

GENENTECH INC  
Form 10-Q  
November 02, 2006

---

---

**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, 2006**

or

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

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

**Commission File Number: 1-9813**

**GENENTECH, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**94-2347624**

(I.R.S. Employer Identification Number)

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

(Address of principal executive offices and Zip Code)

**(650) 225-1000**

(Registrant's telephone number, including area code)

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

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

Edgar Filing: GENENTECH INC - Form 10-Q

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

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

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock \$0.02 par value	1,054,000,743 Outstanding at October 27, 2006

---

---

---

**GENENTECH, INC.**  
**TABLE OF CONTENTS**

		<u>Page No.</u>
<u>PART I—FINANCIAL INFORMATION</u>		
Item 1.	<u>Financial Statements</u>	3
	<u>Condensed Consolidated Statements of Income— for the three and nine months ended September 30, 2006 and 2005</u>	3
	<u>Condensed Consolidated Statements of Cash Flows— for the nine months ended September 30, 2006 and 2005</u>	4
	<u>Condensed Consolidated Balance Sheets— September 30, 2006 and December 31, 2005</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6-19
	<u>Report of Independent Registered Public Accounting Firm</u>	20
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	21-42
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	43
Item 4.	<u>Controls and Procedures</u>	43
<u>PART II—OTHER INFORMATION</u>		
Item 1.	<u>Legal Proceedings</u>	44
Item 1A.	<u>Risk Factors</u>	44-56
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	56
Item 6.	<u>Exhibits</u>	57
	<u>SIGNATURES</u>	58

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

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

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

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

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

	<b>Three Months</b>		<b>Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>Revenues</b>				
Product sales (including amounts from related parties: three months—2006-\$87; 2005-\$58; nine months—2006-\$220; 2005-\$140)	\$ 1,941	\$ 1,451	\$ 5,395	\$ 3,911
Royalties (including amounts from related parties: three months—2006-\$230; 2005-\$123; nine months—2006-\$603; 2005-\$336)	364	238	966	670
Contract revenue (including amounts from related parties: three months—2006-\$52; 2005-\$37; nine months—2006-\$114; 2005-\$94)	79	63	208	159
<b>Total operating revenues</b>	<b>2,384</b>	<b>1,752</b>	<b>6,569</b>	<b>4,740</b>
<b>Costs and expenses</b>				
Cost of sales (including related party amounts: three months—2006-\$63; 2005-\$45; nine months—2006-\$178; 2005-\$134)	297	236	843	766
Research and development (including related party amounts: three months—2006-\$93; 2005-\$55; nine months—2006-\$238; 2005-\$150) (including contract related: three months—2006-\$48; 2005-\$47; nine months—2006-\$135; 2005-\$111)	454	329	1,218	850
Marketing, general and administrative	501	343	1,414	1,006
Collaboration profit sharing (including amounts from related party: three months—2006-\$46; 2005-\$41; nine months—2006-\$137; 2005-\$93)	250	220	735	595
Recurring charges related to redemption	26	27	79	96
Special items: litigation-related	13	14	40	44
<b>Total costs and expenses</b>	<b>1,541</b>	<b>1,169</b>	<b>4,329</b>	<b>3,357</b>
Operating income	843	583	2,240	1,383
Other income (expense):				
Interest and other income, net	74	42	249	98

Edgar Filing: GENENTECH INC - Form 10-Q

Interest expense	(19)	(20)	(56)	(27)
Total other income, net	55	22	193	71
Income before taxes	898	605	2,433	1,454
Income tax provision	330	246	914	514
<b>Net income</b>	<b>\$ 568</b>	<b>\$ 359</b>	<b>\$ 1,519</b>	<b>\$ 940</b>
<b>Earnings per share</b>				
Basic	\$ 0.54	\$ 0.34	\$ 1.44	\$ 0.89
Diluted	\$ 0.53	\$ 0.33	\$ 1.41	\$ 0.87
Shares used to compute basic earnings per share	1,053	1,061	1,053	1,055
Shares used to compute diluted earnings per share	1,072	1,087	1,074	1,081

*See Notes to Condensed Consolidated Financial Statements*

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

	Nine Months Ended September 30,	
	2006	2005
<b>Cash flows from operating activities</b>		
Net income	\$ 1,519	\$ 940
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	298	276
Employee stock-based compensation	225	-
Deferred income taxes	(86)	(67)
Deferred revenue	(13)	(33)
Litigation-related liabilities	39	39
Tax benefit from employee stock options	-	480
Excess tax benefit from stock-based compensation arrangements	(142)	-
Gain on sales of securities available-for-sale and other	(76)	(4)
Write-down of securities available-for-sale and other	1	5
Changes in assets and liabilities:		
Receivables and other assets	(423)	(74)
Inventories	(311)	(31)
Investments in trading securities	(26)	(13)
Accounts payable, other accrued liabilities, and other long-term liabilities	311	131
<b>Net cash provided by operating activities</b>	<b>1,316</b>	<b>1,649</b>
<b>Cash flows from investing activities</b>		
Purchases of securities available-for-sale	(1,078)	(694)
Proceeds from sales and maturities of securities available-for-sale	663	575
Capital expenditures	(888)	(1,107)
Change in other assets	24	(25)
Transfer to restricted cash	(53)	(53)
<b>Net cash used in investing activities</b>	<b>(1,332)</b>	<b>(1,304)</b>
<b>Cash flows from financing activities</b>		
Stock issuances under employee stock plans	286	634
Stock repurchases	(758)	(1,090)
Excess tax benefit from stock-based compensation arrangements	142	-
Repayment of long-term debt and noncontrolling interests	-	(425)
Proceeds from issuance of long-term debt	-	1,988
<b>Net cash (used in) provided by financing activities</b>	<b>(330)</b>	<b>1,107</b>
Net (decrease) increase in cash and cash equivalents	(346)	1,452
Cash and cash equivalents at beginning of period	1,225	270
<b>Cash and cash equivalents at end of period</b>	<b>\$ 879</b>	<b>\$ 1,722</b>

**Supplemental cash flow data**

Edgar Filing: GENENTECH INC - Form 10-Q

Cash paid during the period for:			
Interest	\$	96	\$ 9
Income taxes		851	309
Non-cash investing and financing activities			
Capitalization of construction in progress related to financing lease transaction		84	94
Exchange of note receivable for a prepaid royalty and other long-term asset		-	29

*See Notes to Condensed Consolidated Financial Statements.*



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

	September 30, 2006	December 31, 2005
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 879	\$ 1,225
Short-term investments	1,224	1,140
Accounts receivable—product sales (net of allowances: 2006-\$86; 2005-\$83; including amounts from related parties: 2006-\$12; 2005-\$4)	790	554
Accounts receivable—royalties (including amounts from related parties: 2006-\$287; 2005-\$173)	415	297
Accounts receivable—other (including amounts from related parties: 2006-\$169; 2005-\$132)	234	199
Inventories	1,063	703
Prepaid expenses and other current assets	300	268
Total current assets	4,905	4,386
Long-term marketable debt and equity securities	1,787	1,449
Property, plant and equipment, net	4,047	3,349
Goodwill	1,315	1,315
Other intangible assets	499	574
Restricted cash and investments	788	735
Other long-term assets	511	339
<b>Total assets</b>	<b>\$ 13,852</b>	<b>\$ 12,147</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable (including amounts to related parties: 2006-\$21; 2005-\$1)	\$ 279	\$ 339
Deferred revenue	42	44
Taxes payable	90	62
Other accrued liabilities (including amounts to related parties: 2006-\$164; 2005-\$132)	1,394	1,215
Total current liabilities	1,805	1,660
Long-term debt	2,164	2,083
Deferred revenue	209	220
Litigation-related and other long-term liabilities	784	714
Total liabilities	4,962	4,677
Commitments and contingencies		
Stockholders' equity		
Common stock	21	21
Additional paid-in capital	9,881	9,263
Accumulated other comprehensive income	210	253
Accumulated deficit, since June 30, 1999	(1,222)	(2,067)
Total stockholders' equity	8,890	7,470
<b>Total liabilities and stockholders' equity</b>	<b>\$ 13,852</b>	<b>\$ 12,147</b>



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

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

***Basis of Presentation***

We prepared the Condensed Consolidated Financial Statements following the requirements of the Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by accounting principles generally accepted in the United States of America (or "GAAP") can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Consolidated Financial Statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2005. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of our financial position and operating results.

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

***Principles of Consolidation***

The Condensed Consolidated Financial Statements include the accounts of Genentech and all wholly owned subsidiaries. Material intercompany accounts and transactions have been eliminated.

***Use of Estimates and Reclassifications***

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

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

***Revenue Recognition***

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenue arrangements which 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.

- We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated rebates, healthcare provider contractual chargebacks, prompt pay sales discounts, product returns, wholesaler inventory management incentives, and bad debts. In our domestic commercial collaboration agreements,

we have primary responsibility for the United States (or “U.S.”) product sales commercialization efforts, including selling and marketing, customer service, order entry, distribution, shipping and billing. We record net product sales and related production and selling cost in our income statement line items on a gross basis since we have the manufacturing risk and/or inventory risk, and credit risk, and meet the criteria as a principal under Emerging Issues Task Force (or “EITF”) Issue No. 99-19, “*Reporting Revenue Gross as a Principal Versus Net as an Agent*” (or “EITF 99-19”).

- We recognize revenue from royalties based on licensees' sales of our products or technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectibility is reasonably assured. For the majority of our royalty revenues, estimates are made using historical and forecasted sales trends and used as a basis to record amounts in advance of amounts collected.
- Contract revenue generally includes upfront and continuing licensing fees, manufacturing fees, milestone payments and net reimbursements from collaborators on development, post-marketing and commercial costs. Most of our contract arrangements with up-front license fees were entered into prior to the effective date of July 1, 2003 for EITF Issue No. 00-21 "*Revenue Arrangements with Multiple Deliverables*" (or "EITF 00-21"). Accordingly, our accounting policy on contract revenue, as described below, is focused on describing transactions entered into prior to the effective date of EITF 00-21.
- Nonrefundable upfront fees, including product opt-ins, for which no further performance obligations exist, are recognized as revenue on the earlier of when payments are received or collection is assured.
- Nonrefundable upfront licensing fees, including product opt-ins, and certain guaranteed, time-based payments that require our continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue:
  - ratably over the development period if development risk is significant, or
- ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.
- Upfront manufacturing fees are recognized as revenue as the related manufacturing services are rendered, generally on a straight-line basis over the performance period of the longer of the manufacturing obligation period or the expected product life. Manufacturing profit is recognized when the product is shipped and title passes.
- Fees associated with substantive milestones, which are contingent upon future events for which there is reasonable uncertainty as to their achievement at the time the agreement was entered into, are recognized as revenue when these milestones, as defined in the contract, are achieved.
- Multiple element agreements, or amendments to such agreements, entered into after July 1, 2003, are evaluated under the provisions of EITF 00-21. We evaluate whether there is stand-alone value for the delivered elements and objective evidence of fair value to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), we recognize the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement.
- Commercial collaborations resulting in a net reimbursement of development, post-marketing and commercial costs are recognized as revenue as the related costs are incurred. The corresponding development and post-marketing expenses are included in research and development (or "R&D") expenses and the corresponding commercial costs are included in marketing, general and administrative expenses in the Condensed Consolidated Statements of Income.

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

Revenues from product sales are recorded net of allowances for estimated rebates, healthcare provider contractual chargebacks, prompt pay sales discounts, product returns, wholesaler inventory management allowances, and bad debts, all of which are established at the time of sale. These allowances are based on estimates of the amounts earned

or to be claimed on the related sales. These estimates take into consideration our historical experience,

-7-

---

current contractual and statutory requirements, specific known market events and trends such as competitive pricing and new product introductions, and forecasted customer buying patterns and inventory levels, including the shelf lives of our products. Rebates, healthcare provider contractual chargebacks, prompt pay sales discounts and product returns are product-specific, which can be affected by the mix of products sold in any given period. All our product sales allowances are based on estimates. If actual future results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment. Our product sales allowances and accruals are as follows:

- Rebate allowances and accruals are comprised of both direct and indirect rebates. Direct rebates are contractual price adjustments payable 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 and group purchasing organizations that do not purchase products directly from us. Both types of allowances are based upon definitive contractual agreements or legal requirements (such as Medicaid) related to the dispensing of the product by a pharmacy, clinic or hospital to a benefit plan participant. Rebate accruals are recorded in the same period the related revenue is recognized resulting in a reduction to product sales revenue and the recognition of a contra asset (if due to a wholesaler or specialty pharmacy) or a liability (if due to a third party, such as a healthcare provider) as appropriate, which are included in accounts receivable allowances or other accrued liabilities, respectively. Rebates are estimated using historical and other data, including patient usage, customer buying patterns, applicable contractual rebate rates and contract performance by the benefit providers. Rebate estimates are evaluated quarterly and may require adjustments 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 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.
- Healthcare provider contractual chargebacks are the result of contractual commitments by us to provide products to healthcare providers at specified prices or discounts. These contracted health care providers include (i) hospitals that service a disproportionately high share of economically indigent and Medicaid patients for which they receive little or no reimbursement (i.e. Disproportionate Share Hospitals or “DSH”), (ii) government-owned hospitals that receive discounts, and (iii) hospitals that have contract pricing for certain products usually by way of a group purchasing agreement. Chargebacks occur when a contracted health care provider purchases our products through an intermediary wholesaler at fixed contract prices that are lower than the list prices we charge the wholesalers. The wholesaler, in turn, charges us back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the healthcare providers. Chargebacks are accrued at the time of sale and are estimated based on historical trends, which closely approximate actual results as we generally issue credits within a few weeks of the time of sale.
- Prompt pay sales discounts are credits granted to wholesalers for remitting payment on their purchases within contractually defined cash repayment incentive periods. The contractually defined cash repayment periods are generally 30 days; however, for newly launched products, we have offered and we may offer in the future, for a limited period of time, extended payment terms to wholesalers. In connection with the launch of Lucentis we have offered an extended payment terms program to certain of our wholesalers. This program will be in effect for 12 months ending June 30, 2007. Based upon our experience that it is rare that a wholesaler does not comply with the contractual terms to earn the prompt pay sales discount, we accrue, at the time of original sale 100% of the prompt pay discounts related to the sale.

- Wholesaler inventory management allowances are credits granted to wholesalers for compliance with various contractually-defined inventory management programs. These programs provide monetary incentives in the form of a credit for wholesalers to maintain consistent inventory levels at approximately two to three weeks of sales depending on the product. These wholesaler inventory management credits are calculated based on quarterly product purchases multiplied by a factor to determine the maximum possible credit for a product for the preceding quarter. Adjustments to reduce the maximum credit are made if the wholesaler does not meet and/or comply with the contractually defined metrics. These metrics include data timeliness, completeness and accuracy and deviations outside of the contracted inventory days on hand for each product. The maximum credits are accrued at the time of sale, and are typically granted to wholesaler accounts within 90 days after the sale.
- Product returns allowances are established in accordance with our returns policy, which allows buyers to return our products within two months prior to and six months following product expiration. Most of our products are sold to our wholesalers with at least six months of dating prior to expiration. As part of our estimation process, we calculate historical return data on a production lot basis. Historical rates of return are determined by product and are adjusted for known or expected changes in the marketplace specific to each product. In addition, we review expiration dates to determine the remaining shelf life of each product not yet returned. Although product return allowances are accrued at the time of sale, the majority of returns take place up to two years after the sale.
- Bad debt allowances are based on our estimated uncollectible accounts receivable. Given our historical experience with bad debts, combined with our credit management policies and practices, we do not presently maintain significant bad debt allowances.

Allowances against receivable balances primarily relate to product returns, wholesaler-related direct rebates, prompt pay sales discounts, wholesaler inventory management allowances, and bad debts, and are recorded in the same period the related revenue is recognized, resulting in a reduction to product sales revenue and the reporting of product sales receivable net of allowances. Accruals related to indirect rebates and contractual chargebacks for healthcare providers are recognized in the same period the related revenue is recognized, resulting in a reduction to product sales revenue, and are recorded as other accrued liabilities.

### ***Commercial Collaboration Accounting***

We have domestic commercial collaboration profit sharing agreements with Biogen Idec Inc. on Rituxan, Novartis Pharma AG on Xolair, and with OSI Pharmaceuticals, Inc. on Tarceva. In these agreements, we have primary responsibility for the U.S. commercialization including sales and/or marketing, customer support, order entry, distribution, shipping and billing. In addition to being primarily responsible for providing the product or service to the customer, we have general inventory risk prior to the customer placing an order or upon customer return and we are exposed to customer credit risk. We record net product sales and related production and selling costs for our domestic collaborations in our consolidated income statements on a gross basis since we are the principal in the sales transaction, as defined under EITF 99-19. The collaboration profit sharing expense line in our consolidated income statements primarily includes the profit sharing results with Biogen Idec on Rituxan, with Novartis Pharma AG on Xolair, and with OSI Pharmaceuticals on Tarceva.

We have a European commercial collaboration profit sharing agreement with Novartis Pharma AG on Xolair. We do not record the net product sales and related production and selling costs for our European collaboration in our consolidated income statements on a gross basis since we do not meet the criteria as a principal under EITF 99-19, and instead record our net share of the European collaboration profits as contract revenue (or collaboration losses as collaboration profit sharing expense). See also Note 5, "Relationship with Roche and Related Party Transactions," regarding Novartis related collaboration cost and profit sharing expenses.





**Recent Accounting Pronouncements**

On June 28, 2006, the Financial Accounting Standards Board (or "FASB") ratified the consensus reached by the EITF on EITF Issue No. 06-2, "Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43, Accounting for Compensated Absences" (or "EITF 06-2"). EITF 06-2 states that if all the conditions of paragraph 6 of FASB 43 are met, compensation costs for sabbatical and other similar benefit arrangements should be accrued over the requisite service period. Paragraph 6 of FASB 43 states that a liability should be accrued for employees' future absences if the following are met: (a) the employer's obligation is attributable to employees' services already rendered; (b) the obligation relates to rights that vest or accumulate; (c) payment of the compensation is probable; and (d) the amount can be reasonably estimated. EITF 06-2 is effective for fiscal years beginning after December 15, 2006. Upon adoption of EITF 06-2, we expect to record a one-time charge as a cumulative effect of a change in accounting principle that will reduce diluted net income per share by approximately \$0.02 to \$0.03 per share. We will also begin to record an annual sabbatical expense that will reduce diluted net income per share by approximately \$0.01 to \$0.02 per share in 2007.

In June 2006, the FASB issued FASB Interpretation (or "FIN") No. 48, "Accounting for Uncertainty in Income Taxes." FIN 48 clarifies the application of FASB Statement 109, "Accounting for Income Taxes," by defining criterion that must be met for any part of a benefit related to an individual tax position taken or expected to be taken in an enterprise's tax returns to be recognized in its consolidated financial statements. FIN 48 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition and is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the effect that the adoption of FIN 48 will have on our consolidated results of operations and financial position, but we do not expect the effect to be material.

**Earnings Per Share**

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

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

	<b>Three Months</b>		<b>Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>Numerator:</b>				
Net income	\$ 568	\$ 359	\$ 1,519	\$ 940
<b>Denominator:</b>				
Weighted-average shares outstanding used to compute basic EPS	1,053	1,061	1,053	1,055
Effect of dilutive stock options	19	26	21	26
Weighted-average shares outstanding and dilutive securities used to compute diluted EPS	1,072	1,087	1,074	1,081

Outstanding employee stock options to purchase approximately 22 million and 20 million shares of our Common Stock in the third quarter and first nine months of 2006, respectively, were excluded from the computation of diluted EPS because the effect would have been anti-dilutive.

***Comprehensive Income***

Comprehensive income is comprised of net income and other comprehensive income (or “OCI”). OCI includes certain changes in stockholders’ equity that are excluded from net income. Specifically, OCI includes changes in the estimated fair value of derivatives designated as effective cash flow hedges and unrealized gains and losses on our available-for-sale securities.

-10-

---

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

	September 30, 2006	December 31, 2005
Net unrealized gains on securities available-for-sale	\$ 206	\$ 230
Net unrealized gains on cash flow hedges	4	23
Accumulated other comprehensive income, net of income taxes	\$ 210	\$ 253

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net income	\$ 568	\$ 359	\$ 1,519	\$ 940
Increase (decrease) in unrealized gains on securities available-for-sale	16	(12)	(24)	(67)
Increase (decrease) in unrealized gains on cash flow hedges	1	(1)	(19)	35
Comprehensive income, net of income taxes	\$ 585	\$ 346	\$ 1,476	\$ 908

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

At September 30, 2006, estimated net gains on cash flow hedge derivative instruments, consisting of foreign currency exchange options and marketable equity collars, expected to be reclassified from accumulated OCI to “other income, net” during the next twelve months are \$7 million.

#### ***401(k) Plan***

Our 401(k) Plan (or “the Plan”) covers substantially all of our employees. We match a portion of employee contributions, up to a maximum of 5% of each employee’s eligible compensation. Historically, the match was effective December 31 of each year and fully vested when made. Effective October 1, 2006, the match will be funded concurrently with a participant’s semi-monthly contribution to the Plan. Additionally, we annually contribute to every employee’s account 1% of his or her eligible compensation, regardless of whether the employee actively participates in the Plan. In the third quarter of 2006, we increased the contribution to 2% of the employee’s compensation, beginning with the 2006 annual contribution, and the retroactive increase for 2006 was not material.

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

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), “*Share-Based Payment*” (or “FAS 123R”), which supersedes our previous accounting under APB Opinion No. 25, “*Accounting for Stock Issued to Employees*” (or “APB 25”). FAS 123R requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options and stock issued under our employee stock plans. FAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our Condensed Consolidated Statements of Income. Also, certain of these costs are capitalized into inventory on our Condensed Consolidated Balance Sheets, and generally will be recognized as an expense when the related products are estimated to be sold. We

adopted FAS 123R using the modified prospective transition method, which requires that compensation expense be recognized in the financial statements for all awards granted after the date of adoption as well as for existing awards for which the requisite service has not been rendered as of the date of adoption. The modified prospective transition method does not require restatement of prior periods to reflect the effect of FAS 123R.

In November 2005, the FASB issued FASB Staff Position No. 123R-3, "*Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards.*" We have adopted the simplified method to calculate the beginning balance of the additional paid-in-capital (or "APIC") pool of the excess tax benefit, and to determine the

subsequent effect on the APIC pool and Condensed Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that were outstanding upon our adoption of FAS 123R.

Prior to the adoption of FAS 123R, we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under FAS No. 123, “*Accounting for Stock-Based Compensation*” (or “FAS 123”). Under the intrinsic value method, no employee stock-based compensation expense had been recognized in our Condensed Consolidated Statements of Income for any period prior to our adoption of FAS 123R on January 1, 2006, as the exercise price of the stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

### ***Employee Stock Plans***

We currently have an employee stock purchase plan, adopted in 1991 and amended thereafter (or “the 1991 Plan”). The 1991 Plan allows eligible employees to purchase Common Stock at 85% of the lower of the fair market value of the Common Stock on the grant date or the fair market value on the purchase date. The offering period under the 1991 Plan is currently 15 months, and the purchase price is established during each new offering period. Purchases are limited to 15% of each employee’s eligible compensation and subject to certain Internal Revenue Service restrictions. In general, all of our full-time employees are eligible to participate in the 1991 Plan. Of the 52,400,000 shares of Common Stock reserved for issuance under the 1991 Plan, 46,714,541 shares have been issued as of September 30, 2006.

We currently grant options under the Genentech, Inc. 2004 Equity Incentive Plan, which allows for the granting of non-qualified stock options, incentive stock options and stock appreciation rights, restricted stock, performance units or performance shares to our employees, directors and consultants. Incentive stock options may only be granted to employees under this plan. Generally, stock options granted to employees have a maximum term of 10 years, and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. We may grant options with different vesting terms from time to time. When an employee over the age of 65 retires, the portion of the option that would have vested in the 12 month period following the retirement date, if the retiree had remained an employee, automatically becomes fully vested. The expiration date of the exercisable portion of the option remains the original expiration date at the time the option was granted. Unless an employee’s termination of service is due to retirement, disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of three months or the expiration of the option, whichever is earlier.

### ***Adoption of FAS 123R***

Employee stock-based compensation expense recognized in the three and nine month periods ended September 30, 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

	<b>Three Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2006</b>
Research and development	\$ 35	\$ 101
Marketing, general and administrative	41	124

Edgar Filing: GENENTECH INC - Form 10-Q

Total employee stock-based compensation expense		76		225
Tax benefit related to employee stock-based compensation expense		(30)		(84)
Net effect on net income	\$	46	\$	141
Effect on earnings per share:				
Basic	\$	0.04	\$	0.13
Diluted	\$	0.04	\$	0.13

-12-

---

As of September 30, 2006, total compensation cost related to unvested stock options not yet recognized was \$925 million, which is expected to be allocated to expense and production costs over a weighted-average period of 31 months.

The carrying value of inventory on our Condensed Consolidated Balance Sheet as of September 30, 2006 includes employee stock-based compensation costs of \$49 million. Substantially all of the products sold in 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. As early as the first quarter of 2007, when product manufactured after the adoption of FAS 123R is estimated to be sold or written off, or reserves are required for obsolescence or lack of demand, we will begin to recognize employee stock-based compensation expense in cost of sales (or "COS").

The following pro forma net income and EPS were determined as if we had accounted for employee stock-based compensation for our employee stock plans under the fair value method prescribed by FAS 123 in prior periods and had capitalized certain costs into inventory manufactured in those prior periods, with the resulting effect on COS for the quarter and nine months ended September 30, 2006 when previously manufactured products were sold. *(In millions, except for per share data):*

	<b>Three Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2006</b>
Net income as reported	\$ 568	\$ 1,519
Deduct: Total employee stock-based compensation expense includable in cost of sales, net of related tax effects	(8)	(24)
Pro forma net income	\$ 560	\$ 1,495
Earnings per share:		
Basic-as reported	\$ 0.54	\$ 1.44
Basic-pro forma	\$ 0.53	\$ 1.42
Diluted-as reported	\$ 0.53	\$ 1.41
Diluted-pro forma	\$ 0.52	\$ 1.39

***Pro Forma Information for Periods Prior to Adoption of FAS 123R***

The following pro forma net income and EPS were determined as if we had accounted for employee stock-based compensation for our employee stock plans under the fair value method prescribed by FAS 123. *(In millions, except for per share data):*

	<b>Three Months Ended September 30, 2005</b>	<b>Nine Months Ended September 30, 2005</b>
Net income as reported	\$ 359	\$ 940
Deduct: Total employee stock-based compensation expense determined under the fair value based method for all awards, net of related tax effects	(43)	(126)
Pro forma net income	\$ 316	\$ 814
Earnings per share:		
Basic-as reported	\$ 0.34	\$ 0.89
Basic-pro forma	\$ 0.30	\$ 0.77



Edgar Filing: GENENTECH INC - Form 10-Q

Diluted-as reported	\$	0.33	\$	0.87
Diluted-pro forma	\$	0.29	\$	0.75

-13-

---

**Valuation Assumptions**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Risk-free interest rate	4.6%	4.2%	4.6%	4.2%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	27%	29%	27%	29%
Expected term (years)	4.6	4.2	4.6	4.2

Due to the redemption of our Special Common Stock in June 1999 by Roche, there is limited historical information available to support our estimate of certain assumptions required to value our employee stock options. 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 volatilities of comparable companies.

**Stock Option Activity**

The following is a summary of option activity for the first nine months of 2006 (*shares in millions*):

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted- Average Exercise Price
<b>December 31, 2005</b>	84	83	\$ 46.64
Grants	(17)	17	79.75
Exercises	-	(7)	30.17
Cancellations	2	(2)	60.42
<b>September 30, 2006</b>	69	91	\$ 53.80

The intrinsic value of options exercised during the third quarters of 2006 and 2005 was \$135 million and \$366 million, respectively, and was \$368 million and \$1,135 million in the first nine months of 2006 and 2005, respectively. The estimated fair value of shares vested during the third quarters of 2006 and 2005 was \$92 million and \$68 million, respectively, and was \$274 million and \$199 million in the first nine months of 2006 and 2005, respectively. The weighted-average estimated fair value of stock options granted during the third quarters of 2006 and 2005 was \$24.77 and \$26.01 per option, respectively, and was \$24.92 and \$25.43 per option for the first nine months of 2006 and 2005, respectively, based on the assumptions in the Black-Scholes valuation model discussed above.

The following table summarizes outstanding and exercisable options at September 30, 2006 (*in millions, except exercise price data*):

Range of Exercise Prices	Number of Shares Outstanding	Options Outstanding		Number of Shares Outstanding	Options Exercisable	
		Weighted-Average Contractual Life (in years)	Weighted-Average Exercise Price		Weighted-Average Contractual Life (in years)	Weighted-Average Exercise Price
\$6.27 - \$8.89	0.5	5.15	\$7.66	0.5	5.16	\$7.66
\$10.00 - \$14.35	12.0	5.14	\$13.70	12.0	5.15	\$13.70
\$15.04 - \$22.39	8.2	4.59	\$20.84	8.1	4.57	\$20.87
\$22.88 - \$33.00	0.3	4.72	\$26.66	0.3	4.72	\$26.66
\$35.63 - \$53.23	34.0	7.03	\$46.83	20.5	6.62	\$45.24
\$53.95 - \$75.90	1.4	8.03	\$59.22	0.7	7.97	\$58.30
\$78.99 - \$98.80	34.6	9.44	\$82.95	4.3	8.97	\$85.81
	91.0			46.4		

At September 30, 2006, the aggregate intrinsic value of the outstanding options was \$2,693 million and the aggregate intrinsic value of the exercisable options was \$2,161 million.

### ***Stock Repurchase Program***

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2006, we are authorized to repurchase up to 100 million shares of our Common Stock for an aggregate amount of up to \$6.0 billion through June 30, 2007. During the first nine months of 2006, we repurchased approximately nine million shares at an aggregate cost of \$758 million. Since the program's inception, we have repurchased approximately 59 million shares at a total price of \$4.1 billion. We intend to use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock plans and also to maintain Roche's minimum percentage ownership interest in our stock. See Note 5, "Relationship with Roche and Related Party Transactions," for further discussion about Roche's minimum percentage ownership interest in our stock.

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

#### ***Inventories***

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

	September 30, 2006	December 31, 2005
Raw materials and supplies	\$ 107	\$ 79
Work in process	712	438

Finished goods		244		186
Total	\$	1,063	\$	703

The increase in work in process in the first nine months of 2006 was primarily due to bulk production of our Avastin, Herceptin and Activase products. Included in work in process at September 30, 2006 is approximately \$63 million of Avastin and Rituxan inventories that were manufactured at facilities or through manufacturing processes awaiting regulatory licensure. As of September 30, 2006, approximately \$49 million in employee stock-based compensation costs were capitalized in inventory pursuant to FAS 123R.

#### Note 4. Contingencies

We are a party to various legal proceedings, including patent infringement litigation. We are also a party to various 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: (1) the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, (2) the first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens (approved on February 10, 2006), (3) the first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with cyclophosphamide, vincristine, prednisone (or "CVP") chemotherapy (approved September 29, 2006), (4) the treatment of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy (approved on September 29, 2006), and (5) for use in combination with methotrexate to reduce signs and symptoms in adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies (approved on February 28, 2006). We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. The government has called and is expected to call former and current Genentech employees to appear before a grand jury in connection with this investigation. The outcome of this matter cannot be determined at this time.

On July 29, 2005, a former Genentech employee, whose employment ended in April 2005, filed a qui tam complaint under seal in the United States District Court for the District of Maine against Genentech and Biogen Idec, alleging violations of the False Claims Act and retaliatory discharge of employment. On December 20, 2005, the United States filed notice of its election to decline intervention in the lawsuit. The complaint was subsequently unsealed and we were served on January 5, 2006. The outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (or "COH") are parties to a 1976 agreement relating to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, we have entered into license agreements with various companies to make, use and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the COH filed a complaint against us in the Superior Court in Los Angeles County, California, alleging that we owe royalties to the COH in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. On June 10, 2002, a jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, a jury voted to award the COH an additional \$200 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and are included in the accompanying Condensed Consolidated Balance Sheets in "litigation-related and other long-term liabilities" at September 30, 2006 and December 31, 2005. 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, however, it may take longer than one year to further resolve the matter.

We recorded accrued interest and bond costs of \$13 million in the third quarter of 2006 and \$14 million in the third quarter of 2005, and \$40 million in the first nine months of 2006 and \$41 million in the first nine months of 2005

related to the COH trial judgment. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of \$735 million at December 31, 2005 to secure the bond. During the third quarter of 2006, COH requested that we increase the surety bond value by \$50 million to secure the accruing interest, and we correspondingly increased the pledge amount to secure the bond by \$53 million to \$788 million. These amounts are reflected in “restricted cash and investments” in the accompanying Condensed Consolidated Balance

-16-

---

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. (or “MedImmune”) filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 (or “the ‘415 patent” or “Cabilly patent”) that we co-own with COH and under which MedImmune and other companies have been licensed and are paying royalties to us. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking a ruling that the ‘415 patent is invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the ‘415 patent on sales of its Synagis® antibody product, an injunction to prevent us from enforcing the ‘415 patent, an award of actual and exemplary damages, and other relief. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in our favor on all of MedImmune’s antitrust and unfair competition claims. On April 23, 2004, the District Court granted our motion to dismiss all remaining claims in the case. On October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. MedImmune filed a petition for certiorari with the United States Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune’s petition and the oral argument of this case before the Supreme Court occurred on October 4, 2006. We expect a decision by the Supreme Court no later than June 2007. The outcome of this matter cannot be determined at this time.

On May 13, 2005, a request was filed by a third party for reexamination of the ‘415 or Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent Office ordered reexamination of the ‘415 patent. On September 13, 2005, the Patent Office issued an initial “non-final” Office action rejecting the claims of the ‘415 patent. We filed our response to the Office action on November 25, 2005. On December 23, 2005, a second request for reexamination of the ‘415 patent was filed by another third party, and on January 23, 2006, the Patent Office granted that request. On June 6, 2006, the two reexaminations were merged into one proceeding. On August 16, 2006, the Patent Office issued a non-final Office action in the merged proceeding, rejecting the claims of the ‘415 patent based on issues raised in the two reexamination requests. We filed our response to the Office action on October 30, 2006. The Patent Office has not yet acted on this response. The ‘415 patent, which expires in 2018, relates to methods we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. We have licensed the ‘415 patent to other companies and derive significant royalties from those licenses. The claims of the ‘415 patent remain valid and enforceable throughout the reexamination process. Because the above-described reexamination proceeding is ongoing, the outcome of this matter cannot be determined at this time.

In 2006, we have made development decisions involving our humanized anti-CD20 program. Our collaborator Biogen Idec disagrees with certain of our development decisions and our decision-making rights under our 2003 collaboration agreement with Biogen Idec relating to humanized anti-CD20 products. We believe Genentech is permitted under the agreement to proceed with further trials of certain humanized anti-CD20 antibodies, and Biogen Idec disagrees with our position. We continue to pursue a resolution of our differences with Biogen Idec, and the disputed issues have been submitted to arbitration. Resolution of the arbitration could require that both parties agree on certain development decisions before moving forward with humanized anti-CD20 molecule trials, in which case we may have to alter or cancel planned trials in order to obtain Biogen Idec’s approval. The final outcome of this matter cannot be determined at this time.

On March 24, 2004, Dr. Kourosh Dastgheib filed a lawsuit against Genentech in the U.S. District Court for the Eastern District of Pennsylvania. The lawsuit stems from Dastgheib’s claim that, based on a purported relationship with Genentech in the mid-1990’s, he is entitled to profits or proceeds from Genentech’s Lucentis product. Dastgheib has asserted multiple claims for monetary damages, including a claim under an unjust enrichment theory that he is entitled to the entire net present value of projected Lucentis sales, which he claims is between approximately \$1.4

billion and \$4.1 billion. Genentech denies that he is entitled to any such damages. Trial of this matter began on October 19, 2006 and is ongoing. Because the litigation proceedings are ongoing, the outcome of this matter cannot be determined at this time.

-17-

---



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

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

We issue additional shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that with respect to any issuance of our Common Stock in the future, we will repurchase a sufficient number of shares so that immediately after such issuance, the percentage of our Common Stock owned by Roche will be no lower than 2% below the "Minimum Percentage" (as defined below), provided however, as long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, we will repurchase a sufficient number of shares of our Common Stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The Minimum Percentage equals the lowest number of shares of our Common Stock owned by Roche since the July 1999 offering (adjusted for dispositions of shares of our Common Stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704, the number of shares of our Common Stock outstanding at the time of the July 1999 offering, as adjusted for stock splits. We have repurchased shares of our Common Stock since 2001. The affiliation agreement also provides that, upon Roche's request, we will repurchase shares of our Common Stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. The Minimum Percentage at September 30, 2006 was 57.7% and, under the terms of the affiliation agreement, Roche's ownership percentage is to be no lower than 55.7%. At September 30, 2006, Roche's ownership percentage was 55.8%.

### **Related Party Transactions**

We enter into transactions with our related parties, Roche and other Roche affiliates (including Hoffmann-La Roche) and Novartis AG and other Novartis affiliates (or "Novartis"), under existing agreements in the ordinary course of business. The accounting policies we apply to our transactions with our related parties are consistent with those we apply in transactions with independent third-parties.

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. In circumstances where we are the principal in the transaction, we record the transaction gross in accordance with EITF 99-19; otherwise, our transactions are recorded net.

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

Under our existing arrangements with Hoffmann-La Roche, including our licensing and marketing agreements, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$37 million and \$24 million in the third quarters of 2006 and 2005, respectively, and \$77 million and \$59 million in the first nine months of 2006 and 2005, respectively. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled \$315 million and \$181 million in the third quarters of 2006 and 2005, respectively, and \$819 million and \$471 million in the first nine months of 2006 and 2005, respectively. COS included amounts related to sales to Hoffmann-La Roche of \$59 million and \$45 million in the third quarters of 2006 and 2005, respectively, and \$173 million and \$119 million in the first nine months of 2006 and 2005, respectively. Our reported R&D expenses included \$58 million and \$43 million in the third quarters of 2006 and 2005, respectively, and \$158 million and \$117 million in the first nine months of 2006 and 2005, respectively, related to development activities undertaken on projects on which we collaborate with Hoffmann-La Roche.

In July 2006, we signed two new product supply agreements with F. Hoffmann-La Roche which supplement and supersede existing product supply agreements with F. Hoffmann-La Roche. Under a short-term supply agreement, F.

Hoffmann-La Roche has agreed to purchase specified amounts of Herceptin, Avastin and Rituxan through 2008. Under a longer-term supply agreement, F. Hoffmann-La Roche has agreed to purchase specified amounts of Herceptin and Avastin through 2012 and, on a perpetual basis, either party may order other collaboration products from the other party, including Herceptin and Avastin after 2012, pursuant to certain forecast terms. The longer-term

-18-

---

supply agreement also provides that either party may terminate its obligation to purchase and/or supply Avastin and/or Herceptin with six years notice on or after December 31, 2007.

### *Novartis*

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

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

We, along with Novartis Pharma AG and Tanox, Inc., are co-developing Xolair in the U.S. We and Novartis Pharmaceutical Corporation (a wholly-owned subsidiary of Novartis AG) are co-promoting Xolair in the U.S. and we both make certain joint and individual payments to Tanox; our joint and individual payments are in the form of royalties. We record all sales and COS in the U.S. and Novartis markets the product and records all sales and COS in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. On January 20, 2006, Novartis received FDA approval to manufacture bulk supply of Xolair at their Huningue production facility in France. We now acquire bulk supply of Xolair from Novartis and compensate them on a cost plus mark up basis.

Contract revenue from Novartis related to manufacturing, commercial and ongoing development activities was \$15 million and \$13 million in the third quarters of 2006 and 2005, respectively, and \$37 million and \$35 million in the first nine months of 2006 and 2005, respectively. Revenue from Novartis related to product sales was not material in the third quarters and the first nine months of 2006 and 2005. COS was not material in the third quarters of 2006 and 2005 and in the first nine months of 2006. COS was \$15 million in the first nine months of 2005, which included a one-time payment in the second quarter of 2005 related to our release from future manufacturing obligations. Our reported R&D expenses included \$35 million and \$12 million in the third quarters of 2006 and 2005, respectively, and \$80 million and \$33 million in the first nine months of 2006 and 2005, respectively, related to development activities undertaken on products on which we collaborate with Novartis. Collaboration profit sharing payments from us to Novartis were \$46 million and \$41 million in the third quarters of 2006 and 2005, respectively, and \$137 million and \$93 million in the first nine months of 2006 and 2005, respectively.

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

Our effective income tax rate was 37% in the third quarter of 2006 compared to 41% in the third quarter of 2005. Our tax rate in the third quarter of 2005 included the unfavorable effect of reducing our estimated R&D tax credits for 2005 and prior periods by approximately \$27 million. Our effective income tax rate was 38% in first nine months of 2006 compared to 35% in the first nine months of 2005. The increase in the income tax rate over the first nine months of 2005 reflects higher income before taxes and the December 31, 2005 expiration of the federal R&D tax credit. If legislation to extend the R&D tax credit is passed, we will record any tax benefit for R&D tax credits at that time.

**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, 2006, and the related condensed consolidated statements of income for the three-month and nine-month periods ended September 30, 2006 and 2005, and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2006 and 2005. 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 interim 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, 2005, 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 10, 2006, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2005, 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 6, 2006

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

### GENENTECH, INC. FINANCIAL REVIEW

#### Overview

##### *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 2006*

In the third quarter of 2006, our total operating revenues were \$2,384 million, an increase of 36% from \$1,752 million in the third quarter of 2005, and our net income was \$568 million, an increase of 58% from \$359 million in the third quarter of 2005. Product sales in the third quarter and first nine months of 2006 reflect sales of Lucentis, which were \$153 million in the third quarter and \$163 million since launch on June 30, 2006. In the first nine months of 2006, our total operating revenues were \$6,569 million, an increase of 39% from \$4,740 million in the first nine months of 2005, and our net income was \$1,519 million, an increase of 62% from \$940 million in the first nine months of 2005. Net income in 2006 includes the effect of stock-based compensation expense related to employee stock options and employee stock purchases under Statement of Financial Accounting Standards No. 123 (revised 2004), "*Share-Based Payment*" (or "FAS 123R"), which decreased our net income by \$46 million after taxes in the third quarter and \$141 million after taxes in the first nine months of 2006.

Significant milestones during the third quarter of 2006 were as follows:

*We received the following U.S. Food and Drug Administration (or "FDA") approvals:*

- Rituxan for the first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine, prednisone) chemotherapy;
- Rituxan for the treatment of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy; and
- Avastin for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer (or "NSCLC"), which was approved on October 11, 2006.

In September 2006, we received a Complete Response Letter from the FDA for the supplemental Biologics License Application (or "sBLA") for Avastin with chemotherapy in first-line metastatic breast cancer. The FDA has requested a substantial safety and efficacy update from the E2100 trial, including an independent review of patient scans for progression free survival, the study's primary endpoint. A new six-month review period will begin once the additional information is submitted to the FDA. Based on the scope of the FDA's request, we anticipate we will be able to resubmit the application to the FDA by mid-2007.

In August 2006, the FDA notified us that additional information requested during the review of the sBLA for Herceptin for the treatment of patients with early stage HER2-positive breast cancer was deemed a major amendment. The information requested, additional analyses of previously submitted studies, has already been provided to the agency. In accordance with FDA guidelines, the agency has extended the review period for the sBLA up to an additional 90 days beyond the August 17, 2006 action date.

In October 2006, we announced plans to initiate a program to cap the overall expense of Avastin to \$55,000 per year per eligible patient for any FDA-approved indication. The program will be available for eligible patients regardless of whether they are insured. Patient eligibility will be based on adjusted gross income and other criteria to be announced. We plan to launch the new program in January 2007. We are currently evaluating the effect of this program on our fourth quarter of 2006 and future operating results.

In the third quarter of 2006, the FDA approved the manufacture of bulk Herceptin at Wyeth's Andover, Massachusetts facility.

We recently made changes to our distribution model for Avastin, Herceptin and Rituxan and renegotiated our distribution agreements with a number of our major wholesalers. This resulted in a number of changes in our commercial terms, effective July 1, 2006. As part of these changes, the time at which we recognize products sales revenue for domestic product shipments changed from the time at which we ship our products to the time at which our products arrive at the designated receiving location. We do not believe these distribution changes had a material effect on third quarter 2006 sales. We do not expect the net effect of these changes to be material to our results of operations for the full year 2006.

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

Our business objectives for the years 2006 through 2010 include bringing at least 20 new molecules into clinical development, bringing at least 15 major new products or indications onto the market, becoming the number one U.S. oncology company in sales and achieving certain financial growth measures. These objectives are reflected in our revised Horizon 2010 strategy and goals summarized on our website at <http://www.gene.com>.

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

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

- Our long-term business growth, commercial performance and clinical success depend upon our ability to continue to 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 (or "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.
- We face significant competition in the diseases of interest to us from pharmaceutical companies, and biotechnology companies. The introduction of new competitive products or follow-on biologics, new information about existing products or pricing decisions made by us or our competitors may result in lost market share for us, reduced utilization of our products, and/or lower prices, even for products protected by patents.
- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection on one or more products could result in lost sales to competing products and may negatively affect our sales, royalty revenues and operating results. We are often involved in disputes over contracts and intellectual property and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.





- 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.
- As the Medicare and Medicaid programs are the largest payers for our products, rules relating to coverage and reimbursement continue to represent an important area of focus. New regulations relating to hospital and physician payment continue to be implemented annually. To date, we have not seen any detectable effects of the new rules on our product sales, and we anticipate minimal effects on our revenues in 2006.
- We believe our business model is only sustainable with appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. The pricing of our products has received negative press coverage and public scrutiny. We will continue to meet with patient groups, payers and other stakeholders in the healthcare system to understand their issues and concerns. However, the future reimbursement environment for our products is uncertain.
- 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. In keeping with our desire to maintain and protect our culture, we have continued our broad-based stock option program in 2006.

## Marketed Products

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

*Avastin* (bevacizumab) is an anti-VEGF humanized antibody approved for use in combination with intravenous 5-fluorouracil based chemotherapy as a treatment for patients with first- or second-line metastatic cancer of the colon or rectum. On October 11, 2006, it was also approved for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer.

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

- The treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin’s lymphoma, including retreatment and bulky disease;
- The first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy;
- The first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin’s lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisone) chemotherapy regimens;
- The treatment of patients with low-grade, CD20-positive, B-cell non-Hodgkin’s lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy; and

Use in combination with methotrexate for reducing signs and symptoms in adult patients with moderately-to-severely active rheumatoid arthritis (or “RA”) who have had an inadequate response to one or more tumor necrosis factor antagonist therapies.

*Herceptin* (trastuzumab) is a humanized anti-HER2 antibody approved for the treatment of certain patients with metastatic breast cancer. Herceptin is 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 metastatic breast cancer who have tumors that overexpress the human epidermal growth factor receptor 2 (or “HER2”) protein.

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

*Xolair* (omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis Pharma AG (or “Novartis”). Xolair is approved for the treatment of moderate-to-severe persistent allergic asthma in adults and adolescents 12 years and older whose asthmatic allergic reaction to perennial aeroallergen cannot be adequately controlled with the use of inhalers.

*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.

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

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

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

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

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

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

## **Licensed Products**

We receive royalties from F. Hoffmann-La Roche (or “Hoffmann-La Roche”) on sales of:

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



### **Available Information**

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

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;
- our policies related to corporate governance, including Genentech's Principles of Corporate Governance, Genentech's Good Operating Principles (Genentech's code of ethics applying to our directors, officers and employees) as well as Genentech's Code of Ethics applying to our CEO, CFO and senior financial officials and;
- the charter of the Audit Committee of our Board of Directors.

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

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

We believe the following policies to be critical to understanding our financial condition, results of operations, and our expectations for 2006 because these policies require management to make significant estimates, assumptions and judgments about matters that are inherently uncertain.

#### ***Contingencies***

We are currently and have been, involved in certain legal proceedings, including patent infringement litigation. We are also involved in licensing and contract disputes, and other matters. Refer to Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on these matters. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. We record an estimated loss as a charge to income if we determine that, based on information available at the time, the loss is probable and the amount of loss can be reasonably estimated. Included in "litigation-related and other long-term liabilities" in the accompanying Condensed Consolidated Balance Sheet at September 30, 2006 is \$714 million, which represents our estimate of the costs for the current resolution of these matters. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters different than previously estimated could have a material effect on our financial position or our results of operations in any one quarter.

#### ***Revenue Recognition***

In October 2006, we announced that we plan to initiate a program to cap the overall combined patient and insurer expense of Avastin to \$55,000 per treatment year per eligible patient for any FDA-approved indication. Beyond the point at which the cost cap has been achieved, we will provide free product to physicians for infusion. The program will be available for eligible patients regardless of whether they are insured. For accounting purposes, we expect to defer a portion of our Avastin product revenues based upon an estimate of the free Avastin we expect to provide to

-25-

---

patients under the program. In order to make our estimate of the amount of free Avastin to be provided to patients under the program, we will 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 participate 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. The duration of treatment is significantly influenced by our estimate of the duration of progression-free survival of patients being treated with Avastin. The assumptions underlying this deferred revenue accounting will be based on significant estimates. If actual results vary, we will need to make adjustments to these estimates, which could have an effect on earnings in the period of adjustment. We are currently evaluating the effect of this program on our consolidated financial statements.

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

Revenues from U.S. product sales are recorded net of allowances and accruals for rebates, healthcare provider contractual chargebacks, prompt pay sales discounts, product returns, wholesaler inventory management allowances, and bad debts, 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 total product sales allowances, have been relatively consistent at approximately 7-8% of gross sales. In order to prepare our Condensed Consolidated Financial Statements, we are required to make estimates regarding the amounts earned or to be claimed on the related product sales.

Definitions for the product sales allowance types are as follows:

- Rebate allowances and accruals are comprised of both direct and indirect rebates. Direct rebates are contractual price adjustments payable to 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 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 repayment 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;
- Healthcare provider contractual chargebacks are the result of contractual commitments by us to provide products to healthcare providers at specified prices or discounts; and
- Bad debt allowances are based on our estimated uncollectible accounts receivable.

We believe that our estimates related to product returns allowances, wholesaler inventory management payments, and bad debts are not material amounts, based upon the historical levels of credits and allowances as a percentage of product sales. We believe our estimates related to healthcare provider contractual chargebacks and prompt pay sales discounts do not have a high degree of estimation complexity or uncertainty as the related amounts are settled within a short period of time. We consider rebate allowances and accruals to be the only process that involves both material

amounts, and requires a higher degree of subjectivity and judgment necessary to account for the rebate allowances or accruals. As a result of the uncertainties involved in estimating rebate allowances and accruals, there is a likelihood that materially different amounts could be reported under different conditions or using different assumptions.



Our rebates are based upon definitive contractual agreements or legal requirements (such as Medicaid) after the final dispensing of the product by a pharmacy, clinic or hospital to a medical benefit plan participant. These rebates are primarily estimated using historical and other data, including patient usage, customer buying patterns, applicable contractual rebate rates and contract performance by the benefit providers. Direct rebates are accrued at the time of sale and recorded as allowances against trade accounts receivable; indirect (including Medicaid) rebates are accrued at the time of sale and recorded as liabilities. Rebate estimates are evaluated quarterly and may require changes to better align our estimates with actual results. As part of this evaluation, we review changes to Medicaid legislation, changes to State rebate contracts, changes in the level of discounts, and significant changes in product sales trends. Although rebates are accrued at the time of sale, rebates are typically paid out, on average, up to six months after the sale. We believe our rebate allowances and accruals estimation process provides a high degree of confidence in the amounts established and that the annual allowance amounts provided for would not vary by more than approximately 3% based on our estimate that our changes in rebate allowances and accruals estimates related to prior years have not exceeded 3%. To illustrate our sensitivity to changes in the rebate allowances and accruals process, as much as a 10% change in the rebate allowances and accruals provision we recognized in 2005 (which is in excess of three times the level of variability we have recently observed for rebates) would have an approximately \$13 million effect on our income before taxes (or less than  $\pm$ \$0.01 per share, after tax). The total rebate allowances and accruals recorded in our Condensed Consolidated Balance Sheets were \$53 million as of September 30, 2006 and \$50 million as of December 31, 2005.

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. However, it is possible that we may need to adjust our estimates in future periods. As of September 30, 2006, our Condensed Consolidated Balance Sheet reflected estimated product sales allowance reserves and accruals totaling approximately \$131 million and for the nine months ended September 30, 2006, our net product sales were approximately \$5,395 million.

### ***Royalties***

For substantially all of our agreements with licensees, we estimate royalty revenue and royalty receivables in the periods these royalties are earned, in advance of collection. Our estimate of royalty revenue and receivables in those instances is based upon communication with some licensees, historical information and forecasted sales trends. Differences between actual revenues and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. Historically, such adjustments have not been material to our condensed consolidated financial condition or results of operations.

### ***Income Taxes***

Income tax expense is based on income before taxes and is computed using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past and future levels of R&D spending, and changes in overall levels of income before taxes.

### ***Inventories***

Inventories consist of (i) currently marketed products, (ii) products manufactured under contract, and (iii) currently marketed products manufactured under a new process or at facilities awaiting regulatory approval, all of which are capitalized based on management's judgment of probable near term commercialization. In addition, inventories include employee stock-based compensation costs capitalized under FAS 123R. The valuation of inventory requires us to estimate the value of inventory that may become obsolete 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 judgment, due to, among other potential factors, a denial or delay of approval of a product or the licensure of either a manufacturing facility or a new manufacturing process by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable.

***Employee Stock-Based Compensation—Adoption of FAS 123R***

On January 1, 2006, we began accounting for employee stock-based compensation in accordance with FAS 123R. Under the provisions of FAS 123R, we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Due to the redemption of our Special Common Stock in June 1999 (or “Redemption”) by Roche Holdings, Inc. (or “Roche”), there is limited historical information available to support our estimate of certain assumptions required to value our stock options. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change.

Further, FAS 123R requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. Accordingly, we recognized employee stock-based compensation as part of our operating expenses and we allocated, in the third quarter of 2006, \$35 million to R&D, \$41 million to marketing, general and administrative (or “MG&A”), and we recognized a related tax benefit of \$30 million. In the first nine months of 2006, we allocated \$101 million to R&D, \$124 million to MG&A, and we recognized a related tax benefit of \$84 million. In addition, we capitalized \$49 million of employee stock-based compensation costs in inventory as a cost of production during the first nine months of 2006. We adopted FAS 123R on a modified prospective basis. Substantially all of the products sold in 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; therefore, we did not record any employee stock-based compensation expense as a component of cost of sales (or “COS”) during the first nine months of 2006. As early as the first quarter of 2007, when product manufactured after the adoption of FAS 123R is estimated to be sold or written off, or reserves are required for obsolescence or lack of demand, we will begin to recognize employee stock-based compensation expense in COS. The allocation of employee stock-based compensation costs to each operating expense line and to inventory are estimated based on specific employee headcount information at each grant date and revised, if necessary, in future periods if actual employee headcount information differs materially from those estimates. As a result, the amount of employee stock-based compensation costs we record in future periods in each operating expense line and capitalize in inventory may differ significantly from what we have recorded in the current period. As of September 30, 2006, total compensation cost related to unvested stock options not yet recognized was \$925 million, which is expected to be allocated to expense and production costs over a weighted-average period of 31 months. For the full year 2006, we expect employee stock-based compensation expense to be in the range of \$0.17 to \$0.18 per diluted share.

At this time, we do not include FAS 123 employee stock-based compensation as a reimbursable expense in our collaborations. Therefore, stock-based compensation expense has not affected contract revenue and collaboration profit sharing expense.

There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized under FAS 123R during the three- and nine-month periods ended September 30, 2005.



**Results of Operations***(In millions, except for per share data)*

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	% Change	2006	2005	% Change
Product sales	\$ 1,941	\$ 1,451	34%	\$ 5,395	\$ 3,911	38%
Royalties	364	238	53	966	670	44
Contract revenue	79	63	25	208	159	31
Total operating revenues	2,384	1,752	36	6,569	4,740	39
Cost of sales	297	236	26	843	766	10
Research and development	454	329	38	1,218	850	43
Marketing, general and administrative	501	343	46	1,414	1,006	41
Collaboration profit sharing	250	220	14	735	595	24
Recurring charges related to redemption	26	27	(4)	79	96	(18)
Special items: litigation-related	13	14	(7)	40	44	(9)
Total costs and expenses	1,541	1,169	32	4,329	3,357	29
Operating income	843	583	45	2,240	1,383	62
Other income (expense):						
Interest and other income, net	74	42	76	249	98	154
Interest expense	(19)	(20)	(5)	(56)	(27)	107
Total other income, net	55	22	150	193	71	172
Income before taxes	898	605	48	2,433	1,454	67
Income tax provision	330	246	34	914	514	78
Net income	\$ 568	\$ 359	58	\$ 1,519	\$ 940	62
Earnings per share:						
Basic	\$ 0.54	\$ 0.34	59	\$ 1.44	\$ 0.89	62
Diluted	\$ 0.53	\$ 0.33	61	\$ 1.41	\$ 0.87	62
Pretax operating margin	35%	33%		34%	29%	
Cost of sales as a % of product sales	15	16		16	20	
Research and development as a % of operating revenues	19	19		19	18	
Marketing, general and administrative as a % of operating revenues	21	20		22	21	
Net income as a % of operating revenues	24	20		23	20	

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

***Total Operating Revenues***

Total operating revenues increased 36% in the third quarter of 2006 and 39% in the first nine months of 2006 from the comparable periods in 2005. These increases were primarily due to higher product sales and royalty income, and are further discussed below.

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

	Three Months			Nine Months		
	Ended September 30, 2006	2005	% Change	Ended September 30, 2006	2005	% Change
Net U.S. Product Sales						
Avastin	\$ 435	\$ 325	34%	\$ 1,256	\$ 774	62%
Rituxan	509	456	12	1,511	1,347	12
Herceptin	302	215	40	912	497	84
Lucentis	153	-	-	163	-	-
Tarceva	100	73	37	296	191	55
Xolair	107	82	30	307	227	35
Raptiva	23	21	10	66	59	12
Nutropin products	92	89	3	277	276	0
Thrombolytics	60	58	3	181	160	13
Pulmozyme	50	47	6	146	137	7
Total U.S. product sales	1,830	1,365	34	5,116	3,668	39
Net product sales to collaborators	111	86	29	280	243	15
Total product sales	\$ 1,941	1,451	34	\$ 5,395	3,911	38

The values shown above are exact, which may lead to the appearance of footing errors.

Total product sales increased 34% to \$1,941 million in the third quarter and 38% to \$5,395 million in the first nine months of 2006 from the comparable periods in 2005. Total U.S. product sales increased 34% to \$1,830 million in the third quarter and 39% to \$5,116 million in the first nine months of 2006 from the comparable periods in 2005. The increases in U.S. product sales were due to higher sales across most products, in particular higher sales of our oncology products. Increased U.S. sales volume accounted for 89%, or \$415 million, of the increase in U.S. net product sales in the third quarter of 2006, and 89%, or \$1,286 million, of the increase in the first nine months of 2006. Changes in net U.S. sales prices across the portfolio accounted for most of the remaining increase in net U.S. product sales in the third quarter and first nine months of 2006.

*Avastin*

Net U.S. sales of Avastin increased 34% to \$435 million in the third quarter and 62% to \$1,256 million in the first nine months of 2006 from the comparable periods in 2005. The increases in sales were primarily a result of increased use of Avastin in metastatic NSCLC, approved on October 11, 2006, and metastatic breast cancer, an unapproved use of Avastin. In addition, the increases reflect modest gains in the treatment of metastatic colorectal cancer (or "CRC"), for which Avastin is approved in the first- and second-line; partially offset by declining revenues in metastatic renal cell carcinoma (or "RCC") and metastatic pancreatic cancer, both unapproved uses. Growth in the use of Avastin for the treatment of metastatic NSCLC was due to greater adoption rates and a larger number of physicians using Avastin during the third quarter and first nine months of 2006 as compared to the same periods in 2005. In first-line metastatic CRC patients, we estimate that Avastin penetration was over 66% during the third quarter of 2006 compared to 67% during the third quarter of 2005. Duration of treatment among patients in the first-line metastatic CRC setting who completed Avastin therapy increased slightly relative to the third quarter of 2005, but was flat compared to the first and second quarters of 2006. There were no price increases in 2006 or 2005.

In metastatic breast cancer, adoption has increased relative to last year; however, adoption has remained flat relative to the second quarter of 2006. Despite a U.S. Pharmacopeia Drug Information® compendia listing of Avastin in metastatic breast cancer, we believe physicians' concerns about reimbursement limit their adoption in this setting. As a result of products that have entered the market since the first quarter of 2006, we have seen a decline in the adoption of Avastin in metastatic RCC. Revenues from metastatic pancreatic cancer have also declined following our June 2006 announcement that we halted a Phase III trial of Avastin in combination with chemotherapy for the first-line treatment of advanced pancreatic cancer because of failure to meet the primary endpoint of overall survival.



We anticipate that a portion of Avastin growth for the remainder of 2006 may come from use in the treatment of metastatic NSCLC.

In September 2006, we received a Complete Response Letter from the FDA for an sBLA for Avastin with chemotherapy in first-line metastatic breast cancer. The FDA has requested a substantial safety and efficacy update from the E2100 trial, including an independent review of patient scans for progression free survival, the study's primary endpoint. A new six-month review period will begin once the additional information is submitted to the FDA. Based on the scope of the FDA's request, we anticipate we will be able to resubmit the application to the FDA by mid-2007.

#### *Rituxan*

Net U.S. sales of Rituxan increased 12% to \$509 million in the third quarter and to \$1,511 million in the first nine months of 2006 from the comparable periods in 2005. Net U.S. sales in the first nine months of 2005 included \$10 million for a reorder to replace a shipment that was destroyed while in transit to a wholesaler. The sales growth in 2006 relative to the comparable periods in 2005 resulted from increased use of Rituxan in rheumatoid arthritis and NHL, including areas of unapproved use, and chronic lymphocytic leukemia (or "CLL"), an unapproved use. We estimate that Rituxan's overall adoption rate in combined markets of non-Hodgkin's lymphoma, including areas of unapproved use, and CLL, also an unapproved use, was 82% at the end of the third quarter of 2006 compared to 80% at the end of the third quarter of 2005. Also contributing to the increases in product sales were price increases effective on July 6, 2005, October 5, 2005 and March 29, 2006.

Rituxan was approved for the treatment of adult patients with moderately-to-severely active RA in the first quarter of 2006. Our market research indicates approximately 10,000 RA patients have been treated with Rituxan so far this year, with about 70% of use coming after patients with RA have had an inadequate response to two or more anti-TNF therapies. There are significant hurdles to reliably measuring the portion of Rituxan sales attributable to RA and we do not expect to be able to precisely attribute revenues to the RA indication (or any other non-oncology indication) in the near term.

#### *Herceptin*

Net U.S. sales of Herceptin increased 40% to \$302 million in the third quarter and 84% to \$912 million in the first nine months of 2006 from the comparable periods in 2005. The increases in sales were primarily the result of increased use of Herceptin in the treatment of early stage HER2-positive breast cancer, an unapproved use, increased use in the treatment of first-line HER2-positive metastatic breast cancer, an approved indication, and increased cumulative duration of therapy relative to the comparable periods in 2005. While use in early stage breast cancer patients increased relative to the comparable period in 2005, we believe sales in this setting were flat compared to the second quarter of 2006. In first-line HER2-positive metastatic breast cancer patients, we estimate that Herceptin's penetration was 69% during the third quarter of 2006 compared to 64% during the third quarter of 2005. Also contributing to the increases in product sales, to a lesser extent, was a price increase effective on March 29, 2006.

#### *Lucentis*

We received FDA approval to market Lucentis for the treatment of neovascular (wet) age-related macular degeneration (or "AMD") on June 30, 2006, and we made initial product shipments of \$10 million to distributors on the day of approval. Net U.S. sales were \$153 million for the third quarter 2006, driven by high demand among existing AMD patients previously on other therapies and use by newly diagnosed patients. We estimate that approximately 80% of Lucentis patients were AMD patients previously on other therapies that were switched to Lucentis and the remaining 20% were newly diagnosed patients. Our market research indicates that at nine weeks post launch

approximately 50% of newly diagnosed and treated patients were treated with Lucentis. Continued sales growth will depend primarily on continued conversion of existing AMD patients from other therapies, increasing market share of newly diagnosed patients and the frequency of dosing of existing Lucentis patients by retinal specialists.

-31-

---

### *Tarceva*

Net U.S. sales of Tarceva increased 37% to \$100 million in the third quarter and 55% to \$296 million in the first nine months of 2006 from the comparable periods in 2005. The increases in product sales were primarily due to price increases effective on April 5, 2005 and November 9, 2005. Also affecting our product sales were growth in penetration in second-line NSCLC and first-line pancreatic cancer from the comparable periods in 2005; however, penetration in second-line NSCLC decreased slightly compared to the second quarter of 2006. In the first nine months of 2006, we estimate that Tarceva's penetration averaged 31% in second-line NSCLC and 41% in first-line pancreatic cancer. Future sales growth in NSCLC will depend on further gains in penetration against chemotherapy within second-line NSCLC, increased patient compliance, and increased duration of therapy.

### *Xolair*

Net U.S. sales of Xolair increased 30% to \$107 million in the third quarter and 35% to \$307 million in the first nine months of 2006 from the comparable periods in 2005. The sales growth was primarily driven by increased penetration in the asthma market and, to a lesser extent, price increases effective on July 21, 2005 and April 4, 2006.

### *Raptiva*

Net U.S. sales of Raptiva increased 10% to \$23 million in the third quarter and 12% to \$66 million in the first nine months of 2006 from the comparable periods in 2005. The increases in product sales were primarily due to price increases effective on April 21, 2005 and November 17, 2005.

### *Nutropin Products*

Combined net U.S. sales of our Nutropin products increased 3% to \$92 million in the third quarter of 2006 compared to the third quarter of 2005 and were \$277 million in the first nine months of 2006, essentially flat from the comparable period in 2005. The increases in product sales were due to a price increase effective on January 10, 2006. The increase in price was partially offset by a decrease in sales volume in 2006 from the comparable periods in 2005. This decrease was a result of declining new patient market share and the loss of managed care product placement due to price discounting by competitors.

### *Thrombolytics*

Combined net U.S. sales of our three thrombolytics products, Activase, Cathflo Activase, and TNKase, increased 3% to \$60 million in the third quarter and 13% to \$181 million in the first nine months of 2006 from the comparable periods in 2005. The increases were due to growth in Cathflo Activase sales in the catheter clearance market and increased Activase sales in the acute ischemic stroke market. Also contributing to the increases in product sales were price increases effective on February 14, 2006 and July 6, 2006.

### *Pulmozyme*

Net U.S. sales of Pulmozyme increased 6% to \$50 million in the third quarter and 7% to \$146 million in the first nine months of 2006 from the comparable periods in 2005, primarily reflecting a greater focus on aggressive treatment of cystic fibrosis early in the course of the disease and, to a lesser extent, a price increase effective on April 26, 2005.

### *Sales to Collaborators*

Product sales to collaborators, the majority of which were for non-U.S. markets, increased 29% to \$111 million in the third quarter and 15% to \$280 million in the first nine months of 2006 from the comparable periods in 2005. The increases were primarily due to higher sales of Herceptin to Hoffmann-La Roche.

For the full year 2006, given Roche's higher supply needs, we expect sales to collaborators to increase by approximately 40% over the \$326 million in 2005.

***Royalties***

Royalty revenues increased 53% to \$364 million in the third quarter and 44% to \$966 million in the first nine months of 2006 from the comparable periods in 2005. The increases were primarily due to higher sales by Hoffmann-La Roche of our Herceptin, Avastin and Rituxan products. Of the overall royalties received, royalties from Hoffmann-La Roche represented approximately 63% in the third quarter of 2006 and 62% in the first nine months of 2006 as compared to approximately 54% in the third quarter of 2005 and 51% in the first nine months of 2005. For the full year 2006, we expect royalties to increase by approximately 45% compared to \$641 million in 2005, based on higher sales forecasts from our licensees, in particular Roche.

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 and No. 4,816,567 (the “Cabilly patents”), under which we receive royalty revenue on sales of products that are covered by one or more of the Cabilly patents. The ‘567 patent expired in March 2006, while the ‘415 patent expires in December 2018. The licensed products for which we receive the most significant Cabilly royalties are Humira®, Remicade®, Synagis® and ERBITUX®. Cabilly royalties affect three lines on our Condensed Consolidated Statement of Income: (i) We record gross royalties we receive from Cabilly patent licensees as royalty revenue; (ii) On royalties we receive from Cabilly licensees, we in turn pay City of Hope National Medical Center (or “COH”) a percentage of our royalty income and these payments to COH are recorded with our MG&A expenses as royalty expense; (iii) We pay royalty expenses directly to COH on sales of our products that are covered by the Cabilly patents and these payments to COH are recorded in COS. The overall net after-tax contribution from revenues and expenses related to the Cabilly patents was approximately \$17 million in the third quarter of 2006, or approximately \$0.02 per diluted share, and \$47 million in the first nine months of 2006, or approximately \$0.04 per diluted share. We expect our full year 2006 Cabilly related net income after taxes to be approximately \$0.06 per diluted share. See also Note 4, “Contingencies” in the Notes to Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information on our Cabilly patent reexamination.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase foreign currency put option contracts (or “options”) and enter into foreign currency forward contracts to hedge these foreign currency cash flows. The terms of these options and forwards are generally one to three years. See also Note 1, “Summary of Significant Accounting Policies—Derivative Financial Instruments” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

***Contract Revenues***

Contract revenues increased 25% to \$79 million in the third quarter and 31% to \$208 million in the first nine months of 2006 from the comparable periods in 2005. The increase in the third quarter of 2006 was primarily due to increased revenues from Hoffmann-La Roche driven by higher reimbursements related to R&D development efforts on Avastin and receipt of a Herceptin milestone payment. The increase in the first nine months of 2006 was primarily due to higher contract revenues from Biogen Idec, driven by higher reimbursements related to R&D development efforts on Rituxan (immunology and hematology/oncology indications) and from Hoffmann-La Roche driven by higher reimbursements related to R&D development efforts on Avastin and receipt of a Herceptin milestone payment. See “Related Party Transactions” below for more information on contract revenue from Hoffmann-La Roche.

Contract revenues vary each quarter and are dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, the receipt of milestones and opt-in payments, and new contract arrangements. For the full year 2006, we expect contract revenues to increase slightly as compared to \$210 million in 2005.

***Cost of Sales***

COS as a percentage of product sales was 15% in the third quarter of 2006 compared to 16% in the third quarter of 2005 and 16% in the first nine months of 2006 compared to 20% in the first nine months of 2005. The decreases were primarily due to increased sales volume of our higher margin products (primarily Lucentis and oncology

-33-

---

products), and one-time charges of \$41 million in the second quarter of 2005 representing payments to Amgen Inc. and another collaborator to cancel and amend certain future manufacturing obligations.

For the full year 2006, we expect COS to be approximately 16% of net product sales, compared to 18% in 2005. We expect continued quarter-to-quarter variability based on product volume and mix changes, and there is always potential for an increase in COS if we have unforeseen manufacturing, contract manufacturing, or inventory-related issues.

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

R&D expenses increased 38% to \$454 million in the third quarter and 43% to \$1,218 million in the first nine months of 2006 from the comparable periods in 2005. The higher levels of expenses reflect increased activity across our entire product portfolio, including increased spending on late-stage clinical trials (notably Avastin and Rituxan Immunology) and early stage projects, higher research expenses due to increased headcount and headcount related expenses, higher in-licensing expense and higher clinical manufacturing expenses in support of our clinical trials. In-licensing expense in the third quarter of 2006 included new in-licensing collaborations with Inotek Pharmaceuticals Corporation to discover, develop, manufacture and commercialize inhibitors of poly (ADP-ribose) polymerase (or "PARP") for the potential treatment of cancer and CGI Pharmaceuticals to research, develop, manufacture, and commercialize therapeutics for the potential treatment of cancer and immunological disorders. In addition, R&D expenses included \$35 million in the third quarter and \$101 million in the first nine months of 2006 of employee stock-based compensation expense related to FAS 123R.

R&D as a percentage of operating revenues was 19% in the third quarters of 2006 and 2005 and 19% in the first nine months of 2006 compared to 18% in the first nine months of 2005. We expect R&D absolute dollar spending in 2006 to increase over 2005 levels due to planned in-licensing investments in the last quarter of 2006, continued investment in our late stage pipeline, and the addition of new internally-generated programs in the early stage pipeline.

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

<b><u>Research and Development</u></b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2006</b>	<b>2005</b>	<b>% Change</b>	<b>2006</b>	<b>2005</b>	<b>% Change</b>
Product development (including post marketing)	\$ 316	\$ 266	19%	\$ 900	\$ 652	38%
Research	83	51	63	232	160	45
In-licensing	55	12	358	86	38	126
Total R&D	\$ 454	\$ 329	38	\$ 1,218	\$ 850	43

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

MG&A expenses increased 46% to \$501 million in the third quarter and 41% to \$1,414 million in the first nine months of 2006 from the comparable periods in 2005. The increases were primarily due to: (i) an increase of \$52 million in the third quarter and \$182 million for the first nine months of 2006 in commercial spending primarily in support of launch activities related to Lucentis for AMD and Rituxan for RA and pre-launch activities related to Avastin for potential lung and breast cancer indications; (ii) \$41 million in the third quarter and \$124 million for the first nine months of 2006 of employee stock-based compensation expense related to FAS 123R; (iii) an increase of \$26 million in the third quarter and \$50 million for the first nine months of 2006 in charitable donations primarily related to the timing of co-pay assistance donations this quarter (initial co-pay donations were made in the fourth

quarter of 2005); and (iv) an increase of \$16 million in the third quarter and \$33 million in the first nine months of 2006 in support of our continued corporate growth and infrastructure needs, including headcount growth and the related growth in facilities and systems infrastructure, and higher legal costs.

MG&A as a percentage of operating revenues was 21% in the third quarter of 2006 as compared to 20% in the third quarter of 2005 and was 22% in the first nine months of 2006 compared to 21% in the first nine months of 2005. MG&A absolute dollar spending is expected to increase during the remainder of 2006 primarily driven by higher costs in support of recently launched products and anticipated launches of potential new product indications, and



continued support of our corporate growth and infrastructure needs, including headcount growth and the related growth in facilities and systems infrastructure, and also to support patient access programs.

### ***Collaboration Profit Sharing***

Collaboration profit sharing expenses increased 14% to \$250 million in the third quarter and 24% to \$735 million in the first nine months of 2006 from the same periods in 2005 primarily due to higher sales of Rituxan, Xolair and Tarceva and the related profit sharing expenses. For the full year 2006, our collaboration profit sharing expenses are expected to grow in proportion to our Rituxan, Xolair and Tarceva sales growth.

### ***Recurring Charges Related to Redemption***

We record recurring charges related to the June 1999 redemption of our Special Common Stock and push-down accounting (see discussion below in “Relationship with Roche—Redemption of Our Special Common Stock”). These charges were \$26 million in the third quarter of 2006 and \$27 million in the third quarter of 2005, and \$79 million in the first nine months of 2006 and \$96 million for the first nine months of 2005, and were comprised of the amortization of Redemption-related other intangible assets in the periods presented.

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

We recorded accrued interest and bond costs related to the COH trial judgment of \$13 million for the third quarter of 2006 and \$14 million in the third quarter of 2005, and \$40 million for the first nine months of 2006 and \$41 million for the first nine months of 2005. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter throughout the process of appealing the COH trial results. 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; however, we expect that it may take longer than one year to resolve this matter. Also included in this line are net amounts paid in the third quarter and first nine months of 2005 related to other litigation settlements. See Note 4, “Contingencies,” in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding our litigation.

### ***Operating Income***

Operating income was \$843 million in the third quarter of 2006, a 45% increase from the third quarter of 2005, and \$2,240 million in the first nine months of 2006, a 62% increase from the first nine months of 2005. Our operating income as a percentage of operating revenues (or “pretax operating margin”) was 35% in the third quarter of 2006 and 33% in the third quarter of 2005, and was 34% in the first nine months of 2006 and 29% in the first nine months of 2005.

### ***Other Income, Net***

<b><u>Other Income, Net</u></b>	<b>Three Months</b>			<b>Nine Months</b>		
	<b>Ended September 30,</b>		<b>% Change</b>	<b>Ended September 30,</b>		<b>% Change</b>
<b>2006</b>	<b>2005</b>	<b>2006</b>		<b>2005</b>		
	<i>(In millions)</i>					
Gains on sales of biotechnology equity securities and other	\$ 11	\$ 4	175%	\$ 81	\$ 4	*%
Write-downs of biotechnology debt and	(1)	(2)	(50)	(1)	(5)	(80)

Edgar Filing: GENENTECH INC - Form 10-Q

equity securities						
Interest income	64	40	60	166	99	68
Interest expense	(19)	(20)	(5)	(56)	(27)	107
Other miscellaneous						
income	-	-	-	3	-	*
Total other income, net	\$ 55	\$ 22	150	\$ 193	\$ 71	172

\* Calculation not meaningful.

Other income, net changed primarily due to gains on sales of biotechnology equity securities resulting from Amgen's acquisition of Abgenix, Pfizer's acquisition of Rinat, and Astra Zeneca's acquisition of Cambridge Antibody and the

effects of our debt issuance in July 2005. Interest income from investments increased as a result of the higher bond yields in 2006 combined with higher average cash balances. Interest expense increased due to the debt service costs incurred in the third quarter and first nine months of 2006.

For the full year 2006 we expect other income, net to be approximately 2.5 times the 2005 level of \$91 million, subject to changes in interest rates and the potential change in the value of our biotechnology equity portfolio.

### ***Income Tax Provision***

Our effective income tax rate was 37% in the third quarter of 2006 compared to 41% in the third quarter of 2005. Our tax rate in the third quarter of 2005 included the unfavorable effect of reducing our estimated R&D tax credits for 2005 and prior periods by approximately \$27 million. Our effective income tax rate was 38% in the first nine months of 2006 compared to 35% in the first nine months of 2005. The increase in the income tax rate over the first nine months of 2005 reflects higher income before taxes and the December 31, 2005 expiration of the federal R&D tax credit. If legislation to extend the R&D tax credit is passed, we will record any tax benefit for R&D tax credits at that time.

Various factors may have favorable or unfavorable effects on our effective tax rate during the remainder of 2006 and in subsequent years. These factors include, but are not limited to, changing interpretations of existing tax laws, changes in tax laws and rates, past and future levels of R&D spending, changes of estimates of prior years' items, and changes in overall levels of income before taxes, all of which may result in periodic revisions to our effective tax rate.

### **Liquidity and Capital Resources**

<b><u>Liquidity and Capital Resources</u></b>	<b>September 30, 2006</b>	<b>December 31, 2005</b>
	<i>(In millions)</i>	
Unrestricted cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	\$ 3,891	\$ 3,814
Net receivable - equity hedge instruments	70	73
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity securities, and equity hedge instruments	\$ 3,961	\$ 3,887
Working capital	\$ 3,100	\$ 2,726
Current ratio	2.7:1	2.6:1

Unrestricted cash, cash equivalents, short-term investments and long-term marketable securities, including the fair value of the equity hedge instruments, were approximately \$4.0 billion at September 30, 2006, an increase of approximately \$74 million from December 31, 2005. This increase primarily reflects cash generated from operations, partially offset by cash used for purchases of available-for-sale securities, capital expenditures, repurchases of our Common Stock and an increase in tax payments. To mitigate the risk of market value fluctuation, certain of our biotechnology marketable equity securities are hedged with zero-cost collars and forward contracts, which are carried at fair value. See Note 1, "Summary of Significant Accounting Policies—Comprehensive Income," in the Notes to the Condensed Consolidated Financial Statements of Part I, Item 1 of this Form 10-Q for further information regarding activity in our marketable investment portfolio and derivative instruments.

Our total cash, unrestricted cash equivalents, short-term investments and marketable securities at December 31, 2006 are not expected to change significantly relative to the level at December 31, 2005. We believe our existing unrestricted funds, together with funds provided by operations and our debt issuance in July 2005 will be sufficient to

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

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

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

Our “accounts receivable—product sales” was \$790 million at September 30, 2006, an increase of \$236 million from December 31, 2005. The increase is primarily due to higher product sales of Herceptin and Avastin, and sales of our new product, Lucentis. The average collection period of our “accounts receivable—product sales” as measured in days of sales outstanding (or “DSO”) was 37 days in the third quarter 2006, as compared to 32 days in the third quarter of 2005 and 33 days in the second quarter 2006. The increase in DSO is primarily due to the extended payment terms we offered to certain wholesalers in conjunction with the launch of Lucentis on June 30, 2006. This program will be in effect for 12 months following the launch date; therefore, we expect our DSO to continue to increase in the fourth quarter of 2006 due to these extended payment terms.

Our inventory balance was \$1,063 million at September 30, 2006, an increase of \$360 million from December 31, 2005. The increase is primarily due to bulk production of our Avastin, Herceptin and Activase products. Inventory also increased in the first nine months of 2006 due to non-cash employee stock-based compensation costs of \$49 million that were capitalized in inventory pursuant to our adoption of FAS 123R. We expect that our inventory levels will continue to rise in 2007 in support of sales growth, in particular, sales growth related to our recently approved indications.

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

Cash used in investing activities primarily relates to purchases, sales and maturities of investments and capital expenditures. Capital expenditures were \$888 million during the first nine months of 2006 compared to \$1.1 billion during the first nine months of 2005. Capital expenditures in the first nine months of 2006 included ongoing construction of our second manufacturing facility in Vacaville, California, validation costs at our manufacturing facility in Oceanside, California, the purchase of a second facility in Oceanside, purchase of equipment and information systems, and ongoing expenditures to support our corporate infrastructure needs. Included in capital expenditures in the first nine months of 2005 is \$408 million in cash plus \$9 million in closing costs related to the purchase of our manufacturing facility in Oceanside, California and \$160 million for the repayment of our synthetic lease obligation on a research facility in South San Francisco, California.

Restricted cash increased \$53 million in the third quarter of 2006 due to the additional cash and investments we were required to pledge to secure the COH surety bond. Total cash and investments pledged to secure the COH surety bond was \$788 million at September 30, 2006 and \$735 million at December 31, 2005 and are reflected in the Condensed Consolidated Balance Sheets in “restricted cash and investments”. See Note 4, “Contingencies” in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for further information regarding the COH litigation and related surety bond.

We currently anticipate that our capital expenditures for the full year 2006 will be approximately \$1.3 billion, primarily driven by manufacturing expansion due to ongoing construction of our second manufacturing facility in Vacaville, validation of our Oceanside manufacturing facilities and, for projects related to existing facilities, increases in office space, and land purchases.

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

Cash used in financing activities is primarily related to activity under our employee stock plans and our stock repurchase program. We used cash for stock repurchases of \$758 million during the first nine months of 2006 and \$1.1 billion during the first nine months of 2005 pursuant to our stock repurchase program approved by our Board of Directors. We also received \$286 million during the first nine months of 2006 and \$634 million during the first nine months of 2005 related to stock option exercises and stock issuances under our employee stock plans.

-37-

---

Prior to our adoption of FAS 123R, the tax benefit from stock option exercises was reported as operating cash flows. FAS 123R requires excess tax benefits be reported as a financing cash inflow rather than as a reduction of cash used in operating activities. At September 30, 2006, the excess tax benefit from stock-based compensation arrangements was \$142 million.

In July 2005, we received proceeds of \$2.0 billion from our debt issuance, and we used those proceeds in the third quarter of 2005 to extinguish our remaining \$425 million total lease obligation with respect to our Vacaville, California manufacturing facility.

On April 19, 2006, the Board of Directors approved an extension of our stock repurchase program for the repurchase of up to an additional \$2.0 billion of our Common Stock for a total of \$6.0 billion through June 30, 2007. The Board also amended the current repurchase program by increasing the maximum number of shares that can be repurchased from 80 million to 100 million shares. Under this stock repurchase program, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. Genentech intends to use the repurchased stock to offset dilution caused by the issuance of shares in connection with Genentech's employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage; (ii) to make prudent investments of our cash resources; and (iii) to allow for an effective mechanism to provide stock for our employee stock plans. See below in "Relationship with Roche" for more information on Roche's minimum ownership percentage. We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately four million shares and will run through June 30, 2007.

Our shares repurchased during the first nine months of 2006 were as follows (*shares in millions*):

	<b>Total Number of Shares Purchased in 2006</b>	<b>Average Price Paid per Share</b>
January 1-31, 2006	0.9	\$ 88.37
February 1-28, 2006	0.7	85.31
March 1-31, 2006	1.0	84.24
April 1-30, 2006	0.7	80.31
May 1-31, 2006	2.1	78.83
June 1-30, 2006	1.2	79.30
July 1-31, 2006	0.9	79.39
August 1-31, 2006	0.9	80.89
September 1-30, 2006	0.9	79.84
Total	9.3	\$ 81.38

As of September 30, 2006, 59 million shares have been purchased under our stock repurchase program, and a maximum of 41 million additional shares may be purchased under the program through June 30, 2007.

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

**Off-Balance Sheet Arrangements**

We have certain contractual arrangements that create potential risk for Genentech and are not recognized in our Condensed Consolidated Balance Sheets. Discussed below are those off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operation, liquidity, capital expenditures or capital resources.



### ***Leases***

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to our South San Francisco campus. For accounting purposes, due to the nature of our involvement with the construction of the buildings subject to the Master Lease Agreement, we are considered to be the owner of the assets during the construction period through the lease commencement date, even though the funds to construct the building shell and some infrastructure costs are paid by the lessor. As such, as of September 30, 2006, we have capitalized \$180 million of construction costs, including tenant improvements and capitalized interest, in property, plant and equipment, and have recognized \$176 million as a construction financing obligation in “long-term debt” in the accompanying Condensed Consolidated Balance Sheets. Concurrent with the commencement of the rental period, during the third quarter of 2006, we began the amortization of the construction financing obligation and the amount of amortization was not significant. We expect at the time of completion of the project, if all the buildings and infrastructure were completed by the lessor, our construction asset and related obligation will be up to \$365 million. Our aggregate lease payments as contemplated by the Master Lease Agreement through 2020 will be approximately \$544 million.

### ***Contractual Obligations***

During the first nine months of 2006, we believe there have been no significant changes in our payments due under contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005.

### ***Contingencies***

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

### ***Relationship with Roche***

#### ***Redemption of Our Special Common Stock***

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche Holdings, Inc. (or “Roche”) at a price of \$10.31 per share in cash with funds deposited by Roche for that purpose. We refer to this event as the “Redemption.” As a result, on that date, Roche’s percentage ownership of our outstanding Common Stock increased from 65% to 100%. Consequently, under GAAP, we were required to use push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value. Push-down accounting required us to record \$1,686 million of goodwill and \$1,499 million of other intangible assets on our balance sheet on June 30, 1999. Refer to Note 5, “Other Intangible Assets,” in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2005 for further information about these intangible assets.

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

We issue additional shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that with respect to any issuance of Common Stock by us in the future, we will repurchase a sufficient number of shares so that immediately after such issuance the percentage of our Common Stock owned by Roche will be no lower than 2% below the “Minimum Percentage” (as defined below), provided however, as long as Roche’s percentage ownership is greater than 50%, prior to issuing any shares, we will repurchase a sufficient number of shares of our

Common Stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The Minimum Percentage equals the lowest number of shares of our Common Stock owned by Roche since the July 1999 offering (to be adjusted for dispositions of shares of our Common Stock by Roche as well as for stock splits or stock combinations) divided by 1,018,388,704, the number of shares of our Common Stock outstanding at the time of the July 1999 offering, as adjusted for stock splits. We have repurchased shares of our Common Stock since 2001 (see discussion above in Liquidity and Capital Resources). The affiliation agreement also provides that, upon Roche's request, we will repurchase shares of our Common Stock to increase Roche's

ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. The Minimum Percentage at September 30, 2006 was 57.7% and, under the terms of the affiliation agreement, Roche's ownership percentage is to be no lower than 55.7%. At September 30, 2006, Roche's ownership percentage was 55.8%.

### **Related Party Transactions**

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

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

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

Under our existing arrangements with Hoffmann-La Roche, including our licensing and marketing agreement, we recognized contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities, of \$37 million in the third quarter of 2006 and \$24 million in the third quarter of 2005, and \$77 million in the first nine months of 2006 and \$59 million in the first nine months of 2005. All other revenues from Hoffmann-La Roche and their affiliates, principally royalties and product sales, which are included in product sales to collaborators, totaled \$315 million in the third quarter of 2006 and \$181 million in the third quarter of 2005, and \$819 million in the first nine months of 2006 and \$471 million in the first nine months of 2005. COS included amounts related to sales to Hoffmann-La Roche of \$59 million in the third quarter of 2006 and \$45 million in the third quarter of 2005, and \$173 million in the first nine months of 2006 and \$119 million in the first nine months of 2005. Our reported R&D expenses included \$58 million in the third quarter of 2006 and \$43 million in the third quarter of 2005, and \$158 million in the first nine months of 2006 and \$117 million in the first nine months of 2005, related to development activities undertaken on projects on which we collaborate with Hoffmann-La Roche.

In July 2006, we signed two new product supply agreements with F. Hoffmann-La Roche which supplement and supersede existing product supply agreements with F. Hoffmann-La Roche. Under a short-term supply agreement, F. Hoffmann-La Roche has agreed to purchase specified amounts of Herceptin, Avastin and Rituxan through 2008. Under a longer-term supply agreement, F. Hoffmann-La Roche has agreed to purchase specified amounts of Herceptin and Avastin through 2012 and, on a perpetual basis, either party may order other collaboration products from the other party, including Herceptin and Avastin after 2012, pursuant to certain forecast terms. The longer-term supply agreement also provides that either party may terminate its obligation to purchase and/or supply Avastin and/or Herceptin with six years notice on or after December 31, 2007.

#### ***Novartis***

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

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

-40-

---

We, along with Novartis Pharma AG and Tanox, Inc., are co-developing Xolair in the U.S. We and Novartis Pharmaceutical Corporation (a wholly-owned subsidiary of Novartis AG) are co-promoting Xolair in the U.S. and we both make certain joint and individual payments to Tanox; our joint and individual payments are in the form of royalties. We record all sales and COS in the U.S. and Novartis markets the product and records all sales and COS in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. On January 20, 2006, Novartis received FDA approval to manufacture bulk supply of Xolair at their Huningue production facility in France. We now acquire bulk supply of Xolair from Novartis and compensate them on a cost plus mark up basis.

Contract revenue from Novartis related to manufacturing, commercial and ongoing development activities was \$15 million in the third quarter of 2006 and \$13 million in the third quarter of 2005, and \$37 million in the first nine months of 2006 and \$35 million in the first nine months of 2005. Revenue from Novartis related to product sales was not material in the third quarters and first nine months of 2006 and 2005. COS was not material in the third quarters of 2006 and 2005 and in the first nine months of 2006. COS was \$15 million in the first nine months of 2005, which included a one-time payment in the second quarter of 2005 related to our release from future manufacturing obligations. Our reported R&D expenses included \$35 million in the third quarter of 2006 and \$12 million in the third quarter of 2005, and \$80 million in the first nine months of 2006 and \$33 million in the first nine months of 2005 related to development activities undertaken on products on which we collaborate with Novartis. Collaboration profit sharing payments from us to Novartis were \$46 million in the third quarter of 2006 and \$41 million in the third quarter of 2005, and \$137 million in the first nine months of 2006 and \$93 million in the first nine months of 2005.

## Stock Options

### *Option Program Description*

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

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors or an authorized delegate. See "The Compensation Committee Report" appearing in our 2006 Proxy Statement for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

### *General Option Information*

#### *Summary of Option Activity* (Shares in millions)

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted-Average Exercise Price
<b>December 31, 2004</b>	102	94	\$ 32.32

Edgar Filing: GENENTECH INC - Form 10-Q

Grants	(20)	20		84.01
Exercises	-	(29)		25.88
Cancellations	2	(2)		42.16
<b>December 31, 2005</b>	<b>84</b>	<b>83</b>	<b>\$</b>	<b>46.64</b>
Grants	(17)	17		79.75
Exercises	-	(7)		30.17
Cancellations	2	(2)		60.42
<b>September 30, 2006 (Year to date)</b>	<b>69</b>	<b>91</b>	<b>\$</b>	<b>53.80</b>

-41-

---

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

As of September 30, 2006	Exercisable		Unexercisable			Total	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	
In-the-Money	42	\$ 31.45	31	\$ 65.47	73	\$ 45.83	
Out-of-the-Money <sup>(1)</sup>	4	\$ 86.01	14	\$ 86.38	18	\$ 86.30	
Total Options Outstanding	46		45		91		

(1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of Genentech Common Stock, \$82.70, at the close of business on September 29, 2006.

***Dilutive Effect of Options***

Net grants, as a percentage of outstanding shares, were 1.43% for the nine months ended September 30, 2006, 1.70% for the year ended December 31, 2005 and 1.83% for the year ended December 31, 2004.

***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 the accounting changes concerning sabbatical leave and income taxes on our earnings per share; our plan to cap certain Avastin expenses for patients; our Horizon 2010 strategy of bringing 20 new molecules into clinical development, 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; an sBLA submission to the FDA for Avastin; our ability to successfully integrate new employees; Avastin, Lucentis and Tarceva sales growth; launches of new product indications; Cabilly related net income; royalty and contract revenues; cost of sales as a percentage of net product sales; research and development and marketing, general and administrative spending; sales to collaborators; other income, net; capital expenditures and construction costs; collaboration profit sharing expenses; the level of our cash, unrestricted cash equivalents, short-term investments and marketable securities; our ability to meet our foreseeable operating cash requirements; the effects of new regulations relating to hospital and physician payment on our revenues; the effect of product distribution changes on our results of operations; inventory levels; days of sales outstanding; and employee stock-based compensation expense.

These forward-looking statements involve risks and uncertainties, and the cautionary statements set forth below and those contained in "Risk Factors" 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, unexpected safety, efficacy or manufacturing issues, additional time requirements for data analysis, BLA preparation and decision making, FDA actions or delays, failure to obtain FDA approval, competition, pricing, difficulty in obtaining materials from suppliers, the ability to supply product and meet demand for our products, product withdrawals and new product approvals and launches, our ability to protect our proprietary rights, the effect of pricing decisions by us or our competitors on reimbursement rates, our sales and our stock price, unanticipated expenses such as litigation or legal settlement expenses or equity securities write-downs, fluctuations in royalty and contract revenues, increased costs of sales, research and development and management, general and administrative expenses, variations in collaborator

sales and expenses, fluctuations in interest rates, increased capital expenditures including greater than expected construction and validation costs, our indebtedness and ability to pay our indebtedness, actions by Roche that are adverse to our interests, decreases in third party reimbursement rates, timely payment by customers for our products, reaction to and acceptance by distributors of changes to our distribution strategy, sabbatical leave expense and income taxes, the ability of management and others to integrate new employees into our culture, the number of options granted to employees, and Genentech's stock price and certain valuation assumptions concerning Genentech stock. We disclaim and do not undertake any obligation to update or revise any forward-looking statement in this Form 10-Q.



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

Our market risks at September 30, 2006 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2005 on file with the Securities and Exchange Commission. See also Note 1, “Summary of Significant Accounting Policies—Derivative Financial Instruments” section in the Notes to Condensed Consolidated Financial Statements in Part I of this Form 10-Q.

**Item 4. Controls and Procedures**

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

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

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

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

See also Item 3 of Part I of our report on Form 10-K for the year ended December 31, 2005 and Item 1 of Part II of our reports on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006.

### Item 1A. Risk Factors

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

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

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

- Preclinical tests may show the product to be toxic or lack efficacy in animal models.
- Clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects.
  - Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, extended length of time to achieve study endpoints, additional time requirements for data analysis or Biologic Licensing Application (or “BLA”) preparation, discussions with the U.S. Food and Drug Administration (or “FDA”), FDA requests for additional preclinical or clinical data, analyses or changes to study design, or unexpected safety, efficacy or manufacturing issues.
- Difficulties formulating the product, scaling the manufacturing process or in getting approval for manufacturing.
  - Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being developed or commercialized.
- The contractual rights of our collaborators or others that may prevent the product from being developed or commercialized.

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

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

-44-

---

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

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

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

We are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA’s requirements covering R&D, testing, manufacturing, quality control, labeling and promotion of drugs for human use. A biotherapeutic cannot be marketed in the United States (or “U.S.”) until it has been approved by the FDA, and then can only be marketed for the indications approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application or a BLA, are substantial and can require a number of years. In addition, even if our products receive regulatory approval, they remain subject to ongoing FDA regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and/or a product recall.

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 required approvals as described in “The successful development of biotherapeutics is highly uncertain and requires significant expenditures” above.

Loss of, or changes to, previously obtained approvals, including those resulting from post-approval safety or efficacy issues.

- Failure to comply with existing or future regulatory requirements.
- Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

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

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

Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated for this purpose. It can take longer than five years to design, construct, validate, and license a new biotechnology manufacturing facility. We currently produce our products at our manufacturing facilities located in South San Francisco, California; Vacaville, California; Porriño, Spain; and increasingly, through various contract-manufacturing arrangements. Problems with any of our or our contractors' manufacturing processes could result in failure to produce adequate product supplies or could result in product defects which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all. In addition, we may need to record period charges associated with manufacturing or inventory failures or other production-related costs or incur costs to secure additional sources of capacity. Furthermore, there are inherent uncertainties associated with forecasting future demand, especially for newly introduced products of ours or of those for whom we produce products, and as a consequence we may have inadequate capacity to meet our own actual demands and/or the actual demands of those for whom we produce product.

In order to maintain adequate supply to keep up with growing demand for our products, we must successfully implement a number of manufacturing capacity enhancement projects on schedule, utilize nearly 100 percent of our production capacity in the next several quarters and maintain a state of regulatory compliance at all production sites. If we, or any of our contract manufacturers, for any reason fail to obtain licensure for our capacity enhancement projects on schedule, fail to operate at or near full capacity utilization, fail to maintain a state of regulatory compliance, or if actual demand significantly exceeds our internal forecasts, we may be unable to maintain an adequate supply of our products to meet all demand. Key capacity enhancement projects, which we must successfully implement, include the following: (i) licensure of additional capacity at our Porriño, Spain facility in the fourth quarter of 2006 to produce Avastin bulk drug substance; (ii) licensure of yield improvement processes for Rituxan and Avastin by the end of 2006; (iii) licensure of our Oceanside, California manufacturing facility during the first half of 2007; and (iv) construction, qualification and licensure of our new plant in Vacaville, California in 2009.

If we experience a significant malfunction in our filling facility or those of a contract manufacturer, we could experience a shortfall or stock-out of one or more products, which, if it were to continue for a significant period of time, could result in a material adverse effect on our product sales and our business.

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

Any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall or stock-out of available product inventory, any of which could have a material adverse effect on our business. A number of factors could cause prolonged interruptions, including:

the inability of a supplier to provide raw materials used for manufacture of our products; equipment obsolescence, malfunctions or failures;

- product contamination problems;

-46-

---

- damage to a facility, including our warehouses and distribution facilities, due to natural disasters, including, but not limited to, earthquakes as our South San Francisco, Oceanside and Vacaville facilities are located in areas where earthquakes could occur;
- changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes;
- action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products we make for others due to regulatory issues;
  - a contract manufacturer going out of business or failing to produce product as contractually required;
  - other similar factors.

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

### **We face competition**

We face competition from pharmaceutical companies and biotechnology companies.

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

*Avastin:* Avastin competes with Erbitux® (Imclone/Bristol-Myers Squibb), which is an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer (or "CRC") patients, Nexavar® (sorafenib Bayer Corporation/Onyx Pharmaceuticals, Inc.) for the treatment of patients with advanced renal cell carcinoma (or "RCC"), or kidney cancer (an unapproved use of Avastin), Sutent® (sunitinib malate, Pfizer, Inc.) for use in advanced RCC and Gleevec-refractory/intolerant gastrointestinal stromal tumor (unapproved uses of Avastin), Vectibix™ (panitumumab, Amgen), which received FDA approval in September 2006, for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. Avastin could face competition from products in development that currently do not have regulatory approval. Amgen has stated that it will initiate head-to-head clinical trials comparing AMG 706 and Avastin. Additionally, there are more than 30 molecules that target VEGF inhibition, and over 130 companies that are developing molecules that, if approved, may compete with Avastin.

*Rituxan:* Rituxan's competitors include Bexxar® (GlaxoSmithKline) and Zevalin® (Biogen Idec), both of which are radioimmunotherapies indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma (or "NHL"). While indicated for the treatment of NHL, both products currently represent limited competition for Rituxan. Other potential competitors include Campath® (Berlex, Inc.), which is indicated for B-cell chronic lymphocytic leukemia (an unapproved use of Rituxan), Velcade® (Millennium Pharmaceuticals, Inc.) which is indicated for multiple myeloma (an unapproved use of Rituxan), and HumaxCD20 (GenMab) which is in late-stage development for refractory CLL and NHL. In addition to the products detailed above, we are aware of other anti-CD20 molecules in development that, if successful in clinical trials, may compete with Rituxan.



Rituxan's current biologic competitors in rheumatoid arthritis include Enbrel® (Amgen/Wyeth), Humira® (Abbott), Remicade® (Johnson & Johnson), Orencia® (Bristol-Myers Squibb), and Kineret® (Amgen). These products are indicated for a broader RA patient population than Rituxan.

-47-

---

*Herceptin:* Herceptin could face competition in the future from experimental drugs and products in development that do not currently have regulatory approval for any use outside of clinical trials, including lapatinib ditosylate (Tykerb®), which is being developed by GlaxoSmithKline (or “GSK”). On April 3, 2006, GSK announced that it halted enrollment in its Phase III clinical trial to evaluate lapatinib ditosylate because of positive results in treating HER2-positive metastatic breast cancer in women whose disease had progressed following a Herceptin-containing regimen and other cancer therapies. Results, from this trial, which were presented at this year’s ASCO meeting, showed that lapatinib ditosylate in combination with capecitabine increased time to disease progression compared to capecitabine alone. GSK filed for regulatory approval of lapatinib ditosylate in the third quarter of this year.

*Lucentis:* We are aware that some retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration, an unapproved use for Avastin. We expect Avastin use to continue in this setting. Additionally, the National Eye Institute and National Institute of Health have announced head-to-head trials of Avastin and Lucentis in this setting. Lucentis also competes with laser photocoagulation, Macugen® (Pfizer/OSI Pharmaceuticals), and Visudyne® (Novartis) alone, or in combination with the off-label steroid kenalog, in this setting.

*Tarceva:* Tarceva competes with the chemotherapeutic products Taxotere® (Sanofi-Aventis) and Alimta® (Eli Lilly and Company), both of which are indicated for the treatment of relapsed NSCLC. In front-line pancreatic cancer, Tarceva primarily competes with Gemzar® (Eli Lilly) monotherapy and Gemzar® in combination with other chemotherapeutic agents. Tarceva could also face competition in the future from products in late-phase development that currently do not have regulatory approval for use in NSCLC or pancreatic cancer. Examples of potential competitors include Erbitux® (Bristol-Myers Squibb), Xyotax® (Cell Therapeutics Inc.), Telcyta® (Telik, Inc.), Nexavar® (sorafenib, Bayer/ Onyx) and Zactima® (Astra Zeneca). Examples of potential competitors in Phase III pancreatic cancer trials are Xeloda® (Roche) and Erbitux® (Bristol-Myers Squibb).

*Xolair:* While Xolair has no direct competitors, it 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.

*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 FDA approved biologic agents Amevive® (Astellas) Enbrel® (Amgen), and Remicade® (Centocor, Inc.). In October 2006, Remicade® was approved by the FDA for use in severe psoriasis. Raptiva also competes with the biologic agent Humira® (Abbott Laboratories), which is currently used off-label in the psoriasis market.

*Nutropin:* In the growth hormone market, we face competition from other companies currently selling growth hormone products. Nutropin’s current competitors are Genotropin® (Pfizer), Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly and Company), Tev-Tropin® (Teva Pharmaceutical Industries Ltd.), and Saizen® (Serono, Inc.). In addition, follow-on biologics are beginning to enter the growth hormone market. The FDA recently approved the first follow-on version of a protein product, Omnitrope® (Sandoz) as a biologic similar to Genotropin® (Pfizer). Furthermore, as a result of multiple competitors, we have experienced, and may continue to experience, a loss of patient share and increased competition for managed care product placement. Obtaining placement on the preferred product lists of managed care companies may require that we discount the price of Nutropin in the future.

*Thrombolytics:* We face competition in our acute myocardial infarction market with sales of TNKase and Activase affected by the adoption by physicians of mechanical reperfusion strategies. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. TNKase, for acute myocardial infarction, also faces competition from Retavase® (PDL BioPharma Inc.), which engages in competitive price discounting. Cathflo Activase may face competition in the catheter clearance market from Nuvelo’s Alfimeprase®, currently in ongoing Phase III clinical trials.

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

-48-

---

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

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

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

**Protecting our proprietary rights is difficult and costly**

The patent positions of pharmaceutical and biotechnology companies and other entities can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the breadth of claims allowed in these third-parties' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material litigation and other legal proceedings relating to our proprietary rights, such as the Cabilly reexaminations discussed in Note 4, "Contingencies," in the Notes to Condensed Consolidated Financial Statements of Part I, Item I of this Form 10-Q. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities to third-parties. An adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third-parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

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

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

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

Our activities relating to the sale and marketing of our products are subject to regulation under the U.S. Federal Food, Drug and Cosmetic Act and other federal statutes. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). In 1999 we agreed to pay \$50 million to settle a federal investigation

relating to our past clinical, sales and marketing activities associated with human growth hormone. We are currently being investigated by the Department of Justice with respect to our promotional practices of Rituxan, and may in the future be investigated for our promotional practices relating to any of our products. If the government were to bring charges against or convict us of violating these laws, or if we were subject to third-party litigation relating to the same promotional practices, there could be a material adverse effect on our business, including our financial condition and results of operations.

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

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

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

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

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, (ii) successfully integrate large numbers of new employees into our corporate culture, and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense.

Among other benefits, we use stock options to attract and retain personnel. The number of shares management and our board of directors choose to grant under our stock option plans may be affected by our affiliation agreement with Roche, which provides that we will establish a stock repurchase program designed to maintain Roche’s percentage ownership in our Common Stock if we issue or sell any shares. In addition, stock option accounting rules require us to recognize all employee stock-based compensation costs as expenses. These or other factors could reduce the number of shares management and our board of directors chooses to grant. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships or that the costs of retaining such personnel or maintaining such relationships will not materially increase.

**Other factors could affect our product sales**

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

- The timing of FDA approval, if any, of competitive products.

Our pricing decisions, including a decision to increase or decrease the price of a product, the pricing decisions of our competitors, as well as our program to cap the overall expense of Avastin to \$55,000 per year per eligible patient for any FDA approved indication.

- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.

-50-

---

- Negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party could cause the sales of our products to decrease or a product to be recalled.
- Negative safety or efficacy data from post-approval marketing experience could cause sales of our products to decrease or a product to be recalled.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.
  - The increasing use and development of alternate therapies.
  - The rate of market penetration by competing products.
- Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers who supply our products.

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

#### **Our results of operations are affected by our royalty and contract revenues**

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

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



unpatentable, that determination could cause us to suffer a loss of such royalties and/or revenues, and could cause us to incur other monetary damages.

- Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

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

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

Roche's Minimum 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 plan. In order to maintain Roche's Minimum Percentage we repurchase shares of our Common Stock under the stock repurchase program. See Note 2, "Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for information regarding employee stock plans. While the dollar amounts associated with future stock repurchase programs cannot currently be determined, future stock repurchases could have a material adverse effect on our liquidity, credit rating and ability to access additional capital in the financial markets.

#### **Our affiliation agreement with Roche could limit our ability to make acquisitions**

The affiliation agreement between us and Roche contains provisions that:

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

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

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

As of September 30, 2006, Roche owned 587,189,380 shares of our Common Stock, or 55.8% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by Roche in the public market could adversely affect the market price of our Common Stock.

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

Roche, as our majority stockholder, controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our board of directors shall consist of at least three directors designated by Roche, three independent directors nominated by the nomination committee and one Genentech executive officer nominated by the nominations committee. Our bylaws also provide that Roche will have the right to obtain proportional representation on our board until such time that Roche owns less than 5% of our stock. Currently, three of our directors, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles,

also serve as officers and employees of Roche Holding Ltd and its affiliates. As long as Roche owns in excess of 50% of our Common Stock, Roche directors will comprise two of the three members of the nominations committee. Our certificate of incorporation includes provisions relating to competition by Roche affiliates with us, offering of corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of specified employees. We cannot assure you that Roche will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, persons who are directors and/or officers of Genentech and who are also directors and/or officers of Roche may decline to take action in a manner that might be favorable to us but adverse to Roche.

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

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

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

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

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

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

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

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

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

Our operating results may vary from period to period for several reasons including:

- The overall competitive environment for our products as described in “We face competition” above.
- The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.

-53-

---

- The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the U.S. and the amount and timing of sales to their respective customers, which directly affects both our product sales and royalty revenues.
  - The timing and volume of bulk shipments to licensees.
- The availability and extent of government and private third-party reimbursements for the cost of therapy.
  - The extent of product discounts extended to customers.
- The effectiveness and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.
  - The rate of adoption by physicians and use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
    - The potential introduction of new products and additional indications for existing products.
  - The ability to successfully manufacture sufficient quantities of any particular marketed product.
- Pricing decisions we have adopted or may adopt, including our program to cap the overall expense of Avastin to \$55,000 per year per eligible patient for any FDA-approved indication.

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

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

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

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

In addition, the following factors may have a significant effect on the market price of our Common Stock.

- Announcements of technological innovations or new commercial products by us or our competitors.
- Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors.

Edgar Filing: GENENTECH INC - Form 10-Q

- Concerns about the pricing of our products, or our pricing initiatives (including our program to cap the overall expense of Avastin to \$55,000 per year per eligible patient for any FDA-approved indication), and the potential effect of such on their utilization or our product sales.
- Developments or outcome of litigation, including litigation regarding proprietary and patent rights.

-54-

---

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

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

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

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

As of September 30, 2006, we had approximately \$2.0 billion of long-term debt. Our ability to make payments on and to refinance our indebtedness, including our long-term debt obligations, and to fund planned capital expenditures, R&D, as well as stock repurchases and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase our vulnerability to general adverse economic and industry conditions, require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts and other general corporate purposes, and limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

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

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

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "*Share-Based Payment*" (or "FAS 123R"). As a result, we have included employee stock-based compensation costs in our results of operations for the third quarter and nine months ended September 30, 2006, as discussed in Note 2, "Employee Stock-Based Compensation," in the Notes to Condensed Consolidated Financial Statements of Part I, Item I of this Form 10-Q. Our adoption of FAS 123R is expected to result in compensation expense that will reduce diluted net income per share by approximately \$0.17 to \$0.18 per share for 2006. However, our estimate of future employee stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.



On June 28, 2006, the FASB ratified the consensus reached by the EITF on EITF Issue 06-2, “*Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43, Accounting for Compensated Absences.*” EITF 06-2 states that if all the conditions of paragraph 6 of FASB 43 are met, compensation costs for sabbatical and other similar benefit arrangements should be accrued over the requisite service period. Paragraph 6 of FASB 43 states that a liability should be accrued for employees’ future absences if the following are met: (a) the

-55-

---

employer's obligation is attributable to employees' services already rendered; (b) the obligation relates to rights that vest or accumulate; (c) payment of the compensation is probable; and (d) the amount can be reasonably estimated. EITF 06-2 is effective for fiscal years beginning after December 15, 2006. Upon adoption of EITF 06-2, we expect to record a one-time charge as a cumulative effect of a change in accounting principle that will reduce diluted net income per share by approximately \$0.02 to \$0.03 per share. We will also begin to record an annual sabbatical expense that will reduce diluted net income per share by approximately \$0.01 to \$0.02 per share in 2007.

In June 2006, the FASB issued FASB Interpretation (or "FIN") No. 48, "Accounting for Uncertainty in Income Taxes." FIN 48 clarifies the application of FASB Statement 109, "Accounting for Income Taxes," by defining criterion that must be met for any part of a benefit related to an individual tax position to be recognized in the financial statements. FIN 48 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition and is effective for fiscal years beginning after December 15, 2006.

## 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 2006, we are authorized to repurchase up to 100,000,000 shares of our Common Stock for an aggregate amount of up to \$6.0 billion through June 30, 2007. In this stock repurchase program, 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. We intend to use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to make prudent investments of our cash resources; (ii) to allow for an effective mechanism to provide stock for our employee stock plans; and (iii) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage. See Note 5, "Relationship with Roche and Related Party Transactions" in the Notes to Condensed Consolidated Financial Statements in Part I, Item I of this Form 10-Q for more information on Roche's minimum ownership percentage. We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The current trading plan covers approximately four million shares and will run through June 30, 2007.

Our shares repurchased during the third quarter of 2006 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	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1-31, 2006	0.9	\$ 79.39		
August 1-31, 2006	0.9	80.89		
September 1-30, 2006	0.9	79.84		
Total	2.7	\$ 80.06	59	41

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

**Item 6. Exhibits****Exhibit**

<b><u>No.</u></b>	<b><u>Description</u></b>	<b><u>Location</u></b>
10.1	Form of Genentech, Inc. 2004 Equity Incentive Plan Nonqualified Stock Option Grant Agreement (Employee Version)	Filed on a Current Report on Form 8-K with the U.S. Securities and Exchange Commission on September 26, 2006, and incorporated herein by reference.
10.2	Form of Genentech, Inc. 2004 Equity Incentive Plan Nonqualified Stock Option Grant Agreement (Director Version)	Filed on a Current Report on Form 8-K with the U.S. Securities and Exchange Commission on September 26, 2006, and incorporated herein by reference.
10.3	Genentech, Inc Tax Reduction Investment Plan, as amended and restated	Filed herewith
15.1	Letter regarding Unaudited Interim Financial Information.	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended	Filed herewith
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 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: October 30, 2006

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

Date: October 30, 2006

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

Date: October 30, 2006

/s/JOHN M. WHITING  
John M. Whiting  
Vice President - Finance and  
Chief Accounting Officer