GENENTECH INC
Form 10-Q
November 02, 2007

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007

or

o **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 organization)	(I.R.S. Employer Identification Number)

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

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

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

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

Large accelerated filer þ Accelerated filer o Non-accelerated filer o

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

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	1,053,091,492 Outstanding at October 26, 2007

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

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin® (bevacizumab) anti-VEGF

antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis® (ranibizumab, rhuFab V2) anti-VEGF antibody fragment; Nutropin® (somatropin [rDNA origin] for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen® (somatropin [rDNA origin] for injection) liquid formulation growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva® (efalizumab) anti-CD11a antibody; and TNKase® (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva® (erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks, and trade names of other companies.

PART I—FINANCIAL INFORMATION
Item 1. Financial Statements

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

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

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

See Notes to Condensed Consolidated Financial Statements.

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

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

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

See Notes to Condensed Consolidated Financial Statements.

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

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

Total liabilities and stockholders' equity	$	17,444	$	14,842

See Notes to Condensed Consolidated Financial Statements.

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

Note 1. Summary of Significant Accounting Policies

Basis of Presentation

We prepared the Condensed Consolidated Financial Statements following the requirements of the United States (U.S.) Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that is normally required by U.S. generally accepted accounting principles (GAAP) can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Consolidated Financial Statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2006. In the opinion of management, the financial statements include all adjustments, consisting only of normal and recurring adjustments, considered necessary for the fair presentation of our financial position and operating results.

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

Principles of Consolidation

The consolidated financial statements include the accounts of Genentech and all wholly owned subsidiaries. Following the completion of our acquisition of Tanox, Inc. on August 2, 2007, the financial results of Tanox's operations have been included in the consolidated financial results of Genentech. Material intercompany accounts and transactions have been eliminated.

Use of Estimates and Reclassifications

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

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

Recent Accounting Pronouncements

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

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

adjustment to retained earnings (accumulated deficit). The total amount of unrecognized tax benefits as of the date of adoption was $147 million. Of this total, $112 million represents the amount of unrecognized tax benefits that, if recognized, would favorably affect our effective income tax rate in any future period. As a result of the implementation of FIN 48, we reclassified $147 million of unrecognized tax benefits from current liabilities to long-term liabilities as of December 31, 2006 in the accompanying Condensed Consolidated Balance Sheets.

We file income tax returns in the U.S. federal jurisdiction and various state and international jurisdictions. The Internal Revenue Service (IRS) is examining our U.S. federal income tax returns for 2002 through 2004. As of September 30, 2007, the IRS has not proposed any adjustments. We are also under examination by several state jurisdictions. As of September 30, 2007, no material adjustments related to these audits have been proposed.

We accrue tax-related interest and penalties and include such expenses with income tax expense in the Condensed Consolidated Statements of Income. We recognized approximately $2 million and $6 million in tax-related interest expense during the third quarter and first nine months of 2007, respectively, and had approximately $10 million of tax-related interest accrued at January 1, 2007. Interest amounts are net of tax benefit. No penalties have been accrued.

Revenue Recognition

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

The Avastin Patient Assistance Program is a voluntary program that enables eligible patients who have received 10,000 milligrams of Avastin in a 12-month period to receive free Avastin in excess of the 10,000 milligrams during the remainder of the 12-month period. Based on the current wholesale acquisition cost, 10,000 milligrams is valued at $55,000 in gross revenue. We defer a portion of our gross Avastin product sales revenue to reflect our estimate of the commitment to supply free Avastin to patients who elect to enroll in the program. To calculate our deferred revenue, we estimate the number of patients who will receive free Avastin and the amount of free Avastin that we expect them to receive. Based on those estimates, we defer a portion of Avastin revenue on product vials sold through normal commercial channels. The deferred revenue is recognized when free Avastin vials are delivered or after the associated patient eligibility period has passed.

Earnings Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	**2006**	**2007**	**2006**
Numerator:				
Net income	$ 685	$ 568	$ 2,138	$ 1,519
Denominator:				
Weighted-average shares outstanding used to compute basic earnings per share	1,053	1,053	1,053	1,053
Effect of dilutive stock options	16	19	17	21
	1,069	1,072	1,070	1,074

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

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

Comprehensive Income

Comprehensive income comprises net income and other comprehensive income (OCI). OCI includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in OCI changes in the estimated fair value of derivatives designated as effective cash flow hedges, and unrealized gains and losses on our securities available-for-sale. In accordance with our adoption of Statement of Financial Accounting Standards (FAS) No. 158, *"Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans – an amendment of FASB Statements No. 87, 88, 106, and 132(R),"* in 2006, the gains or losses and prior service costs or credits that arise during the period, but are not recognized as components of net periodic benefit cost, have been recognized in other comprehensive income.

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

	September 30, 2007	December 31, 2006
Net unrealized gains on securities available-for-sale	$ 224	$ 214
Net unrealized losses on cash flow hedges	(6)	(4)
Post-retirement benefit obligation	(6)	(6)
Accumulated other comprehensive income	$ 212	$ 204

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income	$ 685	$ 568	$ 2,138	$ 1,519
Increase (decrease) in unrealized gains on securities available-for-sale	19	16	10	(24)
(Decrease) increase in unrealized gains on cash flow hedges	(13)	1	(2)	(19)
Comprehensive income, net of income taxes	$ 691	$ 585	$ 2,146	$ 1,476

Derivative Instruments

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

Note 2. Employee Stock-Based Compensation

Stock-Based Compensation Expense under FAS 123R

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

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

	Three Months	Nine Months

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

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

The carrying value of inventory on our Condensed Consolidated Balance Sheets as of September 30, 2007 and 2006 includes employee stock-based compensation costs of $77 million and $49 million, respectively. During the third quarter and first nine months of 2007, $16 million and $49 million, respectively, of previously capitalized employee stock-based compensation costs were recognized in cost of sales. Substantially all of the products sold during the first nine months of 2006 were manufactured in previous periods when we did not include employee stock-based compensation expense in our production costs.

Valuation Assumptions

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

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

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

Note 3. Condensed Consolidated Financial Statement Detail

Inventories

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

	September 30, 2007	December 31, 2006
Raw materials and supplies	$ 131	$ 116
Work in process	933	818
Finished goods	361	244
Total	$ 1,425	$ 1,178

Note 4. Contingencies

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

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

discussions with government representatives about the status of their investigation and Genentech's views on this matter. The government has called, and may continue to call, former and current Genentech employees to appear before a grand jury in connection with this investigation. The outcome of this matter cannot be determined at this time.

On July 29, 2005, a former Genentech employee, whose employment ended in April 2005, filed a qui tam complaint under seal in the United States District Court for the District of Maine against Genentech and Biogen Idec Inc., alleging violations of the False Claims Act and retaliatory discharge of employment. On December 20, 2005, the United States filed notice of its election to decline intervention in the lawsuit. The complaint was subsequently unsealed and we were served on January 5, 2006. Genentech filed a motion to dismiss the complaint, and on December 14, 2006, the Magistrate Judge assigned to the case issued a Recommended Decision on that motion, which is subject to review by the District Court Judge. The Magistrate Judge recommended that the False Claims Act portion of the complaint be dismissed, leaving as the only remaining claim against Genentech the plaintiff's retaliatory discharge claim. Plaintiff, Biogen Idec, and Genentech each subsequently filed objections with the District Court Judge concerning certain aspects of the Magistrate Judge's Recommended Decision. On July 24, 2007, the District Court Judge affirmed the dismissal of both claims related to the False Claims Act but denied Genentech's motion to dismiss plaintiff's federal retaliatory discharge claim and granted plaintiff's motion for leave to file a Second Amended Complaint asserting an additional state law employment claim. The outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (COH) are parties to a 1976 agreement related to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, we have entered into license agreements with various companies to manufacture, use, and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to the COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. On June 10, 2002, a jury voted to award the COH approximately $300 million in compensatory damages. On June 24, 2002, a jury voted to award the COH an additional $200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and are included in the accompanying Condensed Consolidated Balance Sheets in "litigation-related and other long-term liabilities" at September 30, 2007 and December 31, 2006. We filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. On October 21, 2004, the California Court of Appeal affirmed the verdict and damages awards in all respects. On November 22, 2004, the California Court of Appeal modified its opinion without changing the verdict and denied Genentech's request for rehearing. On November 24, 2004, we filed a petition seeking review by the California Supreme Court. On February 2, 2005, the California Supreme Court granted that petition. The appeal to the California Supreme Court has been fully briefed, and we are waiting to be assigned an oral argument date. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter. It may take longer than one year to resolve the matter.

We recorded accrued interest and bond costs related to the COH trial judgment of $14 million for the third quarter of 2007 and $13 million for the third quarter of 2006, and $41 million for the first nine months of 2007 and $40 million for the first nine months of 2006. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of $788 million at September 30, 2007 and December 31, 2006 to secure the bond. These amounts are reflected in "restricted cash and investments" in the accompanying Condensed Consolidated Balance Sheets. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results.

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

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

and other relief. On January 14, 2004 (amending a December 23, 2003 order), the U.S. District Court granted summary judgment in our favor on all of MedImmune's antitrust and unfair competition claims. On April 23, 2004, the District Court granted our motion to dismiss all remaining claims in the case. On October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. MedImmune filed a petition for certiorari with the U.S. Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune's petition, and the oral argument of this case before the Supreme Court occurred on October 4, 2006. On January 9, 2007, the Supreme Court issued a decision reversing the Federal Circuit's decision and remanding the case to the lower courts for further proceedings in connection with the patent and contract claims. On August 16, 2007, the U.S. District Court entered a Claim Construction Order defining several terms used in the '415 patent. Discovery and motion practice are ongoing and the trial of this matter has been scheduled for June 23, 2008. The outcome of this matter cannot be determined at this time.

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

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

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

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

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

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

Related Party Transactions

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

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

Roche

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

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

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

Novartis

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

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

We, along with Novartis, are co-developing and co-promoting Xolair in the U.S. We record all sales and cost of sales in the U.S., and Novartis markets the product in and records all sales and cost of sales in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit sharing percentages, and our U.S. and European profit sharing expenses are recorded as collaboration profit sharing expense. Effective with our acquisition of Tanox on August 2, 2007, Novartis also makes royalty payments to us on sales of Xolair worldwide and also pays us a manufacturing fee related to Xolair. See Note 6, “Acquisition of Tanox, Inc.” for more information on the acquisition.

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

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

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

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

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

Note 6. Acquisition of Tanox, Inc.

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

(In millions)		
Assets		
Cash	$	100
Investments		102
Working capital and other, net		56
In-process research and development (IPR&D)		77
Developed product technology		780
Core technology		34
Goodwill		259
Deferred revenue		(185)
Deferred tax liability, net		(217)
Total acquisition consideration and gain	$	1,006
Consideration and Gain		
Consideration	$	925
Transaction costs		8
Gain on settlement of preexisting relationship, net of tax		73
	$	1,006

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

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

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

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

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

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

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

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

Note 7. Income Taxes

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

Note 8. Subsequent Event

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Genentech, Inc.

We have reviewed the condensed consolidated balance sheet of Genentech, Inc. as of September 30, 2007, and the related condensed consolidated statements of income for the three-month and nine-month periods ended September 30, 2007 and 2006, and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2007 and 2006. These financial statements are the responsibility of the Company's management.

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

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

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Genentech, Inc. as of December 31, 2006, and the related consolidated statements of income, stockholders' equity, and cash flows for the year then ended, not presented herein, and in our report dated February 5, 2007, we expressed an unqualified opinion on those consolidated financial statements including an explanatory paragraph relating to the change in method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-based Payment." In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2006, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Ernst & Young LLP

Palo Alto, California
October 29, 2007

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

GENENTECH, INC.
FINANCIAL REVIEW

Overview

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Consolidated Financial Statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2006.

The Company

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

Major Developments in the Third Quarter of 2007

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

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

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

Our Strategy and Goals

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

objectives are reflected in our revised Horizon 2010 strategy and goals summarized on our website at www.gene.com/gene/about/corporate/growthstrategy.

Economic, Industry-wide, and Other Factors

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

- We face significant competition in the diseases of interest to us from pharmaceutical companies and biotechnology companies. The introduction of new competitive products or follow-on biologics, and/or new information about existing products, and/or pricing decisions by us or our competitors, may result in lost market share for us, reduced utilization of our products, lower prices, and/or reduced product sales, even for products protected by patents.
- Our long-term business growth depends upon our ability to continue to successfully develop and commercialize important novel therapeutics to treat unmet medical needs, such as cancer. We recognize that the successful development of biotherapeutics is highly difficult and uncertain, and that it will be challenging for us to continue to discover and develop innovative treatments. Our business requires significant investment in research and development (R&D) over many years, often for products that fail during the R&D process. Once a product receives FDA approval, it remains subject to ongoing FDA regulation, including changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisement to physicians, and/or product recalls or withdrawals.
- Our near-term growth will depend on our ability to execute on recent product approvals, including Lucentis for the treatment of neovascular (wet) age-related macular degeneration (AMD) and Avastin for the treatment of non-small cell lung cancer, and to successfully obtain FDA approvals for potential new indications for our existing products such as Avastin for the treatment of metastatic BC and anti-CD20 molecules for the treatment of immunological disorders.
- Our business model requires appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. The pricing and distribution of our products have received negative press coverage and public scrutiny. We will continue to meet with patient groups, payers, and other stakeholders in the healthcare system to understand their issues and concerns. The reimbursement environment for our products may change in the future and become more challenging.
- As the Medicare and Medicaid programs are the largest payers for our products, rules related to coverage and reimbursement continue to represent an important issue for our business. New regulations related to hospital and physician payment continue to be implemented annually. To date, we have not seen any detectable effects of the new rules on our product sales. As a result of the Deficit Reduction Act, new regulations will take effect in the fourth quarter of 2007 that will impact the discounted price for our products paid by Medicaid and government-affiliated customers. While pricing continues to be an important area of focus, we anticipate minimal impact on our revenue for the remainder of 2007.
- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection could result in lost sales to competing products and may negatively affect our sales, royalty revenue, and operating results. We are often involved in disputes over contracts and intellectual property, and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.

- Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. The manufacture of a biotherapeutic requires developing and maintaining a process to reliably manufacture and formulate the product at an appropriate scale, obtaining regulatory approval to manufacture the product, and is subject to changes in regulatory requirements or standards that may require modifications to the manufacturing process. Additionally, we may have an excess of available capacity, which could lead to an idling of a portion of our manufacturing facilities and incurring unabsorbed or idle plant charges, or other excess capacity charges, resulting in an increase in our cost of sales.
- Our ability to attract and retain highly qualified and talented people in all areas of the company, and our ability to maintain our unique culture, will be critical to our success over the long-term. We are working diligently across the company to make sure that we successfully hire, train, and integrate new employees into the Genentech culture and environment.

Marketed Products

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

Avastin (bevacizumab) is an anti-VEGF humanized antibody approved for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first- or second-line metastatic cancer of the colon or rectum. It is also approved for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer.

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

Herceptin (trastuzumab) is a humanized anti-HER2 antibody approved for use as an adjuvant treatment of node-positive breast cancer as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel for patients who have tumors that overexpress the human epidermal growth factor receptor 2 (HER2) protein. It is also approved for use as a first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy for patients with HER2-positive metastatic BC.

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

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

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

patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. It is also approved, in combination with gemcitabine chemotherapy, for the first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer.

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

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

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

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

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

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

Licensed Products

We receive royalty revenue from various licensees, including significant royalty revenue from Roche Holding AG and affiliates (Roche) on sales of:

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

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

Available Information

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

- Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the U.S. Securities and Exchange Commission;
- Our policies related to corporate governance, including our Principles of Corporate Governance, Good Operating Principles, and Code of Ethics, which apply to our Chief Executive Officer, Chief Financial Officer, and senior financial officials; and
- The charters of the Audit Committee and the Compensation Committee of our Board of Directors.

Critical Accounting Policies and the Use of Estimates

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

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

Contingencies

We are currently, and have been, involved in certain legal proceedings, including patent infringement litigation. We are also involved in licensing and contract disputes, and other matters. See Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for more information on these matters. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. We record an estimated loss as a charge to income if we determine that, based on information available at the time, the loss is probable and the amount of loss can be reasonably estimated. Included in "litigation-related and other long-term liabilities" in the accompanying Condensed Consolidated Balance Sheet at September 30, 2007 is $764 million, which represents our estimate of the costs for the current resolution of the City of Hope National Medical Center (COH) matter. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. The outcomes of such matters that are different from our current estimates could have a material effect on our financial position or our results of operations in any one quarter.

Revenue Recognition – Avastin U.S. Product Sales

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

In order to make our estimate of the amount of free Avastin to be provided to patients under the program, we need to estimate several factors, most notably: the number of patients who are currently being treated for FDA-approved indications and the start date for their treatment regimen, the extent to which doctors and patients may elect to enroll in the program, the number of patients who will meet the financial eligibility requirements of the program, and the duration and extent of treatment for the FDA-approved indications, among other factors. We have based our enrollment assumptions on physician surveys and other information that we consider relevant. We will continue to update our estimates in each reporting period as new information becomes available. If the actual results underlying

this deferred revenue accounting vary significantly from our estimates, we will need to make adjustments to these estimates, which could have a material effect on revenue and earnings in the period of adjustment. Based on these estimates, we defer a portion of Avastin revenue on product vials sold through normal commercial channels. The deferred revenue will be recognized when free Avastin vials are delivered. Enrollment in the program was lower than expected in the first nine months of 2007, and we recorded net decreases in deferred revenue, and

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

Product Sales Allowances

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

Definitions for the product sales allowance types are as follows:

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

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

Our rebates are based on definitive agreements or legal requirements (such as Medicaid). These rebates are primarily estimated using historical and other data, including patient usage, customer buying patterns, applicable contractual rebate rates, and contract performance by the benefit providers. Direct rebates are accrued at the time of sale and recorded as allowances against trade accounts receivable; indirect (including Medicaid) rebates are accrued at the time

of sale and recorded as liabilities. Rebate estimates are evaluated quarterly and may require changes to better align our estimates with actual results. As part of this evaluation, we review changes to Medicaid legislation,

changes to state rebate contracts, changes in the level of discounts, and significant changes in product sales trends. Although rebates are accrued at the time of sale, rebates are typically paid out, on average, up to six months after the sale. We believe that our rebate allowances and accruals estimation process provides a high degree of confidence in the amounts established and that the annual allowance amounts provided for would not vary by more than approximately 3% based on our estimate that our changes in rebate allowances and accruals estimates related to prior years have not exceeded 3%. To illustrate our sensitivity to changes in the rebate allowances and accruals process, as much as a 10% change in our annualized rebate allowances and accruals provision experienced to date in 2007 (which is in excess of three times the level of variability that we reasonably expect to observe for rebates) would have an approximate $18 million effect on our income before taxes (or approximately $0.01 per share after taxes). The total rebate allowances and accruals recorded in our Condensed Consolidated Balance Sheet were $63 million as of September 30, 2007.

All of the aforementioned categories of allowances and accruals are evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could materially affect our results of operations or financial position; however, to date they have not been material. It is possible that we may need to adjust our estimates in future periods. As of September 30, 2007, our Condensed Consolidated Balance Sheet reflected estimated product sales allowance reserves and accruals totaling approximately $166 million.

Royalties

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

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 (the Cabilly patent), under which we receive royalty revenue on sales of products that are covered by the patent. The Cabilly patent, which expires in 2018, relates to methods that we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in those methods. The U.S. Patent and Trademark Office (Patent Office) is performing a reexamination of the patent and on February 16, 2007 issued a final Patent Office action rejecting all 36 claims of the Cabilly patent. We responded to the final Patent Office action on May 21, 2007 and requested continued reexamination. On May 31, 2007, the Patent Office granted the request for continued reexamination, and in so doing withdrew the finality of the February 2007 Patent Office action and agreed to treat our May 21, 2007 filing as a response to a first Patent Office action. The claims of the patent remain valid and enforceable throughout the reexamination and appeals processes. In addition, MedImmune, Inc. has filed a lawsuit against us challenging the Cabilly patent. See also Note 4, “Contingencies,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for more information on our Cabilly patent reexamination and the MedImmune lawsuit.

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

Income Taxes

Income tax provision is based on income before taxes and is computed using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based

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

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

Inventories

Inventories may include currently marketed products manufactured under a new process or at facilities awaiting regulatory licensure. These inventories are capitalized based on management's judgment of probable near-term regulatory licensure. Excess or idle capacity costs, based on estimated plant capabilities, are expensed in the period in which they are incurred. The valuation of inventory requires us to estimate the value of inventory that may expire prior to use or that may fail to be released for commercial sale. The determination of obsolete inventory requires us to estimate the future demands for our products, and in the case of pre-approval inventories, to estimate the regulatory approval date for the product or for the licensure of either the manufacturing facility or the new manufacturing process. We may be required to expense previously capitalized inventory costs upon a change in our estimate, due to, among other potential factors, the denial or delay of approval of a product or the licensure of either a manufacturing facility or a new manufacturing process by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable.

Valuation of Acquired Intangible Assets

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

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

Employee Stock-Based Compensation

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

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

award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date, and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. See also Note 2, “Employee Stock-Based Compensation,” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for more information.

Results of Operations

(In millions, except per share amounts)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	% Change	2007	2006	% Change
Product sales	$ 2,321	$ 1,941	20%	$ 7,094	$ 5,395	31%
Royalties	524	364	44	1,427	966	48
Contract revenue	63	79	(20)	234	208	13
Total operating revenue	2,908	2,384	22	8,755	6,569	33
Cost of sales	406	297	37	1,227	843	46
Research and development	615	454	35	1,828	1,218	50
Marketing, general and administrative	541	501	8	1,564	1,414	11
Collaboration profit sharing	276	250	10	805	735	10
Write-off of in-process research and development related to acquisition	77	–	–	77	–	–
Gain on acquisition	(121)	–	–	(121)	–	–
Recurring charges related to redemption and acquisition	38	26	46	90	79	14
Special items: litigation-related	14	13	8	41	40	3
Total costs and expenses	1,846	1,541	20	5,511	4,329	27
Operating income	1,062	843	26	3,244	2,240	45
Other income (expense):						
Interest and other income, net	84	74	14	233	249	(6)
Interest expense	(18)	(19)	(5)	(53)	(56)	(5)
Total other income, net	66	55	20	180	193	(7)