,041	3,424	18
Income tax provision	428	443	(3)	1,546	1,286	20
Net income	\$ 731	\$ 685	7	\$ 2,495	\$ 2,138	17
Earnings per share:						
Basic	\$ 0.69	\$ 0.65	6%	\$ 2.37	\$ 2.03	17%
Diluted	\$ 0.68	\$ 0.64	6	\$ 2.34	\$ 2.00	17
Cost of sales as a % of product sales	16%	17%		16%	17%	
Research and development as a % of operating revenue	23	21		21	21	

Marketing, general and administrative as a % of operating revenue	18	19	17	18
Pretax operating margin	36%	37%	41%	37%
Effective income tax rate	37%	39%	38%	38%

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

## Total Operating Revenue

Total operating revenue increased 17% in the third quarter and 11% in the first nine months of 2008 from the comparable periods in 2007. These increases were primarily due to higher product sales and royalty revenue, and are discussed below.

Total Product Sales  
(In millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
Net U.S. product sales						
Avastin	\$ 704	\$ 597	18%	\$ 1,954	\$ 1,694	15%
Rituxan	655	572	15	1,911	1,689	13
Herceptin	368	320	15	1,046	960	9
Lucentis	225	198	14	639	618	3
Xolair	136	121	12	382	352	9
Tarceva	110	101	9	340	304	12
Nutropin products	95	93	2	269	278	(3)
Thrombolytics	66	67	(1)	200	202	(1)
Pulmozyme	65	57	14	185	164	13
Raptiva	28	29	(3)	82	80	3
Total U.S. product sales(1)	2,452	2,155	14	7,008	6,341	11
Net product sales to collaborators	182	166	10	541	753	(28)
Total product sales	\$ 2,634	\$ 2,321	13	\$ 7,549	\$ 7,094	6

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

Total product sales increased 13% in the third quarter and 6% in the first nine months of 2008 from the comparable periods in 2007. Total U.S. product sales increased 14% to \$2,452 million in the third quarter and 11% to \$7,008 million in the first nine months of 2008 from the comparable periods in 2007. The increases in U.S. sales were due to higher sales across most products, in particular higher sales of our oncology products. Increased U.S. sales volume accounted for 81%, or \$240 million, of the increase in U.S. net product sales in the third quarter of 2008, and 73%, or \$487 million, of the increase in the first nine months of 2008. Changes in net U.S. sales prices across the majority of products in the portfolio accounted for most of the remainder of the increases in U.S. net product sales in the third quarter and first nine months of 2008.

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 the usage and buying patterns of the end-users of our products, and as indicative of the purchasing patterns of our wholesaler customers. We use statistical analyses and management judgment to interpret the data that we obtain, and as such, the adoption, penetration, and patient share data presented herein represent management's best 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 18% to \$704 million in the third quarter and 15% to \$1,954 million in the first nine months of 2008 from the comparable periods in 2007. Net U.S. sales in the third quarter and first nine months of 2008 excluded net revenue of \$1 million and \$3 million, respectively, that was deferred in connection with our Avastin Patient Assistance Program. The increases in sales were primarily due to increased use of Avastin for first-line treatment of metastatic BC, which received accelerated approval from the FDA in the first quarter of 2008.

Increased use of Avastin for first-line treatment of metastatic NSCLC also contributed to the increase in sales in the first nine months of 2008.

Avastin received accelerated approval on February 22, 2008 for use in combination with paclitaxel chemotherapy for patients who have not received prior chemotherapy for metastatic HER2-negative BC. For first-line treatment of metastatic HER2-negative BC patients, we estimate that Avastin penetration in the third quarter of 2008 was approximately 40%, an increase from the second quarter of 2008 and an increase from the adoption in the third quarter of 2007. With respect to dose, the percentage of metastatic BC patients receiving the high dose of Avastin, defined as 5 mg/kg/weekly-equivalent, was approximately 75% in the third quarter of 2008, in line with the second quarter of 2008. The U.S. labeled dose of Avastin in metastatic BC is 10 mg/kg, administered intravenously every two weeks. Data from AVADO, the Roche-sponsored, placebo-controlled Phase III trial, was presented at the American Society of Clinical Oncology (ASCO) annual meeting in June 2008. Although the study was not designed to detect a difference between two different Avastin doses, a 7.5 mg/kg/every-three-weeks dose and a 15 mg/kg/every-three-weeks dose, positive trends toward the higher dose were seen across the primary and secondary endpoints. The overall survival data for AVADO is anticipated in the first half of 2009. No new safety signals were detected in the study. In order for the FDA to consider converting the accelerated approval into full approval, we are required to submit the results of the AVADO study and RIBBON I, a Phase III study in first-line metastatic BC, to the FDA by mid-2009. The RIBBON I study results are expected later this year, with a primary endpoint of PFS.

Among the approximately 50% to 60% of patients with first-line metastatic NSCLC who are eligible for Avastin therapy, we estimate that penetration in the third quarter of 2008 was approximately 65%, in line with the second quarter of 2008 and the third quarter of 2007. On September 23, 2008, the National Comprehensive Cancer Network updated its guidelines to allow for Avastin use in lung cancer patients with treated brain metastases and previous therapeutic anti-coagulant use. With respect to dose, the percentage of lung cancer patients receiving the high dose of Avastin, defined as at least 5 mg/kg/weekly-equivalent, was approximately 70% in the third quarter of 2008, in line with the second quarter of 2008. The labeled dose of Avastin in lung cancer is 15 mg/kg, administered intravenously every three weeks.

In first- and second-line treatment of metastatic colorectal cancer (CRC), penetration in the third quarter of 2008 was in line with the second quarter of 2008 and the third quarter of 2007.

On October 19, 2008, we announced that the NSABP informed us that an ongoing Phase III study (NSABP C-08) of Avastin plus chemotherapy in patients with early-stage colon cancer will continue as planned. The NSABP's decision to continue the trial was based on a recommendation from an independent data monitoring committee after a planned interim analysis. We anticipate final results from NSABP C-08 in mid-2009.

#### Rituxan

Net U.S. sales of Rituxan increased 15% to \$655 million in the third quarter and 13% to \$1,911 million in the first nine months of 2008 from the comparable periods in 2007. In the oncology setting, sales growth continues to be driven primarily by use of Rituxan following first-line therapy in indolent NHL. Adoption of Rituxan in other areas of NHL, including front-line follicular low-grade indolent, and use of Rituxan in CLL, an unapproved indication, have also increased since the third quarter of 2007.

In the RA setting, we believe that we are experiencing year-over-year growth driven by the launch of our joint protection claim. It remains difficult to precisely determine the sales split between Rituxan use in oncology and immunology, since many treatment centers treat both types of patients. In June 2008, we received a report of a fatal PML case in a patient who received Rituxan in the REFLEX trial and extension study for Rituxan in RA. The final course of Rituxan was completed 18 months prior to the development of PML, and the patient had multiple

confounding factors associated with immunosuppression. Immunology investigators have been informed, and on September 24, 2008 we issued a Dear Healthcare Provider letter to inform prescribers about the case.

On October 6, 2008, we and Biogen Idec announced that a global Phase III study of Rituxan in combination with fludarabine and cyclophosphamide chemotherapy met its primary endpoint of improving PFS, as assessed by investigators, in patients with previously treated CD20-positive CLL compared to chemotherapy alone. There were no new or unexpected safety signals reported in the study. An independent review of the primary endpoint is being

conducted for U.S. regulatory purposes. Data from the study, REACH, will be submitted for presentation at a future medical meeting. Earlier this year, Roche announced that another Phase III study of Rituxan, CLL-8, showed that a similar treatment combination improved PFS in patients with CLL who had not previously received treatment.

#### Herceptin

Net U.S. sales of Herceptin increased 15% to \$368 million in the third quarter and 9% to \$1,046 million in the first nine months of 2008 from the comparable periods in 2007. Herceptin sales in the third quarter of 2008 benefited from an increase in a wholesaler's inventory levels of \$12 million due to a logistical problem at the wholesaler. If this wholesaler's overstocking situation is resolved in the fourth quarter, we expect to see lower sales to this wholesaler for this period. The remaining sales growth was primarily due to price increases in 2008 and 2007 and increased use of Herceptin in the treatment of early-stage HER2-positive BC. We estimate that Herceptin penetration in the adjuvant setting was approximately 80% in the third quarter of 2008, an increase from the third quarter of 2007 but relatively stable throughout 2008. In first-line treatment of patients with metastatic HER2-positive BC, Herceptin penetration was approximately 75% in the third quarter of 2008, and has remained stable since the third quarter of 2007.

#### Lucentis

Net U.S. sales of Lucentis increased 14% to \$225 million in the third quarter and 3% to \$639 million in the first nine months of 2008 from the comparable periods in 2007. Our most recent market research on dosing suggested that on average Lucentis use has increased in the second year of treatment due to shorter intervals between injections. The percentage of newly diagnosed patients who were treated with Lucentis has been relatively stable throughout 2008 in the range of 40% to 45%. The launch of improved patient access programs in March 2008, a revised promotional campaign, enhanced distribution options for Lucentis that began in May 2008, and a more stable market environment also contributed to the sales growth in the third quarter of 2008. While sales increased in the third quarter and first nine months of 2008, the market remains challenging with the continued unapproved use of Avastin and reimbursement concerns from retinal specialists.

#### Xolair

Net U.S. sales of Xolair increased 12% to \$136 million in the third quarter and 9% to \$382 million in the first nine months of 2008 from the comparable periods in 2007. The sales growth in the third quarter and first nine months of 2008 was mainly due to increased sales volume and price increases in 2007 and 2008. The ongoing growth trend is consistent with our efforts to increase adoption of the National Heart, Lung, and Blood Institute asthma guidelines, which incorporate Xolair as a standard part of therapy.

#### Tarceva

Net U.S. sales of Tarceva increased 9% to \$110 million in the third quarter and 12% to \$340 million in the first nine months of 2008 from the comparable periods in 2007. Tarceva sales growth in the third quarter of 2008 was mainly due to a price increase in 2008. Increased return reserve requirements in the third quarter of 2008 were comparable to the increased return reserve requirements in the third quarter of 2007. Sales growth in the first nine months of 2008 was primarily due to price increases and slightly lower return reserve requirements compared to the first nine months of 2007. We estimate that Tarceva penetration in second-line treatment of NSCLC in the third quarter of 2008 remained stable at approximately 30% compared to the same period in 2007. In the first-line pancreatic cancer setting, we estimate that Tarceva penetration in the third quarter of 2008 was approximately 45%, in line with the third quarter of 2007.

On October 5, 2008, we and OSI Pharmaceuticals announced that a randomized Phase III study (BeTa Lung) evaluating Avastin in combination with Tarceva in patients with advanced NSCLC, whose disease had progressed following platinum-based chemotherapy, did not meet its primary endpoint of improving overall survival compared to Tarceva in combination with a placebo. However, there was clear evidence of clinical activity with improvements in the secondary endpoints of PFS and response rate when Avastin was added to Tarceva compared to Tarceva alone. No new or unexpected safety signals for either Avastin or Tarceva were observed in the study, and adverse events were consistent with those observed in previous NSCLC clinical trials evaluating the agents. We are further



analyzing the study results and will submit the data for presentation in November 2008 at the 2008 Chicago Multidisciplinary Symposium in Thoracic Oncology in Chicago, Illinois.

#### Nutropin Products

Combined net U.S. sales of our Nutropin products increased 2% to \$95 million in the third quarter and decreased 3% to \$269 million in the first nine months of 2008 from the comparable periods in 2007.

#### Thrombolytics

Combined net U.S. sales of our three thrombolytics products—Activase, Cathflo Activase, and TNKase—decreased 1% to \$66 million in the third quarter and 1% to \$200 million in the first nine months of 2008 from the comparable periods in 2007. Sales in the third quarter and first nine months of 2008 were favorably affected by price increases in 2008 and 2007 and increases in sales volume. However, these increases were offset by increased product return reserve requirements.

The European Cooperative Acute Stroke Study III results were reported in the New England Journal of Medicine in September 2008. The study met its primary endpoint of reduction in disability at 90 days in patients treated with alteplase between 3 and 4.5 hours after onset of stroke.

#### Pulmozyme

Net U.S. sales of Pulmozyme increased 14% to \$65 million in the third quarter and 13% to \$185 million in the first nine months of 2008 from the comparable periods in 2007.

#### Raptiva

Net U.S. sales of Raptiva decreased 3% to \$28 million in the third quarter and increased 3% to \$82 million in the first nine months of 2008 from the comparable periods in 2007.

On October 2, 2008, we announced that we issued a Dear Healthcare Provider letter to inform potential prescribers of a case of PML in a 70-year-old patient who had received Raptiva for more than four years for treatment of chronic plaque psoriasis. The patient subsequently died. On October 16, 2008, revised prescribing information for Raptiva was approved by the FDA. A boxed warning was added that includes the recently reported case of PML and updated information on the risk of serious infections leading to hospitalizations and death in patients receiving Raptiva. The updated label also includes a warning about certain neurologic events as well as precautions regarding immunizations and pediatric use. A Dear Healthcare Provider letter was issued to communicate this updated prescribing information to healthcare professionals.

#### Sales to Collaborators

Product sales to collaborators, which were for non-U.S. markets, increased 10% to \$182 million in the third quarter and decreased 28% to \$541 million in the first nine months of 2008 from the comparable periods in 2007. The increase from the third quarter of 2007 and the decrease from the first nine months of 2007 were primarily due to the quarterly timing of Herceptin and Avastin sales to Roche. For 2008, we forecast sales to collaborators to increase by approximately 15% over 2007.

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

end of 2008.

#### Royalties

Royalty revenue increased 31% to \$687 million in the third quarter and 35% to \$1,932 million in the first nine months of 2008 from the comparable periods in 2007. Excluding the effect of a collaboration agreement in the second quarter of 2007, which resulted in one-time royalty revenue of approximately \$65 million in that quarter,

-35-

---

royalty revenue increased 42% in the first nine months of 2008 from the comparable period in 2007. The majority of the increases were due to higher sales by Roche of Avastin, Herceptin, and Rituxan/MabThera®, and higher sales by Novartis of Lucentis. In addition, approximately \$10 million of the increase in the third quarter of 2008 and approximately \$110 million of the increase in the first nine months of 2008 were due to net foreign-exchange-related benefits from the weaker U.S. dollar during those periods compared to the same periods in 2007. Our reported royalty revenue in the third quarter benefited from approximately \$30 million of changes in estimates and adjustments related to amounts recorded in earlier periods, primarily the second quarter of 2008, but also included approximately \$5 million related to 2007. Royalty revenue for the first nine months of 2008 also included approximately \$30 million of net changes in estimates and adjustments increasing royalty revenue, primarily due to changes in estimates for amounts reported in 2007, compared to immaterial amounts of such net changes in estimates and adjustments recorded in the first nine months of 2007.

Cash flows from royalty income include revenue denominated in foreign currencies. We currently enter into foreign currency option contracts (options) and forwards to hedge a portion of these foreign currency cash flows. These existing options and forwards are due to expire between 2008 and 2010, and we expect to continue to enter into similar contracts in accordance with our hedging policy.

Of the overall royalties received, royalties from Roche represented approximately 55% in the third quarter and 59% in the first nine months of 2008 compared to approximately 60% in the third quarter and first nine months of 2007. Royalties from other licensees included royalty revenue on our patent licenses, including our Cabilly patent, as discussed below.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Royalty revenue	\$ 106	\$ 75	\$ 265	\$ 183
Gross expenses(1)	\$ 43	\$ 30	\$ 114	\$ 87
Net of tax effect of Cabilly patent on diluted EPS	\$ 0.04	\$ 0.03	\$ 0.09	\$ 0.06

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

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

Royalties are difficult to forecast because of the number of products involved, the availability of licensee sales data, potential contractual and intellectual property disputes, and the volatility of foreign currency exchange rates. For 2008, we forecast royalty revenue to grow approximately 30% to 35% relative to 2007, but a number of factors could affect those results. Licensed product sales that exceed forecasted levels could positively affect royalty revenue. However, royalty revenue growth could be negatively affected by a number of factors, including the strengthening of the U.S. dollar, lower than expected sales of licensees' products, the termination of licenses, changes to the terms of contracts under which licenses have been granted, or the failure of licensees to meet their contractual payment

obligations for any reason, including an adverse decision or ruling in litigation involving the Cabilly patent, the Cabilly patent reexamination, or related proceedings.

#### Contract Revenue

Contract revenue increased 44% to \$91 million in the third quarter and decreased 2% to \$230 million in the first nine months of 2008 from the comparable periods in 2007. The increase in the third quarter of 2008 was mainly due to reimbursements from Roche related to R&D efforts as well as recognition of a portion of the previously deferred opt-in payment received from Roche related to our trastuzumab drug conjugate products, and increased

reimbursements from Novartis related to R&D efforts on Xolair. Contract revenue in the third quarter of 2008 also included our share of European profits related to Xolair and manufacturing service payments related to Xolair, which Novartis pays us as a result of our acquisition of Tanox in 2007. These same items favorably affected contract revenue in the first nine months of 2008, but were offset by decreases due to the receipt of a milestone payment from Novartis in the first quarter of 2007 related to European Union approval of Lucentis and lower reimbursements from Roche related to R&D efforts on Avastin. See “Related Party Transactions” below for more information on contract revenue from Roche and Novartis.

For 2008, we forecast contract revenue to remain relatively flat compared to 2007. However, contract revenue varies each quarter and is dependent upon a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones, opt-in payments received, new contract arrangements, and foreign currency exchange rates.

#### Cost of Sales

Cost of sales (COS) as a percentage of product sales was 16% in the third quarter and first nine months of 2008 compared to 17% for the comparable periods in 2007. COS in the third quarter of 2008 included a charge of \$23 million related to delays in the start-up of one of our new manufacturing facilities. We recorded a non-recurring charge of \$53 million in the third quarter of 2007 to cancel a manufacturing obligation. COS as a percentage of product sales during the first nine months of 2008 was favorably affected by a decreased volume of lower margin sales to collaborators, partially offset by charges of \$83 million related to unexpected failed lots and delays from manufacturing start-up campaigns at our facilities and excess capacity charges, as well as charges related to the effect of our Voluntary Severance Program (VSP). The VSP gave certain manufacturing employees the opportunity to voluntarily resign from the company in exchange for a severance package. For the first nine months of 2008, compensation charges related to the VSP included in COS were \$29 million. All of the employees enrolled under the VSP departed the company during the first nine months of 2008.

#### Research and Development

Research and development (R&D) expenses increased 26% to \$777 million in the third quarter and 12% to \$2,043 million in the first nine months of 2008 from the comparable periods in 2007. The higher levels of expenses in the third quarter and first nine months of 2008 reflected increased development activity, mainly as a result of collaboration arrangements entered into in 2007, increased clinical manufacturing expenses, and higher research expenses. R&D expenses in the third quarter and first nine months of 2008 also included \$105 million of in-licensing expense related to our new collaboration with Roche and GlycArt that we entered into in September 2008, as well as expenses related to the retention plans approved by the Special Committee in August 2008. R&D as a percentage of operating revenue was 23% in the third quarter and 21% in the first nine months of 2008 compared to 21% for the comparable periods in 2007.

#### Marketing, General and Administrative

Marketing, general and administrative (MG&A) expenses increased 13% to \$611 million in the third quarter and 8% to \$1,687 million in the first nine months of 2008 from the comparable periods in 2007. The increases were mainly due to increased royalty expense, primarily to Biogen Idec, resulting from higher Roche sales of Rituxan, expenses related to the retention plans approved by the Special Committee in August 2008, asset impairment charges related to our acquisition of Tanox in 2007, and legal and advisory fees incurred on behalf of the Special Committee in connection with the Roche Proposal. MG&A as a percentage of operating revenue was 18% in the third quarter and 17% in the first nine months of 2008 compared to 19% in the third quarter and 18% in the first nine months of 2007.

Collaboration Profit Sharing

Collaboration profit sharing expenses increased 14% to \$315 million in the third quarter and 13% to \$907 million in the first nine months of 2008 from the comparable periods in 2007, primarily due to higher sales of Rituxan and Tarceva.

-37-

---

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
U.S. Rituxan profit sharing expense	\$ 221	\$ 187	18%	\$ 625	\$ 541	16%
U.S. Tarceva profit sharing expense	45	42	7	144	121	19
Xolair profit sharing expense	49	47	4	138	143	(3)
Total collaboration profit sharing expense	\$ 315	\$ 276	14	\$ 907	\$ 805	13

We and Novartis share the U.S. and European operating profits for Xolair according to prescribed profit sharing percentages. Generally, we evaluate whether we are a net recipient or payer of funds on an annual basis in our cost and profit sharing arrangements. Net amounts received on an annual basis under such arrangements are classified as contract revenue, and net amounts paid on an annual basis are classified as collaboration profit sharing expense. With respect to the U.S. operating results, for the full year in 2007 we were a net payer to Novartis, and we anticipate that for the full year in 2008 we will be a net payer to Novartis. As a result, for the third quarters and first nine months of 2008 and 2007, the portion of the U.S. operating results that we owed to Novartis was recorded as collaboration profit sharing expense. With respect to the European operating results, for the full year in 2007 we were a net payer to Novartis, and we anticipate that for the full year in 2008 we will be a net recipient from Novartis. As a result, for the third quarter and first nine months of 2008, the portion of the European operating results that Novartis owed us was recorded as contract revenue. For the same periods in 2007, however, our portion of the European operating results was recorded as collaboration profit sharing expense. Effective with our 2007 acquisition of Tanox, Novartis also makes additional profit sharing payments to us on U.S. sales of Xolair, which reduces our profit sharing expense.

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

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

Collaboration profit sharing expense, exclusive of R&D expenses, related to Biogen Idec for the periods ended September 30, 2008 and 2007 consisted of the following (in millions):

Three Months Ended September 30,	Nine Months Ended September 30,
-------------------------------------	------------------------------------

Edgar Filing: GENENTECH INC - Form 10-Q

	2008	2007	% Change	2008	2007	% Change
Product sales, net	\$ 655	\$ 572	15%	\$ 1,911	\$ 1,689	13%
Combined commercial costs and expenses	140	129	9	434	405	7
Combined co-promotion profits	\$ 515	\$ 443	16	\$ 1,477	\$ 1,284	15
Amount due to Biogen Idec for their share of co-promotion profits—included in collaboration profit sharing expense	\$ 221	\$ 187	18%	\$ 625	\$ 541	16%

-38-

---



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

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

	Three Months			Nine Months		
	Ended September 30, 2008	2007	% Change	Ended September 30, 2008	2007	% Change
Contract revenue from Biogen Idec (R&D reimbursement)	\$ 26	\$ 27	(4) %	\$ 91	\$ 83	10%
Co-promotion profit sharing expense	\$ 221	\$ 187	18%	\$ 625	\$ 541	16%
Royalty expense on sales of Rituxan outside the U.S. and other patent costs—included in MG&A expenses	\$ 74	\$ 69	7%	\$ 219	\$ 175	25%

#### 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 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.

#### Gain on Acquisition

Under EITF Issue No. 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 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 from Tanox. We evaluate whether the license arrangement is favorable for us, 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 in the third quarter of 2007.

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

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

In the third quarter of 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 our acquisition of Tanox. These charges were \$43 million and \$38 million in the third quarters of 2008 and 2007, respectively, and \$129 million and \$90 million in the first nine months of 2008 and 2007, respectively.

## Special Items: Litigation-Related

The California Supreme Court heard our appeal on the COH matter on February 5, 2008, and on April 24, 2008 overturned the award of \$200 million in punitive damages to COH but upheld the award of \$300 million in compensatory damages. As a result of the California Supreme Court decision, we reversed a \$300 million net litigation accrual related to the punitive damages and accrued interest, which we recorded as “Special items: litigation related” in our Condensed Consolidated Statements of Income for the first quarter and first nine months of 2008. In the third quarter and first nine months of 2007, we recorded accrued interest and bond costs on both the compensatory and punitive damages totaling \$14 million and \$41 million, respectively. We and COH have had discussions, but have not reached agreement, regarding additional royalties and other amounts owed by us to COH under the 1976 agreement for third-party product sales and settlement of a third-party patent litigation that occurred after the 2002 judgment. We recorded additional costs of \$40 million as “Special items: litigation-related” based on our estimate of our range of liability in connection with the resolution of these issues in the third quarter of 2008. See Note 5, “Contingencies,” in the Notes to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information regarding the COH litigation.

## Operating Income

Operating income was \$1,217 million in the third quarter of 2008, a 15% increase from the third quarter of 2007, and \$3,965 million in the first nine months of 2008, a 22% increase from the comparable period in 2007. Our operating income as a percentage of operating revenue (pretax operating margin) was 36% in the third quarter of 2008 and 37% in the third quarter of 2007, and was 41% in the first nine months of 2008 and 37% in the first nine months of 2007.

## Other Income (Expense)

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

	Three Months			Nine Months		
	Ended September 30,		% Change	Ended September 30,		% Change
	2008	2007		2008	2007	
Gains on sales of biotechnology equity securities, net	\$ 22	\$ 5	340%	\$ 66	\$ 17	288%
Write-downs of biotechnology debt and equity securities	–	–	–	(1)	(4)	(75)
Interest income						
Investment income(1)	15	80	(81)	134	219	(39)
Impairment charges	(67)	–	–	(67)	–	–
Interest expense	(25)	(18)	39	(57)	(53)	8
Other miscellaneous income (expense)	(3)	(1)	200	1	1	–
Total other income (expense), net	\$ (58)	\$ 66	(188)	\$ 76	\$ 180	(58)

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

Other income (expense), net was an expense of \$58 million for the third quarter of 2008 compared to income of \$66 million for the third quarter of 2007. For the first nine months of 2008, other income decreased 58% to \$76 million compared to \$180 million for the same period in 2007. These changes were mainly driven by impairment charges of \$67 million in the third quarter of 2008 related to certain U.S. government agency and financial institution preferred securities. Decreases in investment income in the third quarter and first nine months of 2008 were due to higher realized and mark-to-market losses and lower yields, partially offset by higher average cash balances compared to the same periods in 2007. Gains on sales of biotechnology equity securities were higher, mainly due to the sale of a portion of one of the biotechnology equity investments in our portfolio during the third quarter of 2008, and for the first nine months of 2008, also due to the acquisition of Millennium Pharmaceuticals, Inc. by Takeda Pharmaceutical during the second quarter of 2008.

For 2008, we forecast “Other income, net” to be lower by approximately 50% relative to 2007, primarily due to impairment charges and our increasingly conservative investment portfolio strategy relative to 2007. “Other income, net” is difficult to forecast because it is affected by various factors that are outside of our control, such as fluctuations in interest rates, business events related to the biotechnology companies in our equity securities portfolio, rating agency decisions that affect the value of our investments, and other factors.

#### Income Tax Provision

Our effective income tax rate was 37% in the third quarter of 2008 compared to 39% in the third quarter of 2007. The decrease was mainly due to the non-deductible in-process research and development charge in the third quarter of 2007 resulting from our acquisition of Tanox. Our effective income tax rate was 38% in the first nine months of 2008, which included a settlement with the IRS in the second quarter of 2008 for an item related to prior years. Our effective income tax rate was 38% in the first nine months of 2007, which included the non-deductible in-process research and development charge resulting from our acquisition of Tanox. In October 2008, the federal R&D tax credit was re-enacted for 2008 and 2009 as part of the Emergency Economic Stabilization Act. The full-year 2008 tax benefit for the R&D tax credit will be reflected in our income tax rate in the fourth quarter of 2008.

The IRS continues to examine our U.S. income tax returns for 2002 through 2004, and has proposed adjustments related to research credits and other items, including the settlement reached in the second quarter of 2008. We believe it is reasonably possible, that the unrecognized tax benefits, as of September 30, 2008, related to these items could decrease (by payment, release, or combination of both) in the next twelve months by approximately \$100 million.

#### Financial Assets and Liabilities

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

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

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

Level 3—unobservable inputs

The adoption of FAS 157 did not have an effect on our financial condition or results of operations, but FAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure focuses on the inputs used to measure fair value, particularly for instances in which the measurement uses significant unobservable (Level 3) inputs. A substantial majority of our financial instruments are Level 1 and Level 2 assets. Our Level 1 assets include cash, money market instruments, U.S. Treasury securities, marketable equity securities, and equity forwards. As of September 30, 2008, the fair value of our Level 1 assets was \$2.8 billion consisting primarily of cash, money market instruments, marketable equity securities in biotechnology companies with which we have collaboration agreements, and U.S. Treasury securities. Included in this amount were gross unrecognized gains and losses of approximately \$320 million and \$20 million respectively, primarily related to marketable equity securities.

Our Level 2 assets include other government and agency securities, commercial paper, corporate bonds, asset-backed securities, municipal bonds, preferred securities, and other derivatives. As of September 30, 2008, the fair value of our Level 2 assets was \$5.7 billion, consisting primarily of commercial paper, corporate bonds, and government and agency securities. Asset-backed securities and preferred securities represent less than 5% of the total value of Level 2 assets. Included in this total amount were gross unrecognized losses of approximately \$60 million related to corporate bonds, government and agency securities and preferred securities, partially offset by

approximately \$10 million of gross unrecognized gains on various fixed income investments. In addition, the fair value of our Level 2 assets included approximately \$40 million in gross unrecognized gains primarily related to foreign exchange derivative contracts which serve as hedge instruments against anticipated foreign-currency denominated royalty revenue. During the third quarter of 2008, the U.S. Treasury announced actions that significantly reduced the value of U.S. government agency preferred securities, which we hold as investments. As a result, we recorded an impairment charge of \$46 million during the third quarter of 2008. Furthermore, since we intend to hold these investments, we reclassified them from short-term Level 2 assets to long-term Level 2 assets.

Our Level 3 assets include student loan auction-rate securities, structured investment vehicle securities, and the preferred securities of an insolvent company. As of September 30, 2008, we held \$155 million of investments, which were measured using unobservable (Level 3) inputs, representing approximately 2% of the total fair value of our investment portfolio. Student loan auction-rate securities of \$154 million and structured investment vehicle securities of \$1 million were valued based on broker-provided valuation models, which approximate fair value. In addition our Level 3 assets included preferred securities in a financial institution that declared bankruptcy during the third quarter of 2008. We recorded the full carrying amount of \$21 million as an impairment charge, because we do not expect to recover the value of these assets during the bankruptcy proceedings. We also transferred the securities to Level 3 assets from Level 2, assets since we recorded the investment at zero value rather than a value based on observable inputs.

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

	September 30, 2008		December 31, 2007	
	Assets	Liabilities	Assets	Liabilities
Cash and cash equivalents	\$ 4,275	\$ —	\$ 2,514	\$ —
Restricted cash	—	—	788	—
Short-term investments	1,657	—	1,461	—
Long-term marketable debt securities	2,266	—	1,674	—
Total fixed income investment portfolio	\$ 8,198	—	6,437	—
Long-term marketable equity securities	340	—	416	—
Total derivative financial instruments	72	12	30	19
Total	\$ 8,610	\$ 12	\$ 6,883	\$ 19

#### Liquidity and Capital Resources (In millions)

	September 30, 2008	December 31, 2007
Unrestricted cash, cash equivalents, short-term investments, and long-term marketable debt and equity securities	\$ 8,538	\$ 6,065
Net receivable—equity hedge instruments	33	24
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	\$ 8,571	\$ 6,089
Working capital	\$ 6,855	\$ 4,835
Current ratio	3.4:1	2.2:1

Total unrestricted cash, cash equivalents, short-term investments, and long-term marketable securities, including the fair value of the equity hedge instruments, was \$8,571 million as of September 30, 2008, an increase of \$2,482 million

from December 31, 2007. This increase primarily reflects cash generated from operations, the release of restricted cash and investments as a result of the COH litigation settlement, and increases from stock option exercises, partially offset by cash used for tax payments, share repurchases, capital expenditures, and the COH litigation settlement payment. To mitigate the risk of market value fluctuations, one of our most significant biotechnology equity security holdings is hedged with forward contracts, which are carried at estimated fair value. See Note 4, "Investment Securities and Financial Instruments," in the Notes to Consolidated Financial Statements in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2007 for further information regarding activity in our marketable investment portfolio and derivative instruments.



In conjunction with the COH judgment in 2002, we posted a surety bond and were required to pledge cash and investments of \$788 million to secure the bond, and this balance was reflected in “Restricted cash and investments” in the accompanying Condensed Consolidated Balance Sheets. During the third quarter of 2008, the court completed certain administrative procedures to dismiss the case. As a result, the restrictions were lifted from the restricted cash and investments accounts, which consisted of available-for-sale securities, and the funds became available for use in our operations.

#### Cash Provided by Operating Activities

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

Accounts payable, other accrued liabilities, and other long-term liabilities decreased \$214 million in the first nine months of 2008, mainly due to payments to third-party vendors, tax authorities, and employees for accrued bonus costs, partially offset by accruals related to the up-front payment for our new collaboration on the GA101 molecule and the retention plans that was approved in August 2008.

Inventories decreased \$88 million in the first nine months of 2008, as more products were sold than produced during that period. The amount of inventories produced was lower partly due to failed lots and delays in start-up campaigns that we experienced during the first nine months of 2008.

Receivables and other current assets increased \$31 million in the first nine months of 2008. Accounts receivable—product sales, net increased \$15 million from December 31, 2007, primarily due to increased product sales offset by improved collections. The average collection period of our accounts receivable—product sales as measured in days’ sales outstanding (DSO) was 30 days as of September 30, 2008, compared to 33 days as of December 31, 2007 and 40 days as of September 30, 2007. The decrease in DSO from the third quarter of 2007 was primarily due to a reduction in the extended payment terms that we offered to certain wholesalers in conjunction with the launch of Lucentis on June 30, 2006.

As a result of the April 24, 2008 California Supreme Court ruling on the COH matter, we reversed a \$300 million net litigation accrual related to the punitive damages and accrued interest in the first nine months of 2008, and we paid COH \$476 million in the second quarter of 2008 for compensatory damages awarded plus interest, which reduced our cash from operations. We also recorded additional costs of \$40 million as “Special items: litigation-related” in the third quarter of 2008 related to the discussions with COH about additional royalties and other amounts owed by us to COH under the 1976 agreement for third-party product sales and settlement of a third-party patent litigation that occurred after the 2002 judgment.

#### Cash Used in Investing Activities

Cash used in investing activities was primarily due to capital expenditures. Capital expenditures were \$569 million during the first nine months of 2008 compared to \$692 million during the first nine months of 2007. During the first nine months of 2008, capital expenditures were related to construction of our fill-finish facility in Hillsboro, Oregon and our E. coli production facility in Singapore; leasehold improvements for newly constructed buildings on our South San Francisco, California campus; and purchases of equipment and information systems.

We forecast that our 2008 capital expenditures will be approximately \$800 million, excluding capitalized costs related to construction projects for which we are considered the owner during the construction period for accounting

purposes.

In November 2006, we entered into a series of agreements with Lonza, including a supply agreement to purchase products produced by Lonza at their Singapore manufacturing facility, which is currently under construction, and a loan agreement to advance Lonza \$290 million for the construction of that facility. The facility is expected to reach mechanical completion in the fourth quarter of 2008, at which time we expect to advance Lonza in excess of \$200 million pursuant to the loan agreement, subject to certain conditions included in the loan agreement.

-43-

---

## Cash Used in Financing Activities

Cash used in financing activities includes activity under our stock repurchase program and our employee stock plans. We used cash for stock repurchases of \$756 million during the first nine months of 2008 and \$815 million during the first nine months of 2007 pursuant to our stock repurchase program approved by our Board of Directors. We also received \$632 million during the first nine months of 2008 and \$381 million during the first nine months of 2007 related to stock option exercises and stock issuances under our employee stock purchase plan. The excess tax benefits from stock-based compensation arrangements were \$119 million in the first nine months of 2008 and \$160 million in the first nine months of 2007.

Due to the current state of the credit markets and the effect on the interest rates at which we sell commercial paper, as well as our cash balance as of the end of the third quarter of 2008, we stopped issuing commercial paper in September 2008. As a result, \$63 million of our commercial paper obligations matured and were not rolled over in the third quarter of 2008. As of September 30, 2008, we had \$536 million of commercial paper notes payable, and as of October 29, 2008, this outstanding balance was fully paid and we had no commercial paper outstanding.

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2008, we are authorized to repurchase up to 150 million shares of our Common Stock for an aggregate amount of up to \$10.0 billion through June 30, 2009. In this program, as in previous stock repurchase programs, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. We also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities, although as of September 30, 2008, we had not engaged in any such transactions. We use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock purchase plan. However, significant option exercises and stock purchases by employees could result in further dilution, and limitations in our ability to enter into new share repurchase arrangements could negatively affect our ability to offset dilution. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are: (1) to address provisions of our Affiliation Agreement with RHI related to maintaining RHI's minimum ownership percentage, (2) to make prudent investments of our cash resources, and (3) to allow for an effective mechanism to provide stock for our employee stock purchase plans. See "Relationship with Roche Holdings, Inc." below for more information on RHI's minimum ownership percentage.

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

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

In May 2008, we entered into a prepaid share repurchase arrangement with an investment bank pursuant to which we delivered \$500 million to the investment bank. The investment bank delivered approximately 5.5 million shares to us on September 30, 2008.

Our shares repurchased during the third quarter of 2008 were as follows (shares in millions):

	Total Number of Shares Purchased	Average Price Paid per Share
July 1–31, 2008	–	–

Edgar Filing: GENENTECH INC - Form 10-Q

August 1–31, 2008		–	–
September 1–30, 2008	5.5	\$	90.24
Total	5.5	\$	90.24

As of September 30, 2008, 88 million cumulative shares had been purchased under our stock repurchase program for \$6.5 billion, and a maximum of 62 million additional shares for amounts totaling up to \$3.5 billion may be purchased under the program through June 30, 2009.

The par value method of accounting is used for our Common Stock repurchases. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital, with the amounts in excess of the estimated original sales price charged to retained earnings.

#### Roche Proposal-Related Costs

The cost of the retention plans adopted by the Special Committee on August 18, 2008 are estimated to be approximately \$375 million payable in cash. The cash amount is approximately equal to the value of the stock options that would have been granted in our 2008 option grant program, calculated using the methodology used in our financial statements to value our options (Black-Scholes) and applying a discount rate. The discount rate reflects the earlier payment dates of the retention bonus relative to the vesting schedule that would have applied to the planned option grants. The timing of the payments related to these plans will depend on the outcome of the Roche Proposal. If a merger of Genentech with Roche or an affiliate of Roche has not occurred on or before June 30, 2009, we will pay the retention bonus at that time, in accordance with the terms of the plans. We are currently recognizing the retention plan costs in our financial statements ratably over the period from August 18, 2008 to June 30, 2009. If a merger of Genentech with Roche or an affiliate of Roche has occurred on or before June 30, 2009, the timing of the payments and the recognition of the expense will depend on the terms of the merger. During the third quarter and first nine months of 2008, total costs for the retention plans were \$53 million, of which \$44 million was expensed and \$9 million was capitalized into inventory, which will be recognized as COS as products that were manufactured after the initiation of the retention plans are estimated to be sold.

In addition, the Special Committee and the company retained attorneys and third-party advisors in connection with the Roche Proposal. The amount and timing of the payment of the third-party legal and advisory costs also depends upon the resolution of the Roche Proposal. Third-party legal and advisory costs incurred in the third quarter and first nine months of 2008 were \$9 million.

#### Off-Balance Sheet Arrangements

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

#### Contractual Obligations

We believe that there were no significant changes during the first nine months of 2008 in our payments due under contractual obligations, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007, except as noted in "Cash Used in Investing Activities" above.

#### Contingencies

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

#### Relationship with Roche Holdings, Inc.

We issue shares of our 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 its July 1999 offering of our Common Stock (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%. RHI’s ownership percentage of our outstanding shares was 55.8% as of September 30, 2008. Future share repurchases under our share repurchase program may increase Roche’s ownership percentage. However, significant option exercises and stock purchases by employees could result in further dilution, and limitations in our ability to enter into new share repurchase arrangements could negatively affect our ability to offset dilution.

### The Roche Proposal

We announced on July 21, 2008 that we received the Roche Proposal and on July 24, 2008 we announced that the Special Committee was formed to review, evaluate, and, in the Special Committee’s discretion, negotiate and recommend or not recommend the Roche Proposal. On August 13, 2008, we announced that the Special Committee unanimously concluded that the Roche Proposal substantially undervalues the company, but that the Special Committee would consider a proposal that recognizes the value of the company and reflects the significant benefits that would accrue to Roche as a result of full ownership. On August 18, 2008, we also announced that the Special Committee adopted two retention plans which are being implemented in lieu of our 2008 annual stock option grant. See Note 2, “Retention Plans and Employee Stock-Based Compensation,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on the retention plans. In addition, the Special Committee and the company have incurred and will continue to incur third-party legal and advisory costs in connection with the Roche Proposal that are included in the “Marketing, general and administrative” expenses line of our Condensed Consolidated Statements of Income.

The retention plan and third-party legal and advisory costs were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Retention plan costs(1)				
Research and development	\$ 22	\$ –	\$ 22	\$ –
Marketing, general and administrative	22	–	22	–
Total retention plan costs	44	–	44	–
Third-party legal and advisory costs incurred by us on behalf of the Special Committee	6	–	6	–
Other third-party legal and advisory costs	3	–	3	–
Total retention plan costs and legal and advisory costs	\$ 53	\$ –	\$ 53	\$ –

(1) During the third quarter of 2008, \$9 million of retention plan costs were capitalized into inventory, which will be recognized as COS as products that were manufactured after the initiation of the retention plans are estimated to be sold.

### Related Party Transactions

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

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



## Roche

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

Under the July 1999 amended and restated licensing and commercialization agreement, Roche has the right to opt in to development programs that we undertake on our products at certain pre-defined stages of development. Previously, Roche also had the right to develop certain products under the July 1998 licensing and commercialization agreement related to anti-HER2 antibodies (including Herceptin, pertuzumab, and trastuzumab-DM1). When Roche opts in to a program, we record the opt-in payments that we receive as deferred revenue, which we recognize over the expected development periods or product life, as appropriate. As of September 30, 2008, the amounts in short-term and long-term deferred revenue related to opt-in payments received from Roche were \$51 million and \$191 million, respectively. For the third quarter and first nine months of 2008, we recognized \$19 million and \$43 million, respectively, as contract revenue related to opt-in payments previously received from Roche. For the third quarter and first nine months of 2007, we recognized \$10 million and \$33 million, respectively, as contract revenue related to opt-in payments previously received from Roche.

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

In May 2008, Roche acquired Piramed, a privately held entity based in the United Kingdom, and as a result of the transaction, Piramed is considered a related party. Previous to the Roche acquisition of Piramed, we had entered into a licensing agreement with Piramed related to a molecule in our development pipeline.

In June 2008, we entered into a licensing agreement with Roche under which we obtained rights to a preclinical small-molecule drug development program. We recorded \$35 million in R&D expense in the second quarter of 2008 related to this agreement. The future R&D costs incurred under the agreement and any profit and loss from global commercialization will be shared equally with Roche.

In July 2008, we signed an agreement with Chugai, a Japan-based entity and part of Roche, under which we agreed to manufacture Actemra, a product of Chugai, at our Vacaville, California facility. After an initial term of five years, the agreement may be terminated subject to certain terms and conditions under the contract.

In September 2008, we entered into a collaboration agreement with Roche and GlycArt for the joint development and commercialization of GA101, a humanized anti-CD20 monoclonal antibody for the potential treatment of hematological malignancies and other oncology-related B-cell disorders such as NHL. We recorded \$105 million in R&D expense in the third quarter of 2008 related to this collaboration. The future global R&D costs incurred under the agreement will be shared equally with Roche. We received commercialization rights in the U.S. and have the right to manufacture our own commercial requirements for the U.S. On October 28, 2008, Biogen Idec exercised the right under our collaboration agreement with them to opt in to this agreement and paid us an upfront fee of \$32 million as

part of the opt-in, which we will recognize ratably as contract revenue over future periods.

We currently have no commercialized products subject to profit sharing arrangements with Roche.

-47-

---

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

	Three Months		Nine Months	
	Ended September 30, 2008	2007	Ended September 30, 2008	2007
Product sales to Roche	\$ 144	\$ 135	\$ 425	\$ 651
Royalties earned from Roche	\$ 381	\$ 317	\$ 1,142	\$ 855
Contract revenue from Roche	\$ 35	\$ 21	\$ 75	\$ 81
Cost of sales on product sales to Roche	\$ 90	\$ 98	\$ 242	\$ 356
Research and development expenses incurred on joint development projects with Roche	\$ 84	\$ 64	\$ 232	\$ 192
In-licensing expenses to Roche	\$ 105	\$ –	\$ 140	\$ –

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

#### Novartis

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

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

We and Novartis are co-promoting Xolair in the U.S and co-developing Xolair in both the U.S. and Europe. We record sales, COS, and marketing and sales expenses in the U.S.; Novartis markets the product in and records sales, COS, and marketing and sales expenses in Europe and also records marketing and sales expenses in the U.S. We and Novartis share the resulting U.S. and European operating profits according to prescribed profit sharing percentages. Generally, we evaluate whether we are a net recipient or payer of funds on an annual basis in our cost and profit sharing arrangements. Net amounts received on an annual basis under such arrangements are classified as contract revenue, and net amounts paid on an annual basis are classified as collaboration profit sharing expense. With respect to the U.S. operating results, for the full year in 2007 we were a net payer to Novartis, and we anticipate that for the full year in 2008 we will be a net payer to Novartis. As a result, for the third quarters and first nine months of 2008 and 2007, the portion of the U.S. operating results that we owed to Novartis was recorded as collaboration profit sharing expense. With respect to the European operating results, for the full year in 2007 we were a net payer to Novartis, and we anticipate that for the full year in 2008 we will be a net recipient from Novartis. As a result, for the third quarter and first nine months of 2008, the portion of the European operating results that Novartis owed us was

recorded as contract revenue. For the same periods in 2007, however, our portion of the European operating results was recorded as collaboration profit sharing expense. Effective with our acquisition of Tanox on August 2, 2007, Novartis also makes: (1) additional profit sharing payments to us on U.S. sales of Xolair, which reduces our profit sharing expense; (2) royalty payments to us on sales of Xolair worldwide, which we record as royalty revenue; and (3) manufacturing service payments related to Xolair, which we record as contract revenue.

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

	Three Months		Nine Months	
	Ended September 30, 2008	2007	Ended September 30, 2008	2007
Product sales to Novartis	\$ 4	\$ 2	\$ 10	\$ 8
Royalties earned from Novartis	\$ 78	\$ 40	\$ 191	\$ 59
Contract revenue from Novartis	\$ 18	\$ 9	\$ 44	\$ 53
Cost of sales on product sales to Novartis	\$ 4	\$ 2	\$ 9	\$ 9
Research and development expenses incurred on joint development projects with Novartis	\$ 11	\$ 11	\$ 32	\$ 30
Collaboration profit sharing expense to Novartis	\$ 49	\$ 47	\$ 138	\$ 143

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

## Stock Options

### Option Program Description

Our employee stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our program primarily consists of our 2004 Equity Incentive Plan (the Plan), a broad-based plan under which stock options, restricted stock, stock appreciation rights, and performance shares and units may be granted to employees, directors, and other service providers. Substantially all of our employees participate in our stock option program. In the past, we granted options under our amended and restated 1999 Stock Plan, 1996 Stock Option/Stock Incentive Plan, our amended and restated 1994 Stock Option Plan, and our amended and restated 1990 Stock Option/Stock Incentive Plan. Although we no longer grant options under these plans, exercisable options granted under almost all of these plans are still outstanding.

On August 18, 2008, the Special Committee adopted two retention plans that are being implemented in lieu of our 2008 annual stock option grant, which typically occurs in September. The plans cover substantially all of our employees, including our executive officers. See "Relationship with Roche Holdings, Inc." for more information about the Roche Proposal, and see "Liquidity and Capital Resources" for more information about the retention plans.

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors or an authorized delegate. See "Compensation Discussion and Analysis" in our 2008 Proxy Statement for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.



## General Option Information

Summary of Option Activity  
(Shares in millions)

	Options Outstanding		
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price
December 31, 2006	68.7	88.3	\$ 54.43
Grants	(17.8)	17.8	79.40
Exercises	–	(10.4)	32.76
Cancellations	3.5	(3.5)	76.45
December 31, 2007	54.4	92.2	\$ 60.94
Grants	(1.0)	1.0	78.24
Exercises	–	(12.2)	44.75
Cancellations	3.0	(3.0)	80.41
September 30, 2008 (Year to Date)	56.4	78.0	\$ 62.94

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

	Exercisable		Unexercisable		Total	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
As of September 30, 2008						
In-the-Money	52.9	\$ 54.50	23.9	\$ 80.00	76.8	\$ 62.45
Out-of-the-Money(1)	0.7	92.19	0.5	93.36	1.2	92.66
Total Options Outstanding	53.6		24.4		78.0	

(1) Out-of-the-money options have an exercise price equal to or greater than the fair market value of Genentech Common Stock, which was \$88.68 at the close of business on September 30, 2008.

## Dilutive Effect of Options

Grants, net of cancellations, as a percentage of outstanding shares were (0.19)% for the first nine months of 2008, 1.36% for the year ended December 31, 2007, and 1.43% for the year ended December 31, 2006.

## Equity Compensation Plan Information

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

\*\*\*\*\*

This report contains forward-looking statements regarding our Horizon 2010 strategy of bringing new molecules into clinical development, bringing major new products or indications onto the market, becoming the number one U.S. oncology company in sales, and achieving certain financial growth measures; our internal stretch goal to add a total of

30 molecules into development; the availability or presentation of data from clinical studies for Avastin and Rituxan; sales to collaborators; foreign currency option contracts and forwards; tax benefits; royalty revenues; contract revenues; profit sharing with Novartis; development of label extensions for Xolair; other income net; capital expenditures; share repurchases; construction of manufacturing facilities; payments to Lonza; the cost of the retention plans adopted in response to the Roche Proposal; our holding of certain investments; and the liability with respect to COH. These forward-looking statements involve risks and uncertainties, and the cautionary statements set forth below and those contained in “Risk Factors” in this Quarterly Report on Form 10-Q identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. Such factors include, but are not limited to, difficulty in enrolling patients in clinical trials; the



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

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

Under Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007, on file with the U.S. Securities and Exchange Commission, we used value-at-risk (VAR) calculations as a measure to quantitatively disclose our market risks. As of September 30, 2008, our calculated VAR has not changed materially from that disclosed in our Form 10-K for the year ended December 31, 2007. Our VAR model utilizes historical simulation of daily market data over the past three years and calculates market data changes using a 21-trading-day holding period to estimate expected loss in fair value at a 95% confidence level. The VAR model is not intended to represent actual losses but is used as a risk estimation and management tool. The calculated VAR is intended to measure the amount that we could lose from adverse market movements in interest rates, foreign currency exchange rates and equity investment prices, given a specified confidence level, over a given period of time. However, our VAR calculations are not designed to fully factor in all potential future volatility because the calculations are based on historical results which may not be predictive of future results.

Actual future gains and losses associated with our investment portfolio, debt instruments, foreign currency hedges and other derivative positions may differ materially from the VAR analyses performed due to the inherent limitations associated with predicting the timing and amount of changes to interest rates, foreign currency exchanges rates and equity investment prices, as well as our actual exposures and positions.

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

### Item 4. Controls and Procedures

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

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

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

See also Item 3, “Legal Proceedings,” in our Annual Report on Form 10-K for the year ended December 31, 2007 and Part II, Item 1 of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008 and June 30, 2008.

Item 1A. Risk Factors

1A.

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

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

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

- Preclinical tests may show the product to be toxic or lack efficacy in animal models.

- Clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects.

- Failure to receive the necessary United States (U.S.) and international regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies; extended length of time to achieve study endpoints; additional time requirements for data analysis or biologic license application (BLA) or new drug application (NDA) preparation; discussions with the U.S. Food and Drug Administration (FDA); FDA requests for additional preclinical or clinical data; FDA delays due to staffing or resource limitations at the agency; analyses of or changes to study design; or unexpected safety, efficacy, or manufacturing issues.

- Difficulties in formulating the product, scaling the manufacturing process, or getting approval for manufacturing.

- Manufacturing costs, pricing, reimbursement issues, or other factors may make the product uneconomical.

- The proprietary rights of others and their competing products and technologies may prevent the product from being developed or commercialized.

-

The contractual rights of our collaborators or others may prevent the product from being developed or commercialized.

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

large-scale clinical trials for a product are not successful, we will not recover our substantial investments in that product.

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

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

• Future levels of revenue.

• Our ability to supply product for use in clinical trials.

We face competition.

We face competition from pharmaceutical companies and biotechnology companies.

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

Avastin: Avastin competes in metastatic colorectal cancer (CRC) with Erbitux® (Imclone/Bristol-Myers Squibb/Merck KGaA), 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 Inc.), 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). At the American Society of Clinical Oncology (ASCO) annual meeting in 2008, ImClone Systems Incorporated and Bristol-Myers Squibb Company presented data from a Phase III study of Erbitux® in combination with vinorelbine plus cisplatin showing that the study met its primary endpoint of increasing overall survival compared with chemotherapy alone in patients with advanced NSCLC. Merck KGaA has filed a European application for Erbitux® in this indication. Avastin also faces competition in

advanced or metastatic NSCLC from the chemotherapy Alimta® (Eli Lilly and Company), which received approval in the third quarter of 2008 for use in first-line NSCLC in combination with cisplatin. The approval for Alimta® in first line NSCLC is limited to use in patients with non-squamous histology. In NSCLC, both Erbitux® and Alimta® are included in the National Comprehensive Cancer Network (NCCN) guidelines and compendia as first-line options. The Erbitux® listing in the first-line setting is limited to combinations with cisplatin and vinorelbine. Alimta® is listed as an option for non-squamous patients in the first-line setting and as maintenance therapy for patients previously having a response. Other potential competitors include 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 vascular endothelial growth factor (VEGF) inhibitor, VEGF-Trap, in multiple indications, including metastatic CRC and metastatic NSCLC. Avastin could also face competition from the VEGF receptor-2 inhibitor (IMC-1121b) under development by ImClone in several indications, including breast cancer (BC). There are also ongoing head-to-head clinical trials comparing both Sutent® and AZD2171 (AstraZeneca) to Avastin. Likewise, Amgen is conducting head-to-head clinical trials comparing AMG 706 to Avastin in NSCLC and metastatic BC; Pfizer has initiated a head-to-head trial comparing Sutent® to Avastin in BC. Antisoma's vascular disrupting agent, ASA404, has an ongoing Phase III trial in first-line NSCLC (ATTRACT-1), and Antisoma has announced plans to initiate a second-line NSCLC study (ATTRACT-2). Overall, there are more than 65 molecules in clinical development that target VEGF inhibition, and more than 130 companies are developing molecules that, if successful in clinical trials, may compete with Avastin.

Rituxan: Current competitors for Rituxan in hematology-oncology include Bexxar® (GlaxoSmithKline [GSK]) and Zevalin® (Cell Therapeutics), both of which are radioimmunotherapies indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma (NHL). For both radioimmunotherapies, there are studies nearing completion that may expand their label to earlier settings in indolent NHL. Other potential competitors include Campath® (Bayer Corporation/Genzyme Corporation) in previously untreated and 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); Revlimid® (Celgene Corporation), which is indicated for multiple myeloma and myelodysplastic syndromes (both unapproved uses of Rituxan); and Treanda® (Cephalon, Inc.), which was recently approved for the treatment of CLL.

Current competitors for Rituxan 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 an RA patient population that is broader than the approved population for Rituxan. In addition, molecules in development that, if approved by the FDA, may compete with Rituxan in RA include: Actemra™, an anti-interleukin-6 receptor being developed by Chugai Pharmaceutical Co. Ltd. and Roche; Cimzia™ (certolizumab pegol), an anti-tumor necrosis factor (TNF) antibody being developed by UCB S.A.; and CNTO 148 (golimumab), an anti-TNF antibody being developed by Centocor, Inc. (a wholly owned subsidiary of Johnson & Johnson) and Schering-Plough Corporation.

Rituxan may face future competition in both hematology-oncology and RA from HuMax-CD20® (ofatumumab), an anti-CD20 antibody being co-developed by Genmab A/S and GSK. Genmab and GSK announced positive results from their pivotal trial for CLL in July 2008. They continue to communicate their plans to file for approval of HuMax-CD20® in 2008 for monotherapy use in refractory CLL and to complete a monotherapy trial for refractory indolent NHL. In addition, we are aware of other anti-CD20 molecules in development that, if successful in clinical trials, may compete with Rituxan. Rituxan could also face competition from Treanda® in NHL by the end of 2008 based on an FDA submission in December 2007 in refractory indolent NHL. Finally, positive results were announced

from a pivotal trial for BiovaxID™ (BioVest International, Inc.) for indolent NHL patients post front-line induction. BioVest is planning to file for accelerated approval of Biovax ID™ in indolent NHL in the U.S.

Herceptin: Herceptin faces competition in the relapsed metastatic setting from Tykerb® (lapatinib ditosylate) which is manufactured by GSK. Tykerb® is approved in combination with capecitabine, for the treatment of patients with advanced or metastatic BC whose tumors overexpress HER2 and who have received prior therapy, including an anthracycline, a taxane, and Herceptin.



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

**Xolair:** Xolair faces competition from other asthma therapies, including inhaled corticosteroids, long-acting beta agonists, combination products such as fixed-dose inhaled corticosteroids/long-acting beta agonists and leukotriene inhibitors, as well as oral corticosteroids and immunotherapy.

**Tarceva:** Tarceva competes with the chemotherapy agents Taxotere® (Sanofi-Aventis) and Alimta®, both of which are indicated for the treatment of relapsed NSCLC. Tarceva may face future competition in relapsed NSCLC from Zactima™ (AstraZeneca), Erbitux®, and from a potential re-filing of Iressa® (AstraZeneca) in the U.S. Alimta® received approval in the third quarter of 2008 for first-line treatment of locally advanced and metastatic NSCLC, for patients with non-squamous histology. Alimta® is not indicated for treatment of patients with squamous cell NSCLC. Merck KGaA has filed a European application for Erbitux® in first-line NSCLC. Both Alimta® and Erbitux® have recently been compendia listed and included in the NCCN guidelines for first-line metastatic NSCLC in accordance with their trials. In front-line pancreatic cancer, Tarceva primarily competes with Gemzar® (Eli Lilly) monotherapy and Gemzar® in combination with other chemotherapeutic agents. Tarceva could face competition in the future from products in late-phase development, such as Axitinib (Pfizer), in the treatment of pancreatic cancer.

**Nutropin:** Nutropin faces competition in the growth hormone market from five (5) branded competitors, including Humatrope® (Eli Lilly), Genotropin® (Pfizer), Norditropin® (Novo Nordisk), Saizen® (Merck Serono), and Tev-Tropin® (Teva Pharmaceutical Industries Ltd.). Nutropin also faces competition from follow-on biologics, including Omnitrope® (Sandoz Inc.); and Valtropin® (LG Life Sciences Ltd.), which has been approved and is pending launch. In addition, Accretropin® (Cangene Corporation), a non-follow-on biologic growth hormone, has been approved and is also pending launch.

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

**Thrombolytics:** Our thrombolytic products face competition in the acute myocardial infarction market, with sales of TNKase and Activase affected by the adoption by physicians of mechanical reperfusion strategies. We expect that the use of mechanical reperfusion, in lieu of thrombolytic therapy for the treatment of acute myocardial infarction, will continue to grow. TNKase for acute myocardial infarction also faces competition from Retavase® (EKR Therapeutics, 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 30% of cystic fibrosis patients receive

hypertonic saline, and it is estimated that in a small percentage of patients (less than 5%), this use will affect how a physician may prescribe or a patient may use Pulmozyme.

Raptiva: Raptiva competes with established therapies for moderate-to-severe psoriasis, including oral systemics such as methotrexate and cyclosporin as well as ultraviolet light therapies. In addition, Raptiva competes with

-56-

---

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

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

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

Sales of our products will depend significantly on the extent to which reimbursement for the cost of our products and related treatments will be available to physicians and patients from U.S. and international government health administration authorities, private health insurers, and other organizations. Third-party payers and government health administration authorities increasingly attempt to limit and/or regulate the reimbursement of medical products and services, including branded prescription drugs. Changes in government legislation or regulation, such as the Medicare Prescription Drug Improvement and Modernization Act of 2003, the Deficit Reduction Act of 2005, the Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007, and the Medicare Improvements for Patients and Providers Act of 2008; changes in formulary or compendia listings; or changes in private third-party payers' policies toward reimbursement for our products may reduce reimbursement of our products' costs to physicians, pharmacies, and distributors. Decreases in third-party reimbursement for our products could reduce usage of the products, sales to collaborators, and royalties, and may have a material adverse effect on our product sales, results of operations, and financial condition. The pricing and reimbursement environment for our products may change in the future and become more challenging due to, among other reasons, new policies of the next presidential administration or new health care legislation passed by Congress.

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

We are subject to stringent regulations with respect to product safety and efficacy by various international, federal, state, and local authorities. Of particular significance are the FDA's requirements covering R&D, testing, manufacturing, quality control, labeling, and promotion of drugs for human use. As a result of these requirements, the length of time, the level of expenditures, and the laboratory and clinical information required for approval of a BLA or NDA are substantial and can require a number of years. In addition, even if our products receive regulatory approval, they remain subject to ongoing FDA regulations, including, for example, obligations to conduct additional clinical trials or other testing, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

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

- Significant delays in obtaining or failing to obtain approvals, as described above in "The successful development of pharmaceutical products is highly uncertain and requires significant expenditures and time."
- Loss of, or changes to, previously obtained approvals or accelerated approvals, including those resulting from post-approval safety or efficacy issues. For example, with respect to the FDA's accelerated approval of Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not received prior chemotherapy

for metastatic HER2-negative BC, the FDA may withdraw or modify such approval, or request additional post-marketing studies.

• Failure to comply with existing or future regulatory requirements.

-57-

---

• A determination by the FDA that any study endpoints used in clinical trials for our products are not sufficient for product approval.

• Changes to manufacturing processes, manufacturing process standards, or current Good Manufacturing Practices (GMP) following approval, or changing interpretations of those factors.

In addition, the current regulatory framework could change, or additional regulations could arise at any stage during our product development or marketing that may affect our ability to obtain or maintain approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

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

Manufacturing pharmaceutical products is difficult and complex, and requires facilities specifically designed and validated for that purpose. It can take more than five years to design, construct, validate, and license a new biotechnology manufacturing facility. We currently produce our products at our manufacturing facilities 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 or supplies used to manufacture our products.

• Equipment obsolescence, malfunctions, or failures.

• Product quality or contamination problems, due to a number of factors including, but not limited to, human error.

• Damage to a facility, including our warehouses and distribution facilities, due to events such as fires or earthquakes, as our South San Francisco, Vacaville, and Oceanside facilities are located in areas where earthquakes and/or fires have occurred.

• Changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes.

• Action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products that we make for others.

• A supplier or contract manufacturer going out of business or failing to produce product as contractually required.

• Failure to maintain an adequate state of current GMP compliance.

• Problems in integrating our new enterprise resource planning system, including the portions related to manufacturing and distribution.

See also, "Our business is affected by macroeconomic conditions."

In addition, there are inherent uncertainties associated with forecasting future demand or actual demand for our products or products that we produce for others, and as a consequence we may have inadequate capacity or inventory to meet actual demand. Alternatively, as a result of these inherent uncertainties, we may have excess

-58-

---

capacity or inventory, which could lead to an idling of a portion of our manufacturing facilities, during which time we would incur unabsorbed or idle plant charges, costs associated with the termination of existing contract manufacturing relationships, costs associated with a reduction in workforce, costs associated with unsalable inventory, or other excess capacity charges, resulting in an increase in our cost of sales (COS).

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

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

Protecting our proprietary rights is difficult and costly.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the breadth of claims that will be allowed in companies' patents. Patent disputes are frequent and may ultimately preclude the commercialization of products. We have in the past been, are currently, and may in the future be involved in material litigation and other legal proceedings related to our proprietary rights, such as the Cabilly patent litigation and re-examination (discussed in Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q), and disputes in connection with licenses granted to or obtained from third parties. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities with third parties, including the payment of significant royalty expenses, the loss of significant royalty income, or other expenses or losses. Furthermore, an adverse decision or ruling could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision or ruling with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of sales and/or royalties and other revenue from licensing arrangements that we have with third parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

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

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

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

Our activities related to the sale and marketing of our products are subject to regulation under the U.S. Federal Food, Drug, and Cosmetic Act and other federal statutes. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). In 1999, we agreed to pay \$50 million to settle a federal investigation related to our past clinical, sales, and marketing activities associated with human growth hormone. We are currently being investigated by the Department of Justice with respect to our promotional practices and may in



the future be investigated for our promotional practices related to any of our products. If the government were to bring charges against us, if we were convicted of violating federal statutes, or if we were subject to third-party litigation related to the same promotional practices, there could be a material adverse effect on our business, including our financial condition and results of operations.

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

Roche's recent unsolicited proposal and related matters may adversely affect our business.

On July 21, 2008, we announced that we received an unsolicited proposal from Roche to acquire all of the outstanding shares of our Common Stock not owned by Roche (the Roche Proposal). A special committee of our Board of Directors, composed of the independent directors (the Special Committee) was formed to review, evaluate, and, in the Special Committee's discretion, negotiate and recommend or not recommend the Roche Proposal. On August 13, 2008, we announced that the Special Committee unanimously concluded that the Roche Proposal substantially undervalues the company, but would consider a proposal that recognizes the value of the company and reflects the significant benefits that would accrue to Roche as a result of full ownership. The review and consideration of the Roche Proposal and related matters requires the expenditure of significant time and resources by us and may be a significant distraction for our management and employees. The Roche Proposal may create uncertainty for our management, employees, current and potential collaborators, and other third parties. On August 18, 2008, the Special Committee adopted two retention plans that together cover substantially all employees of the company, including our executive officers. The retention plans are being implemented in lieu of our 2008 annual stock option grant. Nevertheless, this uncertainty could adversely affect our ability to retain key employees and to hire new talent, cause collaborators to terminate, or not to renew or enter into, arrangements with us and negatively impact our business during the Special Committee review of the Roche Proposal or anytime thereafter. Additionally, we, members of our Board of Directors, and Roche entities have been named in several purported stockholder class-action complaints related to the Roche Proposal, which are more fully described in Note 5, "Contingencies," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q. These lawsuits or any future lawsuits may become burdensome and result in significant costs of defense, indemnification, and liability. These consequences, alone or in combination, may harm our business and have a material adverse effect on our results of operations.

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

As our majority stockholder, RHI controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our Board of Directors shall consist of at least three directors designated by RHI, three independent directors nominated by the Nominations Committee, and one Genentech executive officer nominated by the Nominations Committee. Our bylaws also provide that RHI will have

the right to obtain proportional representation on our Board of Directors until such time that RHI owns less than five percent of our stock. Currently, three of our directors—Mr. William Burns, Dr. Erich Hunziker, and Dr. Jonathan K. C. Knowles—also serve as officers and employees of Roche. As long as RHI owns more than 50 percent of our Common Stock, RHI directors will be two of the three members of the Nominations Committee. Our certificate of incorporation includes provisions related to competition by RHI affiliates with Genentech, offering of corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of

-60-

---

specified employees. We cannot assure that RHI will not seek to influence our business in a manner that is contrary to our goals or strategies, or the interests of other stockholders. Moreover, persons who are directors of Genentech and who are also directors and/or officers of RHI may decline to take action in a manner that might be favorable to us but adverse to RHI.

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

Our Affiliation Agreement with Roche Holdings, Inc. (RHI) could adversely affect our cash position.

Under our July 1999 Affiliation Agreement with RHI (Affiliation Agreement), we have established a stock repurchase program designed to maintain RHI's percentage ownership interest in our Common Stock based on an established Minimum Percentage. A request by RHI to increase RHI's percentage ownership to the Minimum Percentage may adversely affect our cash position. Based on the trading price of our Common Stock and RHI's approximate ownership percentage as of October 31, 2008, to raise RHI'S percentage ownership to the Minimum Percentage would require us to spend approximately \$3 billion for share repurchases. For more information on our stock repurchase program, see "Liquidity and Capital Resources—Cash Used in Financing Activities," in Management's Discussion and Analysis of Financial Condition and Results of Operations in Part I, Item 2 of this Quarterly Report on Form 10-Q. For information on the Minimum Percentage, see Note 6, "Relationship with Roche Holdings, Inc. and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

RHI's ownership percentage is diluted by the exercise of stock options to purchase shares of our Common Stock by our employees and the purchase of shares of our Common Stock through our employee stock purchase plan. See Note 2, "Retention Plans and Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding employee stock plans. In order to maintain RHI's Minimum Percentage, we repurchase shares of our Common Stock under the stock repurchase program. As of September 30, 2008, if all holders of exercisable in-the-money stock options had exercised their stock options, to offset dilution of such exercises would require us to spend approximately \$2 billion for share repurchases, net of the exercise price of the stock options. In the first quarter of 2008, we received approximately four million shares under a \$300 million prepaid share repurchase arrangement that we entered into and funded in 2007. In the second quarter of 2008, we entered into another prepaid share repurchase arrangement with an investment bank pursuant to which we delivered \$500 million to the investment bank. Under this arrangement, the investment bank delivered approximately 5.5 million shares to us on September 30, 2008. As of September 30, 2008, there were 53 million in-the-money exercisable options. While the U.S. dollar amounts associated with future stock repurchase programs cannot currently be determined, future stock repurchases could have a material adverse effect on our liquidity, credit rating, and ability to access additional capital in the financial markets.

Our Affiliation Agreement with RHI could limit our ability to make acquisitions or divestitures.

Our Affiliation Agreement with RHI contains provisions that:

- Require the approval of the directors designated by RHI to make any acquisition that represents 10 percent or more of our assets, net income or revenue; or any sale or disposal of all or a portion of our business representing 10 percent or more of our assets, net income, or revenue.

• Enable RHI to maintain its percentage ownership interest in our Common Stock.

• Require us to establish a stock repurchase program designed to maintain RHI's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For information regarding the Minimum Percentage, see Note 6, "Relationship with Roche Holdings, Inc. and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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

As of September 30, 2008, RHI owned 587,189,380 shares of our Common Stock, or 55.8% of our outstanding shares. All of our shares owned by RHI are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon RHI's request, we will file one or more registration statements under the Securities Act of 1933 in order to permit RHI to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by RHI in the public market could adversely affect the market price of our Common Stock.

Other factors could affect our product sales.

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

• Efficacy data from clinical studies conducted by any party in the U.S. or internationally showing, or perceived to show, a similar or improved treatment benefit at a lower dose or shorter duration of therapy could cause the sales of our products to decrease.

• Our pricing decisions, including a decision to increase or decrease the price of a product; the pricing decisions of our competitors; as well as our Avastin Patient Assistance Program.

• New negative safety or efficacy data from clinical studies conducted either in the U.S. or internationally by any party could cause the sales of our products to decrease or a product to be recalled or withdrawn.

• Negative safety or efficacy data from post-approval marketing experience or production-quality problems could cause sales of our products to decrease or a product to be recalled or withdrawn.

• The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.

• Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers that supply our products.

• Our decision to no longer allow compounding pharmacies to purchase Avastin directly from wholesale distributors, which could have a negative impact on Lucentis sales as a result of negative reaction to our decision by retinal specialists.

• Product returns and allowances greater than expected or historically experienced.

• The inability of one or more of our major customers to maintain their ordering patterns or inventory levels, to efficiently and effectively distribute our products, or to meet their payment obligations to us on a timely basis or at all.

• The inability of patients to afford co-pay costs due to an economic contraction or recession, increases in co-pay costs, or for any other reason.

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

Our results of operations are affected by our royalty and contract revenue, and sales to collaborators.

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

• Roche's decisions about whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets, and the timing and amount of any related development cost reimbursements.

-62-

---

• 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 or to make other contractual payments, the termination of a contract under which we receive royalties or other revenue, or changes to the terms of such a contract.

• The expiration or invalidation of our patents or licensed intellectual property. See “Protecting our proprietary rights is difficult and costly.”

• Variations in Roche’s or other licensees’ sales of our products due to competition, manufacturing difficulties, licensees’ internal forecasts, or other factors that affect the sales of products.

• Variations in the recognition of royalty revenue based on our estimates of our licensees’ sales, which are difficult to forecast because of the number of products involved, the availability of licensee sales data, potential contractual and intellectual property disputes, and the volatility of foreign exchange rates.

• Fluctuations in foreign currency exchange rates and the effect of any hedging contracts that we have entered into under our hedging policy.

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

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

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

The success of our business depends, in large part, on our continued ability to (1) attract and retain highly qualified management, scientific, manufacturing, and sales and marketing personnel, (2) successfully integrate new employees into our corporate culture, and (3) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense, and may intensify due to, among other reasons, uncertainty regarding the Roche Proposal. 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.

We may incur material product liability costs.

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

-63-

---



Insurance coverage may be more difficult and costly to obtain or maintain.

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

We are subject to environmental and other risks.

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

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

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

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

- The overall competitive environment for our products, as described in “We face competition” above.
- The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns, or sales initiatives that we may undertake from time to time.
- Increased COS; R&D and marketing, general and administrative expenses; stock-based compensation expenses; litigation-related expenses; asset impairments; and equity securities write-downs.
- Changes in the economy, the credit markets, interest rates, credit ratings, and the liquidity of our investments, and the effects that such changes or volatility may have on the value of our interest-bearing or equity investments.
- Changes in foreign currency exchange rates, the effect of any hedging contracts that we have entered into under our policy and the effects that they may have on our royalty revenue, contract revenue, R&D expenses and foreign-currency-denominated investments.
- The amount and timing of our sales to Roche and our other collaborators of products for sale outside the U.S., and the amount and timing of sales to their respective customers, which directly affect both our product sales and royalty

revenue.

• The timing and volume of product produced and bulk shipments to licensees under contract manufacturing arrangements.

-64-

---

• The availability and extent of government and private third-party reimbursements for the cost of our products.

• The extent of product discounts extended to customers.

• The efficacy and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.

• The rate of adoption by physicians and the use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and the use of our products may be affected by the results of clinical studies reporting on the benefits or risks of a product.

• The potential introduction of new products and additional indications for existing products.

• The ability to successfully manufacture sufficient quantities of any particular marketed product.

• Pricing decisions that we or our competitors have adopted or may adopt, as well as our Avastin Patient Assistance Program.

• Our distribution strategy, including the termination of, or any change in, an existing arrangement with any major wholesalers that supply our products.

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

Our business is affected by macroeconomic conditions.

Various macroeconomic factors could affect our business and the results of our operations. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass significant price increases on to our customers due to the process by which physicians are reimbursed for our products by the government. Interest rates and the ability to access credit markets could affect the ability of our customers/distributors to purchase, pay for, and effectively distribute our products. Similarly, these macroeconomic factors could affect the ability of our sole-source or single-source suppliers to remain in business or otherwise supply product; failure by any of them to remain a going concern could affect our ability to manufacture products. Interest rates and the liquidity of the credit markets could also affect the value of our investments. Foreign currency exchange rates may affect our royalty revenues as well as the costs of research and development activities denominated in a currency other than the U.S. dollar.

Our integration of new information systems could disrupt our internal operations, which could decrease revenue and increase expenses.

Portions of our information technology infrastructure may experience interruptions, delays, or cessations of service, or produce errors. As part of our enterprise resource planning efforts, we have implemented new information systems, but we may not be successful in integrating the new systems into our operations. Any disruptions that may occur as a result of the implementation of new systems, or any future systems, could adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, financial position, and cash flows. Disruptions to these systems also could adversely affect our ability to fulfill orders and interrupt other operational processes. Delayed sales, lower margins, or lost customers resulting from these disruptions could adversely affect our financial results.



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

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. In addition, the market price of our Common Stock has been and may continue to be volatile. Among other factors, the following may have a significant effect on the market price of our Common Stock:

• The Roche Proposal to acquire all of the outstanding shares of our Common Stock not owned by Roche. Future developments related to the Roche Proposal may result in further volatility in the price of our Common Stock.

• Announcements of technological innovations or new commercial products by us or our competitors.

• Publicity regarding actual or potential medical results related to products under development or being commercialized by us or our competitors.

• Our financial results.

• Concerns about our pricing initiatives and distribution strategy, and the potential effect of such initiatives and strategy on the utilization of our products or our product sales.

• Developments or outcomes of litigation, including litigation regarding proprietary and patent rights (including, for example, the Cabilly patent discussed in Note 5, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q), and governmental investigations.

• Regulatory developments or delays affecting our products in the U.S. and other countries.

• Issues concerning the efficacy or safety of our products, or of biotechnology products generally.

• Economic and other external factors or a disaster or crisis.

• New proposals to change or reform the U.S. healthcare system, including, but not limited to, new regulations concerning reimbursement or follow-on biologics.

Our effective income tax rate may vary significantly.

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

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

As of September 30, 2008, we had approximately \$2.0 billion of long-term debt and \$536 million of commercial paper notes payable. Our ability to make payments on or to refinance our indebtedness, and to fund planned capital expenditures and R&D, as well as stock repurchases and expansion efforts, will depend on our ability to generate cash in the future. This ability, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory, and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase

our vulnerability to general adverse economic and industry conditions, and require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts, and other

-66-

---

general corporate purposes; and limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

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

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

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

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2008, we are authorized to repurchase up to 150 million shares of our Common Stock for an aggregate amount of up to \$10.0 billion through June 30, 2009. In this program, as in previous stock repurchase programs, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. We also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. As of September 30, 2008, we had not engaged in any such transactions. We use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock purchase plan. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (1) to address provisions of our Affiliation Agreement with RHI related to maintaining RHI's minimum ownership percentage, (2) to make prudent investments of our cash resources, and (3) to allow for an effective mechanism to provide stock for our employee stock purchase plan. See Note 6, "Relationship with Roche Holdings, Inc. and Related Party Transactions," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information on RHI's minimum ownership percentage.

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

Our shares repurchased for the third quarter of 2008 were as follows (shares in millions):

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(2)	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs(2)
July 1–31, 2008	–	–		
August 1–31, 2008	–	–		
September 1–30, 2008(1)	5.5	\$ 90.24		
Total	5.5	\$ 90.24	88	62

(1) In May 2008, we entered into a prepaid share repurchase arrangement with an investment bank pursuant to which we delivered \$500 million to the investment bank.

Under this arrangement, the investment bank delivered approximately 5.5 million shares to us on September 30, 2008.

(2) As of September 30, 2008, 88 million cumulative shares had been purchased under our stock repurchase program for \$6.5 billion, and a maximum of 62 million additional shares for amounts totaling up to \$3.5 billion may be purchased under the program through June 30, 2009.

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



## Item 6. Exhibits.

Exhibit No.	Description	Location
3.1	Amended and Restated Certificate of Incorporation	Filed as an exhibit to our Current Report on Form 8-K filed with the U. S. Securities and Exchange Commission (Commission) on July 28, 1999 and incorporated herein by reference.
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation	Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2000 filed with the Commission and incorporated herein by reference.
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	Filed as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 filed with the Commission and incorporated herein by reference.
3.4	Certificate of Third Amendment of Amended and Restated Certificate of Incorporation	Filed as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 filed with the Commission and incorporated herein by reference.
3.5	Bylaws	Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2005 filed with the Commission and incorporated herein by reference.
4.1	Form of Common Stock Certificate	Filed as an exhibit to Amendment No. 3 to our Registration Statement (No. 333-80601) on Form S-3 filed with the Commission on July 16, 1999 and incorporated herein by reference.
4.2	Indenture, dated as of July 18, 2005, between the Company and Bank of New York, as trustee	Filed on a Current Report on Form 8-K with the Commission on July 19, 2005 and incorporated herein by reference.
4.3	Officers' Certificate of Genentech, Inc. dated July 18, 2005, including forms of the Company's 4.40% Senior Notes due 2010, 4.75 Senior Notes due 2015 and 5.25% Senior Notes due 2035	Filed on a Current Report on Form 8-K with the Commission on July 19, 2005 and incorporated herein by reference.
4.4	Form of 4.40% Senior Note due 2010	Filed on a Current Report on Form 8-K with the Commission on July 19, 2005 and incorporated herein by reference.
4.5	Form of 4.75% Senior Note due 2015	Filed on a Current Report on Form 8-K with the Commission on July 19, 2005 and incorporated herein by reference.
4.6	Form of 5.25% Senior Note due 2035	Filed on a Current Report on Form 8-K with the Commission on July 19, 2005 and incorporated herein by reference.
4.7	Registration Rights Agreement, dated as of July 18, 2005, among Genentech, Inc. and Citigroup Global Markets, Inc. and Goldman, Sachs & Co. as representatives of the initial purchasers	Filed on a Current Report on Form 8-K with the Commission on July 19, 2005 and incorporated herein by reference.

10.1	Genentech, Inc. Executive Retention Plan	Filed on a Current Report on Form 8-K with the Commission on August 21, 2008 and incorporated herein by reference.
10.2	Genentech, Inc. Executive Severance Plan	Filed on a Current Report on Form 8-K with the Commission on August 21, 2008 and incorporated herein by reference.
15.1	Letter regarding Unaudited Interim Financial Information	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 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 3, 2008

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

Date: November 3, 2008

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

Date: November 3, 2008

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

