10-K 1 dna-10k 2003.htm GENENTECH, INC. - FORM 10-K FOR PERIOD ENDING DECEMBER 31, 2003

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 **FORM 10-K**

#### (Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE [x] **SECURITIES EXCHANGE ACT OF 1934** 

For the fiscal year ended December 31, 2003

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)

A Delaware Corporation

(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 (Telephone Number)

Securities registered pursuant to Section 12(b) of the Act:

**Title of Each Class** 

Common Stock, \$0.02 par value

Name of Each Exchange on Which Registered New York Stock Exchange

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 [x] No [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of Act). Yes [x] No []

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.[]

The approximate aggregate market value of voting stock held by non-affiliates of the registrant is \$15,232,305,454 as of June 30, 2003.<sup>(A)</sup>

Number of shares of Common Stock outstanding as of February 17, 2004: 527,028,756

#### Documents incorporated by reference:

Definitive Proxy Statement with respect to the 2004 Annual Meeting of Stockholders to be filed by Part III Genentech, Inc. with the Securities and Exchange Commission (hereinafter referred to as "Proxy Statement")

Excludes 306,641,166 shares of Common Stock held by directors and executive officers of Genentech and Roche Holdings, Inc (A)

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Novartis Exhibit 2265.001 Regeneron v. Novartis, IPR2021-00816

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#### GENENTECH, INC.

#### 2003 Form 10-K Annual Report

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In this report, "Genentech," "we," "us" and "our" refer to Genentech, Inc. "Common Stock" refers to Genentech's common stock, par value \$0.02 per share, "Special Common Stock" refers to Genentech's callable putable common stock, par value \$0.02 per share, all of which was redeemed by Roche Holdings, Inc. 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) tissueplasminogen activator; Avastin<sup>TM</sup> (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis<sup>TM</sup> (ranibizumab, rhuFab V2) anti-VEGF antibody fragment; Nutropin® (somatropin (rDNA origin) for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen® (somatropin (rDNA origin) for injection) liquid formulation growth hormone; Nutropin Depot® (somatropin (rDNA origin) for injectable suspension) encapsulated sustained-release growth hormone; Omnitarg<sup>TM</sup> (pertuzumab) HER dimerization inhibitor; Protropin® (somatrem for injection) growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva<sup>TM</sup> (efalizumab, formerly Xanelim<sup>TM</sup>) anti-CD11a antibody; and TNKase<sup>TM</sup> (teneteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva<sup>TM</sup> (erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks and trade names of other companies.

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PART I

Item 1. BUSINESS

**SIGNATURES** 

Overview

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.002 Regeneron v. Novartis, IPR2021-00816

#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. Seventeen of the currently approved biotechnology products originated from or are based on Genentech science. We manufacture and commercialize in the United States 13 biotechnology products and license several additional products to other companies. See "Marketed Products" and "Licensed Products" below. Genentech was organized in 1976 as a California corporation and was reincorporated in Delaware in 1987.

#### **Redemption of Our Special Common Stock and Public Offerings**

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 \$20.63 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 accounting principles generally accepted in the United States (or 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 \$1,685.7 million of goodwill and \$1,499.0 million of other intangible assets onto our balance sheet on June 30, 1999. For more information about push-down accounting, you should read "Redemption of Our Special Common Stock" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

Roche subsequently completed public offerings of our Common Stock in 1999 and 2000. At December 31, 2003, Roche's percentage ownership of our outstanding common stock was 58.4%. As a result of the Redemption and subsequent public offerings, we amended our certificate of incorporation and bylaws, amended our licensing and marketing agreements with F. Hoffmann-La Roche Ltd (or Hoffmann-La Roche), an affiliate of Roche, and entered into or amended certain agreements with Roche, which are discussed in "Relationship With Roche" of Part II, Item 7 of this Form 10-K.

#### **Marketed Products**

We manufacture and commercialize in the United States 13 biotechnology products listed below.

*Rituxan* (rituximab) anti-CD20 antibody is for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, a cancer of the immune system, including retreatment, times 8 dosing and bulky disease. We co-developed Rituxan with Biogen Idec Inc. (or Biogen Idec), formerly known as IDEC Pharmaceuticals Corporation, from whom we license Rituxan.

*Herceptin* (trastuzumab) anti-HER2 antibody is the first humanized antibody for the treatment of certain patients with metastatic breast cancer whose tumors overexpress the Human Epidermal growth factor Receptor type 2 (or HER2) protein. Herceptin is approved for use as a first-line therapy in combination with Taxol® (paclitaxel), a product made by Bristol-Myers Squibb Company (or Bristol-Myers), and other drugs, and as a single agent in second- and third-line therapy in patients with metastatic breast cancer who have tumors that overexpress the HER2 protein.

*Nutropin Depot* [somatropin (rDNA origin) for injectable suspension] is a long-acting growth hormone for the treatment of growth failure associated with pediatric growth hormone deficiency. It uses ProLease®, an injectable extended-release drug delivery system, which was developed by our collaborator Alkermes, Inc.

Nutropin [somatropin (rDNA origin) for injection] is a growth hormone for the treatment of growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency prior to kidney

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transplantation and short stature associated with Turner syndrome. Nutropin is similar to Protropin (see below); however, it does not have the additional N-terminal amino acid, methionine, found in the Protropin chemical structure.

*Protropin* (somatrem for injection) is a growth hormone approved for the treatment of growth hormone inadequacy in children. Manufacture of Protropin was discontinued at the end of 2002 because physicians are typically initiating therapy with one of the Nutropin family products and the demand for Protropin has declined, but sales are expected to continue through the first half of 2004 or until inventory is depleted.

Nutropin AQ [somatropin (rDNA origin) for injection] is a liquid formulation growth hormone for the same indications as Nutropin and is aimed at providing improved convenience in administration.

TNKase (tenecteplase) is a single-bolus thrombolytic agent for the treatment of acute myocardial infarction (heart attack).

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).

Cathflo Activase (alteplase, recombinant) is a thrombolytic agent 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 for the treatment of cystic fibrosis.

*Xolair* (omalizumab) is an anti-IgE antibody, which we commercialize with Novartis, for the treatment of moderate-to-severe persistent asthma in adults and adolescents. In June 2003, we received U.S. Food and Drug Administration (or FDA) approval to market Xolair. We began shipping Xolair in July 2003.

*Raptiva* (efalizumab) is an anti-CD11a antibody co-developed with XOMA Ltd. It was approved by the FDA in October 2003 for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy. We began shipping Raptiva in November 2003.

*Avastin* (bevacizumab) is an antibody approved by the FDA on February 26, 2004 for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum. We began shipping Avastin on February 26, 2004.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.003 Regeneron v. Novartis, IPR2021-00816

#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Sales of Rituxan and Herceptin accounted for more than 10 percent of our total consolidated revenues in the last three fiscal years. Sales of our growth hormone products accounted for more than 10 percent of our total consolidated revenues in 2002 and 2001. See "Product Sales" under Results of Operations in Part II, Item 7 of this Form 10-K for a discussion of the revenues contributed by each of our products in the last three years.

#### Licensed Products

We receive royalty revenue under license agreements with companies that sell and/or manufacture products based on technology developed by us or on intellectual property to which we have rights. These licensed products are sometimes sold under different trademarks or trade names. Significant licensed products, representing approximately 94% of our royalty revenues in 2003, are as follows:

Product Trade Name		Licensee	Licensed Territory		
D2E7/adalimumab Factor VIII	Humira Kogenate/Helixate	Abbott Bayer Corporation	Worldwide Worldwide		
Recombinant tissue plasminogen activator	Actilyse	Boehringer Ingelheim	Marketing rights in a number of countries outside of U.S., Canada and Japan; manufacturing rights		

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Tenecteplase	Metalyse	Boehringer Ingelheim	Europe, Switzerland and Australia
Infliximab	Remicade	Celltech Pharmaceuticals plc (which transferred rights to Centocor / Johnson & Johnson	Worldwide
Interferon gamma-1b	Actimmune	Connetics Corporation (which transferred rights to InterMune Pharmaceuticals, Inc.)	U.S., Canada and Japan
Human growth hormone <sup>(1)</sup>	Humatrope	Eli Lilly and Company	Worldwide
Hepatitis B vaccine	Engerix-B	GlaxoSmithKline plc	Worldwide
Rituximab	Rituxan/MabThera	Hoffmann-La Roche	Worldwide excluding U. S. and Japan
Trastuzumab	Herceptin	Hoffmann-La Roche	Worldwide excluding U. S.
Dornase alfa, recombinant	Pulmozyme	Hoffmann-La Roche	Worldwide excluding U. S.
Alteplase and Tenacteplase	Activase and TNKase	Hoffmann-La Roche	Canada
Somatropin and Somatrem	Nutropin and Protropin	Hoffmann-La Roche	Canada
Etanercept	ENBREL	Immunex Corporation	Worldwide
Palivizumab	Synagis	MedImmune, Inc.	Worldwide
Bovine growth hormone	Posilac	Monsanto Company	Worldwide
Somatropin <sup>(1)</sup>	Genotropin and Genotropin MiniQuick	Pharmacia Corporation	Worldwide

#### (1) Licensing arrangement expired in 2003

#### **Products in Development**

Our product development efforts, including those of our collaborative partners, cover a wide range of medical conditions, including cancer, respiratory disorders, cardiovascular diseases, endocrine disorders, and inflammatory and immune problems. Below is a summary of products, the related stages of development, and the estimate of completion of the phase.

Description	Phase*
	2004

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Estimate of

Novartis Exhibit 2265.004 Regeneron v. Novartis, IPR2021-00816

#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Nutropin is an approved product indicated for the long-term treatment of growth failure in pediatric patients due to inadequate endogenous growth hormone (GH) secretion, for growth failure in pediatric patients associated with chronic renal insufficiency (CRI) up to the time of renal transplantation, for the long-term treatment of short stature associated with Turner's syndrome in pediatric patients, and for the replacement of endogenous GH in eligible patients diagnosed with adult growth hormone deficiency (AGHD). We filed a New Drug Application (or NDA) for the additional indication of long-term treatment of idiopathic short stature in December 2003.

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Preparing for Filing		
Nutropin Depot	Nutropin Depot is a long-acting formulation of growth hormone that is approved for the treatment of growth failure associated with pediatric growth hormone deficiency. We are preparing to submit a Supplemental NDA (or sNDA) for the treatment of adults with growth hormone deficiency. This product is being developed in collaboration with Alkermes.	2004
Rituxan	An antibody approved for the treatment of relapsed or refractory low-grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma, a cancer of the immune system, including retreatment, times 8 dosing and bulky disease. We are preparing to submit a Supplemental BLA (or sBLA) for the treatment of indolent front-line non-Hodgkin's lymphoma. This product is being developed in collaboration with Hoffmann-La Roche and Biogen Idec.	2004
Phase III		
Rituxan	We are in Phase III clinical trials for the treatment of indolent and aggressive non-Hodgkin's lymphoma, indolent maintenance in non-Hodgkin's lymphoma and relapsed chronic lymphocytic leukemia. We are also in Phase III clinical trials for anti-TNF refractory rheumatoid arthritis. This product is being developed in collaboration with Hoffmann-La Roche and Biogen Idec.	2005-2008
Herceptin	An antibody approved for the treatment of HER2-positive overexpressing metastatic breast cancer. We are conducting Phase III trials for adjuvant treatment of early-stage breast cancer in patients who overexpress the HER2 protein. This product is being developed in collaboration with Hoffmann-La Roche.	2007
Tarceva	A small molecule tyrosine kinase inhibitor directed against epidermal growth factor receptor (or EGFR) for the potential treatment of solid tumors. We have initiated four Phase III clinical trials and numerous additional trials as part of the clinical development program. Two first-line Phase III studies of Tarceva plus standard chemotherapy in metastatic non-small cell lung cancer did not meet their primary endpoints of improving overall survival. Phase III trials are evaluating Tarceva for refractory non-small cell lung cancer and pancreatic cancer. This product is being developed in collaboration with OSI Pharmaceuticals and Hoffmann-La Roche.	2004-2005
Avastin	An antibody approved for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum. Phase III programs in renal cell carcinoma,	2005-2007

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Genentech, Inc. - Form 10-K for the period ending 12/31/2003

non-small cell lung cancer, and breast cancer are being conducted. This product is being developed in collaboration with Hoffmann-La Roche.

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Lucentis AMD (formerly rhuFab V2 AMD)	A customized fragment of an anti-VEGF antibody for the potential treatment of age-related macular degeneration (or AMD). We are in Phase III clinical trials for AMD. This product is being developed in collaboration with Novartis.	2005
Preparing for Phase III		
Rituxan	We are currently planning for Phase III clinical trials in systemic lupus eruthematosus, lupus nephritis and ANCA- associated vasculitis. This product is being developed in collaboration with Biogen Idec.	2004
Xolair	An antibody approved by the FDA for the treatment of moderate-to-severe persistent asthma in adults and adolescents. We are currently planning for Phase III clinical trials in pediatric asthma. This product is being developed in collaboration with Novartis and Tanox.	2004-2005
Avastin	We are currently planning for Phase III clinical trials in adjuvant colorectal cancer and pancreatic cancer. This product is being developed in collaboration with Hoffmann La Roche.	2004
Phase II		
Omnitarg (formerly 2C4 antibody)	An antibody directed against the human epidermal growth factor receptor, type 2 (or HER2) as a potential treatment for cancer. We are in Phase II clinical trials for ovarian cancer, prostate cancer, HER2 negative breast cancer, and non-small cell lung cancer. This product is being developed in collaboration with Hoffmann-La Roche.	2004-2006
Raptiva	An 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. XOMA is conducting a Phase II study in psoriatic arthritis. This product is being developed in collaboration with XOMA.	2004
Tarceva	We are in Phase II clinical trials for glioblastoma multiforme (brain cancer). This product is being developed in collaboration with OSI Pharmaceuticals and Hoffmann-La Roche.	2004-2005
Rituxan	We are in a Phase IIb clinical trial for the treatment of moderate-to-severe rheumatoid arthritis. This product is being developed in collaboration with Biogen Idec and Hoffmann La Roche.	2004-2005
Preparing for Phase II		
Xolair	We are currently planning for Phase II clinical trials in peanut allergy. This product is being developed in collaboration with Novartis and Tanox.	2004
Rituxan	We are currently planning for a Phase II clinical trial in multiple sclerosis. This product is being developed in collaboration with Biogen Idec.	2004

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Novartis Exhibit 2265.006 Regeneron v. Novartis, IPR2021-00816 Page 5

Preparing for Phase I		
PRO70769	A humanized anti-CD20 antibody that binds CD20 antigen that is predominantly expressed on B-lymphocytes. We filed an Investigational New Drug Application (or IND) in 2003 and expect to begin enrolling patients to a clinical trial for rheumatoid arthritis. This product is being developed in collaboration with Hoffmann-La Roche and Biogen Idec.	2004
PRO1762 (formerly Apo2L/TRAIL)	A recombinant soluble human protein involved in the regulation of apoptosis. We are preparing to file an IND in 2004. This product is being developed in collaboration with Immunex, a wholly-owned subsidiary of Amgen Inc., with whom we have an agreement for both development and commercialization of this potential product.	2004
VEGF	Vascular endothelial growth factor is being evaluated in diabetic wound healing.	2004-20

\* Note: For those projects preparing for a Phase, the estimated date of completion refers to the date the project enters that Phase for which it was preparing

#### **Collaboration Arrangements**

In December 2003, we entered into a non-exclusive long-term manufacturing agreement with Lonza Biologics, a subsidiary of Lonza Group Ltd, under which Lonza will manufacture commercial quantities of Rituxan for us at Lonza's production facility in Portsmouth, New Hampshire. We may be obligated to make milestone payments to Lonza subject to Lonza's achievement of a series of factory preparation and process validation milestones, as well as receipt of FDA approval for the manufacturing of Rituxan bulk drug at the Lonza facility; the amounts of such payments cannot be estimated at this time. Following FDA approval at the Lonza facility, it is expected that commercial production would begin in 2005.

In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under Hoffmann-La Roche's licensing agreement with us, which is discussed further in Part II, Item 7, "Relationship With Roche." As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 75% of subsequent global development costs related to the metastatic colorectal cancer indication of Avastin and all others unless Hoffmann-La Roche specifically opts out of the development of certain other indications. In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. (other than territory previously licensed to others) under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of subsequent global development of certain indications. We will receive royalties on net sales of Avastin and PRO70769 in countries outside of the U.S.

In June 2003, we entered into an agreement with Novartis Opthalmics, an affiliate of Novartis AG, under which Novartis Opthalmics licensed the exclusive right to develop and market Lucentis outside of North America for indications related to diseases of the eye. As part of this agreement, Novartis Opthalmics agreed to an upfront milestone and R&D reimbursement fee of \$46.6 million and will pay 50% of Genentech's ongoing Phase III and related development expenses. Genentech is not responsible for any portion of the development and commercialization costs incurred by Novartis outside of North America, but we may receive additional payments for Novartis' achievement of certain clinical development and product approval milestones outside of North America. In addition, we will receive royalties on net sales of Lucentis products, which we will manufacture and supply to Novartis, outside of North America.

In August 2002, we entered into an agreement with Serono S.A. which, in addition to granting Serono marketing rights in specific areas of the world, included an arrangement to co-develop additional indications of Raptiva and share certain global development costs. We also have a supply agreement with Serono, under which we may have a loss exposure up to a maximum of \$10.0 million.

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In the second quarter of 2002, we entered into a manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, to provide Immunex with additional manufacturing capacity for ENBREL® (etanercept) at Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we are responsible for facility modifications needed to manufacture ENBREL, including the internal labor costs and costs of certain raw materials for development runs. The facility modification and services costs, which include engineering and equipment costs, are reimbursable by Immunex. However, if certain milestones are not met, we are required to reimburse Immunex for up to 45% of the facility modification and services costs. Costs associated with development runs are reflected in R&D expense as incurred. Shipment of the product, including pre-approval product, to Immunex would be recorded as product sales based on

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### Novartis Exhibit 2265.007 Regeneron v. Novartis, IPR2021-00816

#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003

an agreed upon price with the associated costs reflected in cost of sales. In the fourth quarter of 2003, we determined that certain milestones, including obtaining FDA approval for the manufacturing process, would likely not be met in the pre-agreed upon timeframe. As a result, certain equipment paid for by us related to ENBREL manufacturing will not qualify for reimbursement by Immunex. Certain ENBREL-related equipment in our consolidated balance sheet will be depreciated over the estimated useful life of the equipment and certain of it will be depreciated over the term of the supply arrangement.

In April 1996, we entered into a research collaboration agreement with XOMA to develop and commercialize Raptiva. The agreement was subsequently modified in the first quarter of 2003 to provide a convertible equity loan to XOMA of up to \$80.0 million (outstanding at any one time) for its share of development costs for Raptiva through FDA approval, and a cash loan of up to \$15.0 million for its share of U.S. marketing and sales costs prior to the date of regulatory approval of Raptiva. On October 27, 2003, the FDA approved Raptiva for the treatment of chronic moderate-to-severe plaque psoriasis. Under the provisions of the agreement, XOMA elected to defer payment of \$40.0 million of the development loan, of which we had previously recognized \$11.9 million as an other-than-temporary impairment charge, as an offset against the proceeds from its share of U.S. operating profits on Raptiva. XOMA repaid the remaining development loan balance of approximately \$29.6 million, of which we had previously recognized \$8.8 million as an other-than-temporary impairment charge, with Series B preference shares. The Series B preference shares are convertible at our option into XOMA common shares at \$7.75 per share. As of December 31, 2003, the commercial loan balance was \$13.5 million, which will be repaid in cash through April 2004.

#### Distribution

We have a U.S.-based pharmaceutical marketing, sales and distribution organization. Our sales efforts are focused on specialist physicians in private practice or at hospitals and major medical centers in the United States. In general, our products are sold largely to wholesalers, specialty distributors or directly to hospital pharmaceus. We utilize common pharmaceutical company marketing techniques, including sales representatives calling on individual physicians and distributors, advertisements, professional symposia, direct mail, public relations and other methods.

Our products are also available at no charge to qualified patients under our uninsured patient programs in the United States. We have established the Genentech Endowment for Cystic Fibrosis to assist cystic fibrosis patients in the United States with obtaining Pulmozyme and the Genentech Access To Care Foundation for all other Genentech products.

We provide certain customer service programs relating to our products. We maintain a comprehensive patient-related product wastage replacement program for Rituxan, Activase and TNKase that, subject to specific conditions, provides customers the right to return these products to us for replacement. We also maintain expired product programs for all our products that, subject to certain specific conditions, provides customers the right to return products to us for replacement or credit for the price paid related to product expiration. We maintain the right to renew, modify or discontinue the above programs.

As discussed in the "Segment, Significant Customer And Geographic Information" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K, we had three major customers who individually provided over 10% of our total operating revenues in each of the last three years. Also discussed in the note are material net foreign revenues by country in 2003, 2002 and 2001.

#### **Raw Materials**

Raw materials and supplies required for the production of our principal products are available, in some instances from one supplier and in other instances, from multiple suppliers. In those cases where raw materials are only available through one supplier, such supplier may be either a sole source (the only recognized supply source available to us) or a single source (the only approved supply source for us among other sources). We have adopted policies to minimize raw material supply risks to the Company, including maintenance of greater levels of raw materials inventory and coordination with our collaborators to implement raw materials sourcing strategies.

#### **Proprietary Technology - Patents and Trade Secrets**

We seek patents on inventions originating from our ongoing research and development (or R&D) activities. Patents, issued or applied for, cover inventions ranging from basic recombinant DNA techniques to processes relating to specific products and to the products themselves. Our issued patents extend for varying periods according to the date of patent application filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. We have either been issued patents or have patent applications pending that relate to a number of current and potential products including products licensed to others. We consider that in the aggregate our patent applications, patents and licenses under patents owned by third-parties are of material importance to our operations. Important legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the United States and other important markets outside of the United States. We expect that litigation will likely be necessary to determine the validity and scope of certain of our proprietary rights. We are currently involved in a number of patent lawsuits, as either a plaintiff or defendant, and administrative proceedings relating to the scope of protection and validity of our patents and those of others. These lawsuits and proceedings may result in a significant commercial protection and proceedings we hold will afford us significant commercial protection.

In general, we have obtained licenses from various parties that we deem to be necessary or desirable for the manufacture, use or sale of our products. These licenses (both exclusive and non-exclusive) generally require us to pay royalties to the parties on product sales.

Our trademarks, Activase, Avastin, Cathflo, Herceptin, Lucentis, Nutropin, Nutropin Depot, Nutropin AQ, Nutropin AQ Pen, Omnitarg, Protropin, Pulmozyme, Raptiva, Rituxan (licensed from Biogen Idec), TNKase, Xolair (licensed from Novartis) and Tarceva (licensed from OSI), in the aggregate are considered to be of material importance. All are covered by registrations or pending applications for registration in the U.S. Patent and Trademark Office and in other countries. Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed, but renewable, terms.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Our royalty income for patent licenses, know-how and other related rights amounted to \$500.9 million in 2003, \$365.6 million in 2002, and \$264.5 million in 2001. Royalty expenses were \$244.6 million in 2003, \$204.4 million in 2002 and \$150.4 million in 2001.

#### Competition

We face competition from pharmaceutical companies, pharmaceutical divisions of chemical companies, and biotechnology companies of various sizes. Some competitors have greater clinical, regulatory and marketing resources and experience than we do. Many of these companies have commercial arrangements with other companies in the biotechnology industry to supplement their own research capabilities.

The introduction of new products or biogeneric versions of products or the development of new processes by competitors or new information about existing products may result in price reductions or product replacements, even for products protected by patents. However, we believe our competitive position is enhanced by our commitment to

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research leading to the discovery and development of new products and manufacturing methods. Other factors that should help us meet competition include ancillary services provided to support our products, customer service, and dissemination of technical information to prescribers of our products and to the health care community, including payers.

Over the longer term, our and our collaborators' abilities to successfully market current products, expand their usage and bring new products to the marketplace will depend on many factors, including but not limited to the effectiveness and safety of the products, FDA and foreign regulatory agencies' approvals of new products and indications, the degree of patent protection afforded to particular products, and the effect of managed care as an important purchaser of pharmaceutical products.

We face competition in five of our therapeutic markets. First, in the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to Centocor's Retavase® (approved in 1996 for the treatment of acute myocardial infarction) and to the use of mechanical reperfusion therapies to treat acute myocardial infarction; the resulting adverse effect on sales has been and could continue to be material. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. In addition, we face potential competition in the catheter clearance market from the reintroduction of Abbott Laboratories' Abbokinase® (urokinase) in October 2002.

Second, in the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. As a result of that competition, we have experienced a loss in market share in the past. Competitors have also received approval to market their existing growth hormone products for additional indications. As a result of this competition, market share of our growth hormone products may decline. In addition, we have certain patents related to the production of growth hormone that have expired and as a consequence those patents no longer exclude others from making growth hormone using the processes claimed by those patents. Any competitive entry as a result of expiration of our patents may cause further decline in our market share.

Third, in the non-Hodgkin's lymphoma market, Corixa Corporation received FDA approval in June 2003, for Bexxar<sup>TM</sup> (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan. Biogen Idec received marketing approval from the FDA and began commercial shipments in late March 2002 for Zevalin<sup>TM</sup> (ibritumomab tiuxetan), a product that could also potentially compete with Rituxan. Both Bexxar and Zevalin are radiolabeled molecules while Rituxan is not. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

Fourth, 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 Biogen Idec's biologic therapy Amevive® (alefacept), approved by the FDA in January 2003 for the treatment of moderate-to-severe psoriasis. Raptiva also competes with drugs approved for other indications that are used in psoriasis. Additional biologic therapies are expected to enter the psoriasis market in the next several years. ENBREL® (etanercept), marketed by Amgen and Wyeth in the U.S., is already approved for psoriatic arthritis, a condition associated with psoriasis. In the first quarter of 2003, Amgen announced positive phase III trial results using ENBREL for moderate-to-severe plaque psoriasis, and in July 2003 announced that ENBREL was filed for FDA approval to treat the condition. Other products are known to be in development for the psoriasis market.

Finally, Avastin may compete with Oxaliplatin. Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil ("5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with an irinotecan-based regimen, 5-FU/Leucovorin and CPT-11 (or "the Saltz Regimen"). In another Phase II trial, Avastin was found to provide benefit for first line patients when used in combination with 5-FU/Leucovorin alone. These regimens represent approximately 40% of all treatments used in the first-line setting. However, the use of these regimens is likely to decline as more physicians adopt Oxaliplatin-based regimens in the first-line setting. Avastin is currently being studied in combination with 5-FU/Leucovorin and Oxaliplatin (the "FOLFOX Regimen") in patients with relapsed, metastatic colorectal cancer in a large randomized study through the Eastern Cooperative Oncology Group (the "E3200 Trial"). If the results from the E3200 Trial are positive for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin or show a similar magnitude of benefit as previous colorectal cancer studies with Avastin, use of Avastin may increase as physicians

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increase their use of Avastin in combination with Oxaliplatin-based regimens in the relapsed, and also the first-line setting. However, if the results of the E3200 Trial are negative for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin, potential sales of Avastin may be materially adversely affected as physicians may limit their use of Avastin to irinotecan-based regimens. Physicians may also restrict their use of Avastin to first-line patients only.

#### **Government Regulation**

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of our products and in ongoing research and product development activities. All of our products require regulatory approval by governmental agencies prior to commercialization. In particular, our products are subject to rigorous preclinical and clinical testing and other premarket approval requirements by the FDA and regulatory authorities in other countries. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of such products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain or maintain, or any delay in obtaining or maintaining, regulatory approvals could materially adversely affect our business.

The activities required before a pharmaceutical product may be marketed in the United States begin with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application (or IND), which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the early safety profile and the pattern of drug distribution and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specified disease in order to provide enough data to statistically evaluate the preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large scale, multicenter, comparative clinical trials are conducted with a strateging of a chemical pharmaceutical product are then efficacy and safety of the FDA in the form of a New Drug Application (or NDA), or for a biological pharmaceutical product in the form of a Biologic License Application (or BLA), for approval to commerce commercial sales. In responding to a NDA or a BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. We can not assure you that any approval required by the FDA will be obtained on a timely basis, if at all.

Among the conditions for a NDA or a BLA approval, is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform on an ongoing basis with current Good Manufacturing Practices (or GMP). Before approval of a BLA, the FDA will perform a prelicensing inspection of the facility to determine its compliance with GMP and other rules and regulations. In complying with GMP, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance. After the establishment is licensed for the manufacture of any product, manufacturers are subject to periodic inspections by the FDA. Any determination by the FDA of manufacturing related deficiencies could materially adversely affect our business.

The requirements that we must satisfy to obtain regulatory approval by governmental agencies in other countries prior to commercialization of our products in such countries can be as rigorous, costly and uncertain.

We are also subject to various laws and regulations relating to safe working conditions, clinical, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of governmental regulation that might result from any legislative or administrative action cannot be accurately predicted.

The levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third-party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to

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governmental control. In the United States there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

In addition, in the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the physician or consumer from third-party payers, such as the government or private insurance plans. Government and private third-party payers are increasingly challenging the prices charged for medical products and services, through class action litigation and otherwise. For example, the Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003 (the "Medicare Act"), decreased the Medicare reimbursement rate for many drugs, including our oncology products, possibly offset to some extent by increased physician payment rates for drug administration services related to certain of our oncology products. It is unclear how these changes in reimbursement rates for products administered by oncologists in the office setting will affect physician prescribing practices and ultimately the sales of our products. Depending on changes in physician prescribing conduct or usage of the product as a result of this legislation or any future legislation limiting or decreasing drug reimbursement rates to physicians, sales of our products may be materially adversely affected. See "Decreases in Third Party Reimbursement Rates May Affect our Product Sales" under "Forward-Looking Information and Cautionary Factors that May Affect Future Results."

#### **Research and Development**

A major portion of our operating expenses to date is related to R&D. R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. R&D expenses were \$722.0 million in 2003, \$623.5 million in 2002, and \$526.2 million in 2001. Our R&D efforts have been the primary source of our products. We intend to maintain our strong commitment to R&D as an essential component of our product development effort. Licensed technology developed by outside parties is an additional source of potential products.

#### Human Resources

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As of December 31, 2003, we had 6,226 employees.

#### Environment

We seek to comply with all applicable statutory and administrative requirements concerning environmental quality. We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws have not had, and are not expected to have, a material effect on our capital expenditures, results of operation, or competitive position.

#### 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:

- 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 Good Operating Principles (Genentech's code of ethics applying to Genentech's directors, officers and employees) as well as Genentech's Code of Ethics applying to our chief executive officer and senior financial officials; and
- the charter of the Audit Committee of our Board of Directors.

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#### Item 2. PROPERTIES

Our primary facilities are located in a research and industrial park in South San Francisco, California in both leased and owned properties. In South San Francisco, we currently occupy 33 buildings for our research and development, manufacturing, marketing and administrative activities. Of the buildings, 19 are owned and 14 are leased. Of the 14 leased buildings, 4 were leased as of December 31, 2003, pursuant to synthetic lease arrangements. On January 2, 2004, upon the expiration of one of the synthetic leases, we purchased the related land and office building from our lessor at a cost of \$25.0 million. In late 2003, we purchased a building in Redwood City, California, to accommodate our data center. We have made and continue to make improvements to these properties to accommodate our growth.

We also lease a manufacturing facility in Vacaville, California. This property is leased pursuant to a synthetic lease arrangement and is consolidated in accordance with accounting rules adopted in 2003 and included in our property, plant and equipment in the accompanying consolidated balance sheet at December 31, 2003. See "Leases, Commitments and Contingencies" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for a discussion of our synthetic lease arrangements.

Outside of North America we are finishing construction on a cell culture manufacturing facility and a warehouse in Porrino, Spain for the manufacture of Avastin for clinical trials.

We also lease additional office facilities in several locations throughout the United States. We believe our facilities are in good operating condition and that the real property owned or leased are adequate for all present and near term uses. We have over 275,000 liters of installed fermentation capacity worldwide to support our current clinical and commercial production needs. Additionally, in December 2003, we entered into a non-exclusive long-term manufacturing agreement with Lonza to help us meet a portion of our Rituxan production requirements for the next several years. Additional manufacturing capacity may be added to Vacaville or other sites depending on the success of potential products in clinical trials. We believe our capital resources are sufficient to purchase or construct any additional facilities required to meet our long-term growth needs.

#### Item 3. LEGAL PROCEEDINGS

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

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, Genentech has 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. The first trial of this suit began on August 28, 2001. On October 24, 2001, the jury hearing the lawsuit announced that it was unable to reach a verdict and on that basis the Court declared a mistrial. COH requested a retrial, and the retrial began on March 20, 2002. On June 10, 2002, the jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, the 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 were included in litigation-related liabilities in the consolidated balance sheets at December 31, 2003 and 2002. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. The appeal process is ongoing. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

On June 7, 2000, Chiron Corporation filed a patent infringement suit against us in the U.S. District Court in the Eastern District of California (Sacramento), alleging that the manufacture, use, sale and offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 6,054,561. This patent was granted on April 25, 2000, and will expire on June 28, 2005, and it relates to certain antibodies that bind to breast cancer cells and/or other cells. Chiron is seeking compensatory damages for the alleged infringement, additional damages (e.g., for

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willful infringement), and attorneys' fees and costs. On April 22, 2002, the Court issued its decision ("Markman Order") construing certain aspects of the patent claims that are in dispute. On June 25, 2002, the Court issued several decisions regarding summary judgment motions that previously had been filed by Chiron and us. In those decisions, the Court ruled as a matter of law that Herceptin infringes claims 1 to 25 of Chiron's patent, and also ruled as a matter of law in favor of Chiron on some but not all of Genentech's defenses and counterclaims regarding the alleged invalidity and/or unenforceability of the patent. The trial of this suit began on August 6, 2002. Following the first phase of the trial, which related to Genentech's remaining defenses and counterclaims regarding the alleged invalidity of the patent, the jury unanimously found that claims 1 to 25 of Chiron's patent were invalid, and on that basis the Court entered judgment in favor of Genentech. Chiron filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit, and Genentech filed a notice of cross-appeal. The appeal process is ongoing and therefore the outcome of this matter cannot be determined at this time.

On August 12, 2002, the U.S. Patent and Trademark Office (or Patent Office) declared an interference between the Chiron patent involved in the above-mentioned lawsuit (U.S. Patent No. 6,054,561) and a patent application exclusively licensed by Genentech from a university relating to anti-HER2 antibodies. An interference proceeding is declared to decide who first made a particular invention where two or more parties claim the same invention, whether the parties' claims are patentable, and consequently who is or is not entitled to a patent on the invention. In declaring this interference, the Patent Office has determined that there is a substantial question as to whether the inventors of the Chiron patent were first to invent and are entitled to this patent. If the Patent Office were to decide that the inventors of the university's patent application were first to invent and that their claims are patentable, a new patent would be issued to the university and the Chiron patent application, a number of patent and patent applications owned by either Chiron or Genentech, including Chiron's U.S. Patent No. 4,753,894 that is also at issue in the separate patent infringement lawsuit described below. The interference proceeding is ongoing and therefore the outcome of this matter cannot be determined at this time.

On March 13, 2001, Chiron filed another patent infringement lawsuit against us in the U.S. District Court in the Eastern District of California, alleging that the manufacture, use, sale and/or offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 4,753,894. Chiron is seeking compensatory damages for the alleged infringement, additional damages, and attorneys' fees and costs. Genentech filed a motion to dismiss this second lawsuit, which was denied. On November 1, 2002, the parties filed a proposed stipulation to stay all proceedings in this lawsuit until (1) the interference involving U.S. Patent No. 4,753,894 is resolved or (2) two years from entry of the proposed stipulation, whichever is sooner. On or about November 13, 2002, the Court entered the stipulation, staying the proceedings as requested by the parties. This lawsuit is separate from and in addition to the Chiron suit mentioned above.

We and Tanox Biosystems, Inc. (or Tanox) are parties to a July 1996 Settlement and Cross-Licensing Agreement relating to the development and manufacture of certain antibody products directed towards immunoglobin E, including Xolair and Hu-901. On February 20, 2002, Tanox filed an amended demand in an ongoing arbitration proceeding between Genentech and Tanox that is being conducted by the American Arbitration Association in San Francisco. In its amended demand, Tanox has claimed breach of the July 1996 Agreement, conversion, tortious interference, unjust enrichment, and unfair competition by Genentech, and requests injunctive relief as well as monetary damages "many times in excess of \$100,000,000." On March 14, 2002, Genentech denied all of Tanox's claims, and counterclaimed for breach of contract, theft of trade secrets, misappropriation, breach of confidence, interference with contract, and interference with economic expectancies by Tanox. Genentech requested injunctive relief and monetary damages. On October 16, 2002, Tanox announced that in a dispute between it and Novartis, an arbitration panel ruled that Tanox is not entitled to develop independently the Hu-901 antibody product. The Novartis/Tanox panel also ruled that Tanox is entitled to receive certain know-how from Novartis. Tanox arbitration, if any, on Tanox's claims against Genentech cannot be determined since the arbitrators in the Tanox/Genentech proceedings have not yet resolved it. As a general matter, the claims are divided into two categories: (1) compensation for lost rights under agreements with Genentech and Novartis, and (2) additional royalties on future sales. On February 25, 2004, the parties settled and agreed to dismiss with prejudice all claims from the arbitration that began on January 13, 2003.

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On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, City of Hope National Medical Center (or COH), and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 ("the '415 patent") that is co-owned by Genentech and COH and under which MedImmune and other companies have been licensed and are paying royalties to Genentech. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking to have the '415 patent declared 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 Genentech from enforcing the '415 patent, an award of actual and exemplary damages, and other relief. Genentech intends to vigorously defend itself against all of the allegations and claims in this lawsuit. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in Genentech's favor on all of MedImmune's antitrust and unfair competition claims. MedImmune is seeking to amend its complaint to reallege certain claims for antitrust and unfair competition and the case on the remaining claims is ongoing and trial is currently set to begin on August 30, 2004. An estimate of any potential loss or range of loss cannot be made at this time.

We recorded \$53.9 million in 2003 for accrued interest and bond costs related to the COH trial judgment. In 2002, we recognized \$543.9 million of litigationrelated special charges, which included the COH trial judgment, including accrued interest and bond costs, and certain other litigation-related matters. In conjunction with the COH trial judgment, in the second quarter of 2002 we posted a \$600.0 million surety bond and as part of this arrangement, we were required to pledge \$630.0 million in cash and investments to secure the bond. The \$630.0 million cash and investments were classified as restricted cash and investments on our consolidated balance sheets at December 31, 2003 and 2002. In addition, we accrued \$4.7 million in 2003 and \$9.1 million in 2002 of royalty expenses related to the COH trial judgment, which were reflected in marketing, general and administrative expenses. We expect that we will continue to incur interest charges on the

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judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results. These special charges represent our best estimate of the costs for the current resolution of these matters and are included in litigation and other long-term liabilities in the consolidated balance sheets at December 31, 2003 and 2002. We developed this estimate in consultation with outside counsel handling our defense in these matters using the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

See the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding our litigations.

#### Litigation Settlement

In August 2003, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately \$0.19 in earnings per diluted share for 2003 and was reported as a litigation-related special item in our consolidated statements of income. In November 2003, we received a settlement payment from Bayer, one of our licensees, in connection with the settlement of a breach of contract action, which resulted in an increase of approximately \$0.03 in earnings per diluted share for 2003 and was reported as a litigation-related special item.

#### Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

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#### **Executive Officers of the Company**

The executive officers of the Company and their respective ages (ages as of December 31, 2003) and positions with the Company are as follows:

Name	Age	Position
Arthur D. Levinson, Ph.D.*	53	Chairman, President and Chief Executive Officer
Susan D. Desmond-Hellmann, M.D., M.P.H.*	46	Executive Vice President, Development and Product Operations and Chief Medical Officer
Stephen G. Juelsgaard, J.D.*	55	Executive Vice President, General Counsel and Secretary
Louis J. Lavigne, Jr.*	55	Executive Vice President and Chief Financial Officer
Myrtle S. Potter*	45	Executive Vice President, Commercial Operations and Chief Operating Officer
Richard H. Scheller, Ph.D.*	50	Executive Vice President, Research
David A. Ebersman	34	Senior Vice President, Product Operations
Robert L. Garnick, Ph.D.	54	Senior Vice President, Regulatory, Quality and Compliance
John M. Whiting	48	Vice President, Controller and Chief Accounting Officer

\* Members of the Executive Committee of the Company

The Board of Directors elects all officers annually. There is no family relationship between or among any of the officers or directors.

#### **Business Experience**

*Arthur D. Levinson, Ph.D.* was appointed Chairman of the Board of Directors in September 1999 and was elected President and Chief Executive Officer and a director of the Company in July 1995. Since joining the Company in 1980, Dr. Levinson has been a Senior Scientist, Staff Scientist and Director of the Company's Cell Genetics Department. Dr. Levinson was appointed Vice President of Research Technology in April 1989, Vice President of Research in May 1990 and Senior Vice President in January 1993. Dr. Levinson was formerly on the editorial boards of "Molecular Biology and Medicine" and "Molecular and Cellular Biology," and is active in the American Society of Microbiology, the New York Academy of Sciences, the American Association for the Advancement of Science, and the American Society for Biochemistry and Molecular Biology. From 1977 to 1980, Dr. Levinson was a Postdoctoral Fellow in the Department of Microbiology at the University of California, San Francisco. In 1977, Dr. Levinson received his Ph.D. in Biochemistry from Princeton University. Dr. Levinson also serves as a member of the Board of Directors of Apple Computer, Inc.

Susan D. Desmond-Hellmann, M.D., M.P.H. was appointed Executive Vice President, Development and Product Operations in September 1999. She has served as Chief Medical Officer since December 1996. She previously served as Senior Vice President, Development from December 1997 until September 1999, among other positions, since joining Genentech in March 1995 as a Clinical Scientist. Prior to joining Genentech, she held the position of Associate Director at Bristol-Myers Squibb.

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Stephen G. Juelsgaard, J.D. was appointed Executive Vice President in September 2002, Vice President and General Counsel in July 1994 and Secretary in April 1997. He joined Genentech in July 1985 as Corporate Counsel and subsequently served as Senior Corporate Counsel from 1988 to 1990, Chief Corporate Counsel from 1990 to 1993, Vice President, Corporate Law from 1993 to 1994, Assistant Secretary from 1994 to 1997 and Senior Vice President from April 1998 to September 2002.

*Louis J. Lavigne, Jr.* was appointed Executive Vice President of Genentech in March 1997 and Chief Financial Officer in August 1988. He previously served as Senior Vice President from July 1994 to March 1997 and as Vice President from July 1986 to July 1994. Mr. Lavigne joined Genentech in July 1982 from Pennwalt Corporation and became Controller in May 1983 and an officer of Genentech in February 1984.

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*Myrtle S. Potter* was appointed Executive Vice President, Commercial Operations and Chief Operating Officer in May 2000. Prior to joining Genentech, she held the positions of President of U.S. Cardiovascular/Metabolics from November 1998 to May 2000, Senior Vice President of Sales, U.S. Cardiovascular/Metabolics from March 1998 to October 1998, Group Vice President of Worldwide Medicines Group from February 1997 to February 1998 and Vice President of Strategy and Economics, U.S. Pharmaceutical Group from April 1996 to January 1997 at Bristol-Myers Squibb. Previously, she held the position of Vice President of the Northeast Region Business Group at Merck & Co., Inc. from October 1993 to March 1996.

*Richard H. Scheller, Ph.D.* was appointed Executive Vice President, Research in September 2003. Previously, he served as Senior Vice President, Research from March 2001 to September 2003. Prior to joining Genentech, he served as Professor of Molecular and Cellular Physiology and of Biological Sciences at Stanford University Medical Center from September 1982 to February 2001 and as an investigator at the Howard Hughes Medical Institute from September 1990 to February 2001. He received his first academic appointment to Stanford University in 1982. He was appointed to the esteemed position of professor of Molecular and Cellular Physiology in 1993 and as an investigator in the Howard Hughes Medical Institute in 1994.

David A. Ebersman was appointed Senior Vice President, Product Operations in May 2001. He joined Genentech in February 1994 as a Business Development Analyst and subsequently served as Manager, Business Development from February 1995 to February 1996, Director, Business Development from February 1996 to March 1998, Senior Director, Product Development from March 1998 to February 1999 and Vice President, Product Development from February 1999 to May 2001. Prior to joining Genentech, he held the position of Research Analyst at Oppenheimer & Company, Inc.

*Robert L. Garnick, Ph.D.* was appointed Senior Vice President, Regulatory, Quality and Compliance in February 2001. Previously, he served as Vice President, Regulatory Affairs from February 1998 to February 2001, Vice President, Quality from April 1994 to February 1998, Senior Director, Quality Control from 1990 to 1994 and Director, Quality Control from 1988 to 1990. He joined Genentech in August 1984 from Armour Pharmaceutical, where he held various positions.

John M. Whiting was appointed Vice President in January 2001 and Controller and Chief Accounting Officer in October 1997. He previously served as Director, Financial Planning and Analysis from January 1997 to October 1997 and as Director, Operations, Financial Planning and Analysis from December 1996 to January 1997. He also served in a variety of financial positions at Genentech from 1989 to 1996. Prior to joining Genentech, he served as Senior Audit Manager at Arthur Young.

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#### PART II

## Item 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

See the footnotes labeled "Redemption of Our Special Common Stock," "Relationship With Roche" and "Capital Stock" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

#### Stock Trading Symbol: DNA

#### Stock Exchange Listing

Our Common Stock trades on the New York Stock Exchange under the symbol "DNA." No dividends have been paid on the Common Stock. We currently intend to retain all future income for use in the operation of our business and for future stock repurchases and, therefore, do not anticipate paying any cash dividends in the foreseeable future.

#### **Common Stockholders**

As of December 31, 2003, there were approximately 1,921 stockholders of record of our Common Stock, one of which is Cede & Co., a nominee for Depository Trust Company (or DTC). All of the shares of Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are

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deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder.

#### Stock Prices

	Common Stock							
	20	03	2002					
	High	Low	High	Low				
4 <sup>th</sup> Quarter	\$ 95.35	\$ 76.29	\$ 36.85	\$ 29.50				
3rd Quarter	88.00	70.30	37.49	25.10				
2 <sup>nd</sup> Quarter	77.50	33.80	52.44	30.02				
1 <sup>st</sup> Quarter	39.75	31.53	55.15	45.72				

#### Stock Repurchases

See the "Capital Stock" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for information on our stock repurchases.

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#### SELECTED FINANCIAL DATA

#### Item 6.

The following selected consolidated financial information has been derived from the audited consolidated financial statements. The information below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-K and the consolidated financial statements and related notes thereto included in Item 8 of this Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

#### SELECTED CONSOLIDATED FINANCIAL DATA (in millions, except per share amounts)

			,									
		2003		2002		2001		2000		199	99	
									De	New Basis (June 30 to ecember 31) <sup>(9)</sup>		Old Basis (January 1 to June 30) <sup>(9)</sup>
Total operating revenues <sup>(1)</sup>	\$3	3,300.2	\$ 2	,583.7	\$ 2	2,044.1	\$ 1	,514.2	\$	653.6	\$	638.6
Product sales		2,621.4	2	,163.6	]	1,742.9	1	,278.3		535.7		503.4
Royalties		500.9		365.6		264.5		207.3		96.7		92.6
Contract revenue		177.9		54.5		36.7		28.6		21.2		42.6
Income before cumulative effect of accounting changes Cumulative effect of	\$	610.1	\$	63.8	\$	155.9	\$	(16.4)	\$ (1	1,245.1)	\$	87.6
accounting changes, net of tax		(47.6)(3)		-		(5.6)(6)		(57.8)(8)		-		-
Net income (loss) <sup>(2)</sup>	\$	562.5 (3)	\$	63.8 (5)	\$	150.3 (6)	\$	(74.2)(8)	\$ (	1,245.1)(10)	\$	87.6 (12)
Basic earnings (loss) per share Diluted earnings (loss) per share	\$	1.09 1.06	\$	0.12 0.12	\$	0.29 0.28	\$	(0.14) (0.14)	\$	(2.43) (2.43)	\$	0.17 0.16
Total assets	\$ 8	3,736.2 (4)	\$ 6.	,758.1	\$ 7	7,146.9	\$ <del>(</del>	5,728.4	\$	6,549.8		-
Long-term debt		412.3 (4)		- (7)		- (7)		149.7		149.7		-

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	Stockholders' equity	6,520.3	5,338.9	5,919.8	5,674.2	5,269.8 (11)		

We have paid no dividends

All per share amounts reflect two-for-one stock splits that were effected in 2000 and 1999

- (1) Effective January 1, 2003, we made certain classification changes to our consolidated statements of income Comparable amounts in prior years have been reclassified to conform to the 2003 presentation For more information on our classification changes, see the "Description of Business and Summary of Significant Accounting Policies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K
- (2) Net income (loss) includes recurring charges of \$154 3 million in 2003, \$155 7 million in 2002, \$321 8 million in 2001 and \$375 3 million in 2000 related to the June 30, 1999 redemption of our special common stock (or the Redemption) See Note (10) below for the redemption charges in 1999
- (3) Net income in 2003 includes litigation settlements with Amgen, Inc and Bayer, net of accrued interest and bond costs related to the City of Hope litigation judgment Net income in 2003 also reflects our adoption of the Financial Accounting Standards Board Interpretation No 46 (or FIN 46), "Consolidation of Variable Interest Entities," on July 1, 2003, which resulted in a \$47 6 million charge, net of \$31 8 million in taxes, (or \$0 09 per share) as a cumulative effect of an accounting change in 2003
- (4) Upon adoption of FIN 46, we consolidated the entity from which we lease our manufacturing facility located in Vacaville, California Accordingly, we have included \$348 4 million of assets in property, plant and equipment at December 31, 2003 We also consolidated the entity's debt of \$412 3 million and noncontrolling interests of \$12 7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, at December 31, 2003
- (5) Net income in 2002 includes \$543 9 million of litigation-related special charges, which are comprised of the City of Hope litigation judgment in the second quarter of 2002, and accrued interest and bond costs, and certain other litigation-related matters. Net income in 2002 also reflects our adoption of Statement of Financial Accounting Standards (or FAS) 141 and 142 on January 1, 2002 As a result of our adoption, reported net income increased by approximately \$157 6 million (or \$0 30 per share) due to the cessation of goodwill amortization and the amortization of our trained and assembled workforce intangible asset

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- (6) Net income in 2001 reflects a \$5 6 million charge (net of \$3 8 million in taxes) as a cumulative effect of a change in accounting principle and changes in fair value of certain derivatives (\$10 0 million gain) recorded in "other income, net" as a result of our adoption of FAS 133 on January 1, 2001
- (7) The \$149 7 million of convertible subordinated debentures was reclassified to current liabilities in 2001 to reflect the March 27, 2002 maturity. We redeemed the debentures in cash at maturity
- (8) Net loss in 2000 includes costs of \$92 8 million related to the sale of inventory that was written up at the Redemption and a \$57 8 million (net of \$38 5 million in taxes) cumulative effect of a change in accounting principle as a result of our adoption of Securities and Exchange Commission's Staff Accounting Bulletin No 101, "Revenue Recognition in Financial Statements" on January 1, 2000
- (9) The June 30, 1999 Redemption created our New Basis of accounting The Redemption was effective as of June 30, 1999; however, the transaction was reflected as of the end of the day on June 30, 1999 in the financial statements As such, a vertical black line is inserted to separate the "Old Basis" presentation Accordingly, the Old Basis reflects the period January 1 through June 30, 1999, and all periods prior to the Redemption, and the New Basis reflects the period from June 30 through December 31, 1999, and all subsequent periods
- (10) Net loss for the period from June 30, 1999 to December 1999, New Basis, includes all amounts related to the Redemption of our Special Common Stock transaction. The net loss includes charges of \$1,207 7 million related to the Redemption, legal settlements of \$180 0 million, recurring charges of \$197 7 million related to the Redemption and costs of \$93 4 million related to the sale of inventory that was written up at the Redemption
- (11) Reflects the impact of the Redemption and related push-down accounting of \$5,201 9 million of excess purchase price over net book value, net of charges and accumulated amortization of goodwill and other intangible assets at December 31, 1999
- (12) Net income for the period from January 1, 1999 to June 30, 1999, Old Basis, includes charges of \$50 0 million related to legal settlements

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### Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

In 2003, we delivered strong top-line and bottom-line growth. Operating revenues for 2003 increased 28 percent to more than \$3 billion. Diluted earnings per share for 2003 increased to \$1.06 per share compared to 12 cents per share for 2002, and net income for 2003 increased to \$562.5 million compared to \$63.8 million for 2002. Our financial position remains strong, with approximately \$2.9 billion in unrestricted cash and marketable securities.

Key commercial successes in 2003 include total product sales of \$2.6 billion, a 21 percent increase over 2002. Our marketed products continue to drive performance, with every product reporting growth in 2003. Total oncology sales increased 24 percent over 2002 and now constitute 73 percent of total product sales. In addition, 2003 included the approval and launch of two new products for immunological diseases, Xolair® (Omalizumab) for persistent asthma and Raptiva<sup>TM</sup> (efalizumab) for chronic plaque psoriasis. We launched Xolair in July 2003 and Raptiva in November 2003.

On our product development efforts, after receiving positive results from the pivotal trial of Avastin<sup>TM</sup> (bevacizumab) in first-line metastatic colorectal cancer, we filed the Biologics License Application (BLA) and received priority review status from the U.S. Food and Drug Administration (FDA). In early 2004, we received FDA approval for Avastin for use in combination with intravenous 5-fluorourcil-based chemotherapy as a treatment for patients with first-line - or previously untreated - metastatic cancer of the colon or rectum. Avastin is the first FDA-approved therapy designed to inhibit angiogenesis, the process by which new blood vessels develop, which is necessary to support tumor growth and metastasis. Finally, we filed a supplemental New Drug Application (sNDA) for the additional

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indication of Nutropin® [somatropin (rDNA origin) for injection]/Nutropin AQ® [somatropin (rDNA origin) injection] for the long-term treatment of idiopathic short stature.

Our development pipeline has over 20 projects in various stages. In 2003, we and our collaborators began enrollment in multiple clinical trials, including Rituxan® (Rituximab) for rheumatoid arthritis, Lucentis<sup>™</sup> (ranibizumab) for age-related macular degeneration, Avastin and Omnitarg<sup>™</sup> (pertuzumab) in multiple tumor types, and Raptiva for psoriatic arthritis. We also entered more than 10 new projects into our development portfolio, including two new molecular entities: the fully humanized anti-CD20 antibody, which we will jointly develop with Biogen Idec and F. Hoffmann-La Roche Ltd (or Hoffmann-La Roche), an affiliate of Roche, and PRO1762 (formerly Apo2L/TRAIL), which we will jointly develop with Immunex, a subsidiary of Amgen, Inc.

We also finalized several business development agreements in 2003, including agreements with: Novartis Ophthalmics for ex-North American marketing of Lucentis for age-related macular degeneration; Biogen Idec Inc. for the development of one or more new humanized anti-CD20 antibodies for a broad range of diseases; Biogen (now Biogen Idec) for research and development of a BR3 modulator; Curis for a molecule in the hedgehog signaling pathway; and Lonza Group Ltd. for third-party manufacturing of Rituxan.

On the operations front, both our South San Francisco and Vacaville facilities have ramped up manufacturing efforts in order to meet the increased product demand. As mentioned above, we entered into a long-term manufacturing agreement with Lonza Biologics, under which Lonza will manufacture commercial quantities of Rituxan at Lonza's production facility in Portsmouth, New Hampshire. Finally, we made progress on our facility in Porriño, Spain (Genentech España) and now expect to bring it online in 2004 to produce Avastin for clinical trials. Both projects are important to have sufficient capacity to meet expected demand for our products.

In terms of our ongoing research projects, we continue our work in oncology, including our Tumor Antigen Program and mechanism of action studies. Angiogenesis also remains an important and broad arena of study for us, not only in oncology but also in vascular biology. Immunology is a growing area of expertise and emphasis for Genentech, and we are exploring several promising areas of research, including TNF (tumor necrosis factor) super family members, autoimmunity, transplant issues and allergy/asthma. Finally, we are developing a focus on diagnostics for our novel, targeted treatments in order to strive to increase development success rates in our clinical trials and deliver the right drugs to the right patients.

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In 2003, we were involved in challenges over contracts and intellectual property. We were able to resolve or make substantial progress in resolving several major contract differences through confidential negotiations. We settled our patent litigation with Amgen, resulting in a one-time payment to Genentech, increasing earnings per diluted share for 2003 by approximately \$0.19. We also settled our litigation with Bayer for a one-time payment from that company. On February 25, 2004, Genentech, Novartis Pharma AG and Tanox, Inc. agreed that they have settled all litigation among them and finalized the detailed terms of their three-party collaboration.

#### **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 consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our 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. Actual results could differ materially from these estimates.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

#### Legal Contingencies

We are currently involved in certain legal proceedings as discussed in the "Leases Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K. We assess the likelihood of any adverse judgments or outcomes to these legal matters as well as potential ranges of probable losses. As of December 31, 2003, we have accrued \$608.3 million, which represents our estimate of the costs for the current resolution of these matters. We developed these estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances known to us at that time. 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 outcome of these matters. An outcome of such matters different than previously estimated could materially impact our financial position or our results of operations in any one quarter.

#### **Revenue Recognition**

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenue arrangements with 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, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated uncollectible amounts, product returns and discounts.
- 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 reliably measured and collectibility is reasonably assured. Royalty estimates are made in advance of

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amounts collected using historical and forecasted trends.

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- Contract revenue generally includes upfront and continuing licensing fees, manufacturing fees, milestone payments and reimbursements of development costs and post-marketing costs.
  - 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 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.
  - Manufacturing fees are recognized as revenue as the related manufacturing services are rendered, generally on a straight-line basis over the longer of the manufacturing obligation period or the expected product life.
  - Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
  - · Reimbursements of development and post-marketing costs are recognized as revenue as the related costs are incurred.

#### Income Taxes

Income tax expense (benefit) is based on pretax financial accounting income under 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 enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision (benefit) for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. We believe that our estimates are reasonable and that our reserves for income tax related uncertainties are adequate. Various internal and external factors may have favorable or unfavorable effects on our future effective 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, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings.

#### Inventories

Inventories consist of currently marketed products, products manufactured under contract and product candidates awaiting regulatory approval, which are capitalized based on management's judgment of probable near term commercialization. The valuation of inventory requires us to estimate obsolete or excess inventory. The determination of obsolete or excess inventory requires us to estimate the future demands for our products, and in the case of pre-approval inventories, an estimate of the regulatory approval date for the product. We may be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies.

#### Nonmarketable Equity Securities

As part of our strategic efforts to gain access to potential new products and technologies, we invest in equity securities of certain private biotechnology companies. Our nonmarketable equity securities are carried at cost unless we determine that an impairment that is other than temporary has occurred, in which case we write the investment

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down to its impaired value. We periodically review our investments for impairment; however, the impairment analysis requires significant judgment in identifying events or circumstances that would likely have significant adverse effect on the fair value of the investment. The analysis may include assessment of the investee's (i) revenue and earnings trend, (ii) business outlook for its products and technologies, (iii) liquidity position and the rate at which it is using its cash, and (iv) likelihood of obtaining subsequent rounds of financing. If an investee obtains additional funding at a valuation lower than our carrying value, we presume that the investment is other than temporarily impaired. We have experienced impairments in our portfolio due to the decline in equity markets over the past few years. However, we are not able to determine at the present time which specific investments are likely to be impaired in the future, or the extent or timing of the individual impairments.

#### Results of Operations

(in millions, except per share amounts)

Annual Percent Change

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	Genentech, Inc	Forn	n 10-K for	the p	eriod ending	g 12/31/2003	
	2003		2002		2001	2003/2002	2002/2001
Product sales	\$ 2,621.4	\$	2,163.6	<b>\$</b> 1	,742.9	21 %	24 %
Royalties	500.9		365.6		264.5	37	38
Contract revenue	177.9		54.5		36.7	226	49
Total operating revenues	\$ 3,300.2	\$	2,583.7	\$2	2,044.1	28 %	26 %
Cost of sales	\$ 480.1	\$	441.6	\$	354.5	9 %	25 %
Research and development	722.0		623.5		526.2	16	18
Marketing, general and administrative	794.8		546.2		446.9	46	22
Collaboration profit sharing	457.5		350.7		246.7	30	42
Recurring charges related to redemption	154.3		155.7		321.8	(1)	(52)
Special items: litigation-related	(113.1)		543.9		-	*	*
Total costs and expenses	\$ 2,495.6	\$	2,661.6	\$1	,896.1	(6)%	40 %
Operating margin	\$ 804.6	\$	(77.9)	\$	148.0	*	*
Other income, net	92.8		107.7		135.0	(14)	(20)
Income before taxes and cumulative							
effect of accounting changes	897.4		29.8		283.0		
Income tax provision (benefit)	287.3		(34.0)		127.1		
Income before cumulative effect of accounting changes	610.1		63.8		155.9		
Cumulative effect of accounting changes net of tax	(47.6)		-		(5.6)		
Net income	\$ 562.5	\$	63.8	\$	150.3		
Pre-tax operating margin as a % of operating revenues	24 9	2/0	(3)%	ź	7 %		
COS as a % of product sales	18		20	-	20		
R&D as a % of operating revenues	22		24		26		
MG&A as a % of operating revenues	24		21		22		
NI as a % of operating revenues	17		2		7		

Certain reclassifications were made in 2002 and 2001 to conform to the 2003 presentation Percentages in this table and throughout our discussion and analysis of financial condition and results of operations may reflect rounding adjustments

\* Calculation not meaningful

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#### **Total Operating Revenues**

Total operating revenues increased 28% to \$3,300.2 million in 2003 and 26% to \$2,583.7 million in 2002. Increases in both years were driven by all components of operating revenues, in particular, higher product sales. These revenue increases are further discussed below (in millions).

				Annual	Percent Change
Product Sales	2003	2002	2001	2003/2002	2002/2001
Rituxan	\$ 1,489	9.1 \$ 1,162	.9 \$ 818.6	28 %	42 %

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	Herceptin	424.8	385.2	346.7	10	11
	Growth Hormone	321.9	297.2	250.2	8	19
	Thrombolytic	185.2	180.2	197.1	3	(9)
	Pulmozyme	167.2	138.1	123.0	21	12
	Actimmune	-	-	7.3	-	-
	Xolair	25.3	-	-	-	-
	Raptiva	1.4	-	-	-	-
	Product manufactured under contract	6.5	-	-	-	-
	Total product sales	\$ 2,621.4	\$ 2,163.6	\$ 1,742.9	21 %	24 %
	Product sales as a % of total operating revenues	79 %	84 %	85 %		

#### **Total Product Sales**

Total net product sales increased 21% to \$2,621.4 million in 2003 and 24% to \$2,163.6 million in 2002. In both years, the increases were due to higher sales across most products, in particular Rituxan. Combined sales of our bio-oncology products, Rituxan and Herceptin, represented 73% of total product sales in 2003, 72% in 2002, and 67% in 2001. Increased sales volume for our products accounted for a 16% increase, or \$337.9 million in 2003, and higher sales prices accounted for the remainder of the increase. Increased sales volume for our products accounted for a 20% increase, or \$343.3 million in 2002, and higher sales prices accounted for the remainder of the increase. See "Relationship With Roche" and "Related Party Transactions" below for further information about our licensing agreement with and revenue from Hoffmann-La Roche.

#### Rituxan

Net sales of Rituxan increased 28% to \$1,489.1 million in 2003 and 42% to \$1,162.9 million in 2002. These increases were primarily driven by higher worldwide sales volume due to increased use of the product for the treatment of B-cell non-Hodgkin's lymphoma in indolent and aggressive non-Hodgkin's lymphoma (or NHL), as well as chronic lymphocytic leukemia (or CLL), used in both monotherapy and combination therapy settings. Rituxan's average overall adoption rate in the combined NHL and CLL markets showed modest growth in 2003. In addition to the above factors, we implemented price increases in both 2003 and 2002, which contributed, to a lesser extent, to the increases.

The current approved label indication is for relapsed or refractory, low grade or follicular NHL. At the 2003 American Society of Hematologists (ASH) meeting, positive data on use of Rituxan in the indolent front line setting were presented. A U.S. Cooperative Group study of Rituxan in the indolent front line NHL setting (ECOG 1496) and an international study of Rituxan in aggressive front line NHL (the MabThera International Trial sponsored by Roche) both reached their efficacy endpoints earlier than planned and were therefore stopped. We expect these factors to continue to positively impact Rituxan sales in 2004, however, the rate of sales growth is expected to be more modest than that seen in 2003 and 2002. Furthermore, future sales of Rituxan may be adversely affected if physicians prescribe less of Rituxan in light of the decrease in the Rituxan reimbursement rate under the Medicare Prescription Drug Improvement and Modernization Act, enacted December 2003 (or the Medicare Act). However, given Rituxan's unique clinical benefits and lack of a direct substitute therapy, we currently believe there will be limited impact on its usage.

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#### Herceptin

Net sales of Herceptin increased 10% to \$424.8 million in 2003 and 11% to \$385.2 million in 2002. The 2003 increase was driven by multiple factors, including treating more patients, extending the average treatment duration and a price increase. These increases were slightly offset by a decrease in ex-U.S. Herceptin sales from 2002. First-line penetration has remained stable. However, there has been an increase in the use of Herceptin in more than one line of therapy and we expect this to lead to continued growth in 2004. The increase in 2002 was primarily due to an increase in first-line use in the metastatic breast cancer market and the extension of the average treatment duration. While there was a price increase on sales of Herceptin in the U.S. in 2002, this increase was partially offset by a decrease in the price at which we sell the product to Hoffmann-La Roche. Furthermore, future sales of Herceptin may be adversely affected if physicians prescribe less Herceptin in light of the decrease in the Herceptin reimbursement rate under the Medicare Act. However, we currently believe there will be limited impact on Herceptin's usage, particularly in light of the increase in drug administration services reimbursement rates.

In late September 2002, Hoffmann-La Roche received approval from the European Committee for Proprietary Medicinal Products to manufacture Herceptin at its Penzberg, Germany facility. During 2003, the Penzberg facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories.

#### Growth Hormone

Combined net sales of our four growth hormone products, Nutropin Depot, Nutropin AQ, Nutropin, and Protropin, increased 8% to \$321.9 million in 2003 and 19% to \$297.2 million in 2002. The net sales growth resulted from continued strong demand for the products and price increases. The price increase in 2003 accounted for a more significant portion of the growth in 2003 than our 2002 price increase did in 2002. The continued strong demand reflects our focus on new

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patient starts using our Nutropin AQ Pen (which is a delivery system, launched in July 2002, for Nutropin AQ), continued growth in the adult patient market, higher dosing during puberty and an incremental increase in the length of therapy. Nutropin Depot is a long-acting dosage form of recombinant growth hormone approved for pediatric growth hormone deficiency. Manufacture of Protropin was discontinued at the end of 2002 because physicians are typically initiating therapy with one of the Nutropin family products and the demand for Protropin has declined, but sales are expected to continue through the first half of 2004 or until inventory is depleted.

#### Thrombolytic

Combined net sales of our three thrombolytic products, Activase, TNKase and Cathflo Activase, increased 3% to \$185.2 million in 2003 following a decrease of 9% to \$180.2 million in 2002. The increase in 2003 was positively impacted by the implementation of a new business model which took advantage of our comprehensive thrombolytic portfolio and allowed us to focus our marketing efforts on accounts with the highest potential. The higher sales in 2003 were primarily due to Cathflo Activase for catheter clearance. Although Cathflo Activase received FDA approval and was launched in September 2001, we observed an increased acceptance and use of the product in 2003. Additionally, modest increases in Activase usage for acute ischemic stroke were observed. Also contributing to the increase in 2003 were price increases on certain of our thrombolytic products.

The decrease in Activase and TNKase sales in 2002 was attributable to the decline in the overall size of the thrombolytic market, reflecting growth in the peripheral markets (including catheter clearance), the increased use of mechanical reperfusion, and early intervention with other preventive therapies in the treatment of heart attacks. The decrease in 2002 was only partially offset by new sales of Cathflo Activase.

Our sales in 2003 and 2002 were also impacted by continued competition from Centocor, Inc.'s Retavase® (reteplase) and its aggressive price discounting. Competition and declines in the acute myocardial infarction market are expected to be offset by growth in the area of catheter clearance resulting in expected sales of our thrombolytic products in 2004 to be comparable to 2003.

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#### Pulmozyme

Net sales of Pulmozyme increased 21% to \$167.2 million in 2003 and 12% to \$138.1 million in 2002. These increases primarily reflect an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and price increases.

#### Xolair

We received FDA approval to market Xolair in June 2003 and began shipping Xolair in July 2003. Xolair achieved total net sales of \$25.3 million in 2003, reflecting distribution of product into the supply channel and positive physician adoption rates. Some physicians feel that the insurance reimbursements they receive for administration of Xolair do not adequately cover their costs and they are working to resolve the issue with insurance providers. Future sales revenue and related expenses are subject to risks and uncertainties, including continued physician adoption rates, third-party payer reimbursement and coverage decisions, and future trial results.

#### Raptiva

We received FDA approval to market Raptiva in October 2003 and began shipping Raptiva in November 2003. Raptiva achieved total net sales of \$1.4 million in 2003, reflecting initial distribution of product into the supply channel and initial reorders. The Raptiva reimbursement model has been received positively. We work with a network of specialty pharmacies in processing reimbursements and the early indications are favorable. Future sales revenue and the continued acceptance of this biologics class are subject to risks and uncertainties, including how well Raptiva is able to compete with other new and established therapies for moderate-to-severe psoriasis.

#### Royalties

Royalty income increased 37% to \$500.9 million in 2003 and 38% to \$365.6 million in 2002. The increases in both 2003 and 2002 were due to higher third-party sales by various licensees, primarily Hoffmann-La Roche (see "Related Party Transactions" below) for higher sales of Herceptin and Rituxan products, and gains related to foreign currency exchange rates. The increase in 2002 was also due to new royalties earned under a patent issued to Genentech and our collaborator relating to methods using recombinant DNA technology to make antibodies. We expect that in 2004, the increase in royalty income will be at a slower rate than 2003.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase simple foreign currency put option contracts (or options) to hedge these foreign royalty cash flows. The term of these options is generally one to five years. See the "We Are Exposed to Risks Relating to Foreign Currency Exchange Rates and Foreign Economic Conditions" section of the Forward-Looking Information below for a discussion of market risks related to these financial instruments.

#### **Contract Revenue**

Contract revenue increased 226% to \$177.9 million in 2003 and 49% to \$54.5 million in 2002. The increase in 2003 was primarily driven by revenues from our collaborators for amounts earned on development efforts related to Raptiva, Avastin, Lucentis, Tarceva and Omnitarg, and on upfront payments on new product arrangements for Avastin, Lucentis and PRO70769, a humanized antibody that binds to CD20. The increase in 2002 was primarily due to higher revenues from collaborators, including Hoffmann-La Roche and a new out-licensing arrangement. See "Related Party Transactions" below for more information on contract revenue from Hoffmann-La Roche and Novartis.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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We expect that contract revenues will increase in 2004, but at a more modest pace than in 2003. We also expect contract revenues to fluctuate depending on the level of revenues earned for ongoing development efforts, the level of milestones received, the number of new contract arrangements and Hoffmann-La Roche's potential opt-ins for products.

#### Cost of Sales

Cost of sales (or COS) increased 9% to \$480.1 million in 2003 and 25% to \$441.6 million in 2002. COS as a percentage of product sales in 2003 was 18%, a decrease from 20% in 2002 and 2001. This decrease primarily reflects higher sales of more favorable margin products (primarily Rituxan and Herceptin) and lower production costs for product sold in 2003.

As mentioned earlier, the Penzberg facility is the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Accordingly, as our ex-U.S. Herceptin sales have declined this year, our cost as a percentage of sales has also declined slightly due to a reduction in the lower gross margins generated by the ex-U.S. Herceptin sales.

As discussed in Part I, Item 1, "Collaboration Arrangements," in December 2003, we entered into an arrangement with Lonza Biologics, a subsidiary of Lonza Group Ltd, to provide additional manufacturing capacity for Rituxan. We do not expect this arrangement to have a significant impact on our overall cost of sales as a percentage of product sales.

COS for products sold to Hoffmann-La Roche totaled \$90.6 million in 2003, \$99.2 million in 2002 and \$63.8 million in 2001.

#### **Research and Development**

Research and development (or R&D) expenses increased 16% to \$722.0 million in 2003 and 18% to \$623.5 million in 2002. R&D as a percentage of operating revenues in 2003 was 22%, a decrease from 24% in 2002 and 26% in 2001. R&D expenses are expected to increase in 2004 as development of and support for our pipeline products increases and as we make full use of our 2003 expansion of our research center in South San Francisco. Coupled with our expectations for higher revenues, R&D as a percentage of operating revenues in 2004 is expected to increase slightly over 2003, but will likely decline over the longer term. We manage our R&D expenses within each of the categories as indicated in the following table and described in more detail below *(in millions)*.

Research and Development	2003	2002	2001	2003/2002	2002/2001
Product development	\$ 449.0	\$ 417.1	\$ 315.7	8 %	32 %
Post-marketing	81.0	45.5	47.2	78	(4)
Total development	\$ 530.0	\$ 462.6	\$ 362.9	15	27
Research	149.0	131.9	122.5	13	8
In-licensing	43.0	29.0	40.8	48	(29)
Total	\$ 722.0	\$ 623.5	\$ 526.2	16 %	18 %

Development Product development expenses include costs of preclinical development and conducting clinical trials. Such costs include costs of personnel, drug supply costs, research fees charged by outside contractors, co-development costs, and facility expenses, including depreciation. Post-marketing expenses include Phase IV and investigator-sponsored trials and product registries. Total development expenses increased 15% to \$530.0 million in 2003 and 27% to \$462.6 million in 2002.

The increase in 2003 was largely due to higher spending of \$31.9 million by us and our collaborators on the clinical development of our pipeline products, including Lucentis, Herceptin, Omnitarg and Rituxan Immunology, partially offset by less spending on Xolair, which was launched in July 2003. We also had in 2003 an increase of \$35.5 million related to Phase IV and investigator-sponsored trials for products, including Raptiva, Avastin and Xolair.

The increase in 2002 was primarily due to higher clinical development expenses related to projects primarily in late-stage development, including \$14.1 million for Tarceva, \$10.0 million for Avastin, \$8.4 million for Raptiva, \$6.7 million for Xolair and \$2.9 million for Lucentis. The increase in 2002 was also due to increased manufacturing of pre-approval development products, including Avastin, and process implementation for contract manufacturing for Immunex Corporation, a wholly-owned subsidiary of Amgen. See discussion on ENBREL in Part I, Item 1, "Collaboration Arrangements."

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Annual Percent Change

Biopharmaceutical products that we develop internally generally take 10 to 15 years (an average of 12 years) to research, develop and bring to market a new prescription medicine in the United States. Drug development in the U.S. is a process that includes several steps defined by the FDA. The process begins with the filing of an Investigation New Drug Application (or IND) which, if successful, allows opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of study: Phase I, II, and III, and we have found that it accounts for an average of seven years of a drug's total development time. The most significant costs associated with clinical development are the Phase III trials as they tend to be the longest and largest studies conducted during the drug development process. The successful development of our products is highly uncertain. An estimation of product completion dates and completion costs can vary significantly for each product and are difficult to predict. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could have a material adverse affect on our business. In responding to a New Drug Application (or NDA) or a Biologic License Application (or BLA), the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. We cannot assure you that any approval to be the lowel by the FDA will be obtained on a timely basis, if at all. For additional discussion of the risks and uncertainties associated with completing development of potential products, see "The Successful Development of Biotherapeutics is

We have established strategic alliances with various companies to gain additional access to potential new products and technologies, and to utilize companies to help develop potential new products. These companies are developing technologies that may fall outside of our research focus; through technology exchanges and investments with these companies, we may have the potential to generate new products. As part of certain of these strategic alliances, we have acquired equity or convertible debt securities of such companies. We have also entered into product-specific collaborations to acquire development and marketing rights for potential products. See discussion in Part I, Item 1, "Collaboration Arrangements."

*Research* Research includes expenses associated with research and testing of our product candidates prior to reaching the development stage. Such expenses primarily include the costs of internal personnel, outside contractors, facilities, including depreciation, and lab supplies. Personnel costs primarily include salary, fringe benefits, recruiting and relocation costs. Research expenses increased 13% to \$149.0 million in 2003 and 8% to \$131.9 million in 2002. The primary driver of the increase in both years was an increase in internal personnel and outside contractors for research and testing of product candidates.

*In-licensing* In-licensing includes costs to acquire licenses to develop and commercialize various technologies and molecules. In-licensing expenses increased 48% to \$43.0 million in 2003 and decreased 29% to \$29.0 million in 2002. The increase in 2003 was primarily due to new collaborations, including \$13.6 million of upfront payments for the purchase of in-process research and development (or IPR&D) under in-licensing agreements. This 2003 IPR&D expense, \$4.0 million in 2002 and \$19.0 million in 2001 represent acquired IPR&D that was not yet technologically feasible and had no future uses, and therefore was expensed. Of the \$19.0 million of IPR&D in 2001, \$15.0 million relates to an upfront payment to OSI Pharmaceuticals, Inc. (or OSI) under an agreement with us, OSI and Hoffmann-La Roche for the global co-development and commercialization of Tarceva for the potential treatment of solid tumor cancers. One of the members of the Board of Directors of OSI is also a member of the Board of Directors of Genentech.

#### Marketing, General and Administrative

Marketing, general and administrative (or MG&A) expenses increased 46% to \$794.8 million in 2003 and 22% to \$546.2 million in 2002. The increase in 2003 was due to: (i) a \$127.6 million increase in marketing activities and headcount expenses primarily related to the launch of Xolair and Raptiva and launch preparations for Avastin; (ii) a \$59.3 million increase related to headcount growth and increased commercial training programs in support of all products, including increases in field sales bonus expenses; (iii) a \$43.6 million increase in corporate bonus and

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corporate functional expenses (primarily related to information systems technologies), and increased headcount and related expenses across most corporate functions, partially offset by lower fixed asset disposals, and (iv) an \$18.2 million increase in royalty expenses, primarily related to Biogen Idec.

The increase in 2002 was primarily related to higher general and administrative (or G&A) expense. The increase in G&A was primarily due to a \$32.5 million increase in royalty expenses associated with higher sales by various licensees for which we have royalty obligations and a \$15.9 million charge primarily for the redesign of research facilities, and the write-off of building improvements and equipment. These increases were partially offset by a \$9.3 million reimbursement of legal costs. Marketing and sales expense was higher by \$40.0 million in 2002 as compared to 2001 primarily in support of our bio-oncology and pipeline products, new information technology and increased headcount in support of all products.

MG&A expenses are expected to rise in the near term, in particular, the marketing and sales component as we continue to market our newer products, Xolair and Raptiva and as we launch Avastin in early 2004. However, as we expect revenues to rise, MG&A as a percentage of operating revenues will likely decline over the longer term.

#### **Collaboration Profit Sharing**

Collaboration profit sharing consists primarily of the net operating profit sharing with Biogen Idec on commercial activities underlying Rituxan sales and, to a much lesser extent, the sharing of the commercial net operating results of Xolair with Novartis. Collaboration profit sharing expenses increased 30% to \$457.5 million in 2003 and 42% to \$350.7 million in 2002. These increases were primarily driven by increased Rituxan profit sharing with Biogen Idec due to higher Rituxan sales.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Collaboration profit sharing expense is expected to increase in 2004 consistent with the expected collaboration operating results associated with increased Rituxan and Xolair sales.

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

We began recording recurring charges related to the Redemption and push-down accounting in the third quarter of 1999. In 2003 and 2002, these charges were comprised of the amortization of other intangible assets. In 2001, these charges were primarily comprised of to the amortization of other intangible assets and goodwill. See also the "Redemption of our Special Common Stock" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

On January 1, 2002, we adopted Statement of Financial Accounting Standards (or FAS) 141, "Business Combinations" and FAS 142, "Goodwill and Other Intangible Assets." In accordance with FAS 141 and 142, we discontinued the amortization of goodwill and our trained and assembled workforce intangible asset, which resulted in an increase in reported net income by approximately \$157.6 million (or \$0.30 per share) in 2002 as compared to the accounting prior to the adoption of FAS 141 and 142. We performed an impairment test of goodwill at transition on January 1, 2002, and an annual impairment test on September 30, 2003 and 2002, and found no impairment. We will continue to evaluate our goodwill for impairment on an annual basis each September and whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. See also the "Goodwill and Other Intangible Assets" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

#### Special Items: Litigation-Related

In August 2003, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately \$0.19 in earnings per diluted share for 2003 and was reported as a litigation-related special item in our consolidated statements of income. In November 2003, we received a settlement payment from Bayer, one of our licensees, in connection with the settlement of a breach of contract action which resulted in an increase of approximately \$0.03 in earnings per diluted share for 2003 and was reported as a litigation-related special item. In addition, we recognized \$53.9 million in 2003 for accrued interest and bond costs related to the City of Hope National Medical Center (or COH) trial judgment described further below.

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In 2002, we recognized \$543.9 million of litigation-related special charges. These special charges were comprised of the COH litigation judgment including accrued interest and costs related to obtaining a surety bond and certain other litigation-related matters. 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. These special charges represent our estimate of the costs for the current resolution of these matters and are included in litigation and other long-term liabilities in the consolidated balance sheet at December 31, 2003 and 2002. We developed this estimate in consultation with outside counsel handling our defense in these matters and the estimate is based upon the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. The amount of cash, if any, to be paid in connection with the COH matter will depend on the outcome of the appeal. See the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding our litigations.

#### Other Income, Net

As part of our strategic alliance efforts, we invest in debt and equity securities of certain biotechnology companies with which we have or have had collaborative agreements. "Other income, net" includes realized gains and losses from the sale of certain of these biotechnology equity securities as well as changes in the recoverability of our debt securities. In addition, "other income, net" includes write-downs for other-than-temporary declines in the fair value of certain of these biotechnology debt and equity securities, interest income and interest expense, net of amounts capitalized in 2002 and 2001.

					Annual Percen	t Change
Other Income, Net	2003		2002	2001	2003/2002	2002/2001
		(in	millions)			
Gains on sales of biotechnology equity securities and other	\$ 21.1	\$	47.9	\$ 37.7	(56) %	27 %
Write-downs of biotechnology debt and equity securities	(3.8)		(40.8)	(27.5)	(91)	48
Interest income	78.4		101.4	130.5	(23)	(22)
Interest expense	(2.9)		(0.8)	(5.7)	263	(86)
Total other income, net	\$ 92.8	\$	107.7	\$ 135.0	(14)%	(20)%

"Other income, net" decreased 14% to \$92.8 million in 2003 and 20% to \$107.7 million in 2002. The decrease in 2003 was due to lower gains on sales of biotechnology equity securities coupled with a favorable change in the recoverability of a previously written-down debt security in 2002. Also contributing to the

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year-to-year decrease was lower interest income as a result of lower investment portfolio yields, which was partially offset by higher average portfolio balances. The decrease over 2002 was partially offset by the favorable effect of lower write-downs of our biotechnology equity securities due to overall improved market conditions in 2003. Although we have had minimal biotechnology marketable equity security write-downs in 2003, we may determine in future periods, depending on market conditions, that certain of such unhedged securities are impaired and require a write-down to market value.

The decrease in 2002 was due to lower interest income due to lower portfolio yields and, to a lesser extent, lower average portfolio balances. The lower portfolio balances were primarily due to the repurchase of 18.2 million shares of our common stock at a cost of approximately \$692.8 million during 2002. (See the "Capital Stock" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.) The year over year decrease was also due to an increase in write-downs of biotechnology debt and equity securities due to the decline in the overall market conditions in 2002. These unfavorable variances were partially offset by a favorable change in the recoverability of a previously written-down debt security and higher gains from the sale of biotechnology equity securities, and lower interest expense in 2002. The decrease in interest expense was a result of the repayment of our debentures, which matured in March 2002, and were redeemed in cash. See the "Debt Obligations" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding these debentures.

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#### Income Tax Provision (Benefit)

The income tax provision of \$287.3 million in 2003 differed from the income tax benefit of \$34.0 million in 2002 primarily due to increased 2003 pre-tax income. The income tax benefit in 2002 differed from the income tax provision of \$127.1 million in 2001 primarily due to substantially reduced pretax income and the elimination of non-deductible goodwill pursuant to the adoption of FAS 141 and FAS 142 in January 2002. The 2001 income tax provision reflects decreased benefit of R&D tax credits, which was offset by prior years' items. Prior years' items relate principally to changes in estimates resulting from events that provided greater certainty as to the expected outcome of these matters.

Our 2004 tax rate is expected to be approximately 35% for the year, an increase from 32% in 2003. This is due to favorable changes in estimates from prior years' items and foreign revenue items affecting the tax rate in 2003 but not in 2004. Other factors may have favorable or unfavorable effects upon our effective tax rate in 2004 and subsequent years. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, future levels of R&D spending, future levels of capital expenditures and changes in overall levels of pretax earnings.

#### Cumulative Effect of Accounting Changes and Other Changes in Accounting Principles

Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46) "Consolidation of Variable Interest Entities," as amended, an interpretation of Accounting Research Bulletin No. 51, issued in January 2003, requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE's expected losses, receives a majority of the entity's expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003, however, the FASB deferred the effective date for VIEs created before February 1, 2003 to the quarter ended March 31, 2004 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

We adopted FIN 46 on July 1, 2003, and consolidated the entity from which we lease our manufacturing facility located in Vacaville, California as of that date, as we determined that this entity is a VIE, as defined by FIN 46, and that we absorb a majority of its expected losses. Accordingly, we consolidated assets, which consist of the Vacaville manufacturing building and related equipment, net of accumulated depreciation. Such property and equipment had a carrying value of \$348.4 million at December 31, 2003 and was included in property, plant and equipment in the accompanying consolidated balance sheet. We also consolidated the entity's debt of \$412.3 million and noncontrolling interests of \$12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, in the accompanying consolidated balance sheet at December 31, 2003. We recorded a \$47.6 million charge, net of \$31.8 million in taxes, (or \$0.09 per share) as a cumulative effect of the accounting change in the third quarter of 2003. We had previously accounted for our involvement with this entity as an operating lease. See also "Leases" below for a discussion of all of our leases.

On January 1, 2002, we adopted FAS 141, "Business Combinations" and FAS 142, "Goodwill and Other Intangible Assets." Under the new rules, goodwill is no longer amortized but is subject to an impairment test at least annually. FAS 141 specifically identified assembled workforce as an intangible asset that is not to be recognized apart from goodwill and it was subsumed into goodwill on January 1, 2002. In accordance with FAS 141 and 142, we discontinued the amortization of goodwill and our trained and assembled workforce intangible asset, which resulted in an increase in reported net income by approximately \$157.6 million (or \$0.30 per share) in 2002, as compared to the accounting prior to the adoption of FAS 141 and 142. See also the "Goodwill and Other Intangible Assets" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

See also the "Description of Business and Summary of Significant Accounting Policies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for information on our adoption of FAS 141, 142, and FIN 46.

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We adopted FAS 133, "Accounting for Derivative Instruments and Hedging Activities," on January 1, 2001. Upon adoption, we recorded a \$5.6 million charge, net of \$3.8 million in taxes, (\$0.01 per share) as a cumulative effect of a change in accounting principle, recognized \$6.0 million in gains, net of \$4.0 million in taxes, (\$0.01 per share) in "other income, net" related to certain hedging instruments and increased other comprehensive income by \$5.0 million, net of \$3.3 million in taxes, as a result of recording derivative instruments at fair value.

The effects of the accounting changes described above are as follows (in millions, except per share amounts):

Net Income and Earnings Per Share	2003	:	2002	2001
Net income	\$ 562.5	\$	63.8	\$ 150.3
Earnings per share:				
Basic:				
Earnings before cumulative effect of accounting changes	1.18		0.12	0.30
Cumulative effect of accounting changes, net of tax	(0.09)		-	(0.01)
Net earnings per share	\$ 1.09	\$	0.12	\$ 0.29
Diluted:				
Earnings before cumulative effect of accounting changes Cumulative effect of accounting changes, net of tax	\$ 1.15 (0.09)	\$	0.12	\$ 0.29 (0.01)
Net earnings per share	\$ 1.06	\$	0.12	\$ 0.28

#### Net Income and Earnings Per Share

Net income increased in 2003 to \$562.5 million, or \$1.06 per diluted share, from a net income in 2002 of \$63.8 million, or \$0.12 per diluted share. The increase was primarily due to changes in year-to-date litigation-related special items from charges of \$543.9 million in 2002 to settlement receipts (net of charges) of \$113.1 million in 2003. Also contributing to the increase were higher operating revenues in 2003, driven mostly by higher product sales, partially offset by higher operating expenses in 2003.

Net income decreased in 2002 to \$63.8 million, or \$0.12 per diluted share, from a net income of \$150.3 million in 2001, or \$0.28 per diluted share. The decrease primarily reflects the 2002 litigation-related special charges, and also reflects increased collaboration profit sharing, R&D, MG&A and COS expenses and decreased "other income, net." These unfavorable changes were partially offset by increased product sales, royalties and contract revenues and decreased recurring charges related to the Redemption.

#### **In-Process Research and Development**

At June 30, 1999, the Redemption date, we determined that the acquired in-process technology was not technologically feasible and that the in-process technology had no future alternative uses. In 1990 and 1991 through 1997, Roche Holdings, Inc. (or Roche) purchased 60% and 5%, respectively, of our outstanding common stock. The push-down effect of Roche's aggregate purchase price is allocated based on Roche's ownership percentages as if the purchases had occurred at the original purchase dates for the 1990 and 1991 through 1997 purchases. Therefore, 65% of the purchase price allocated to IPR&D as of September 7, 1990, or 65% of \$770.0 million (\$500.5 million) was recorded as an adjustment to additional paid-in capital related to the 1990-1997 acquisitions. The remaining 35% of our outstanding common stock not owned by Roche was purchased in 1999. Accordingly, 35% of \$2,150.0 million of total fair value at the Redemption date, or \$752.5 million, was expensed on June 30, 1999.

The amounts of IPR&D were determined based on an analysis using the risk-adjusted cash flows expected to be generated by the products that result from the inprocess projects. The analysis included forecasted future cash flows that were expected to result from the progress made on each of the in-process projects prior to the purchase dates. These cash flows were estimated by first forecasting, on a product-by-product basis, total operating revenues expected from sales of the first generation of each in-process product. A portion of the gross in-process product revenues was then removed to account for the contribution provided by any core technology, which was considered to benefit the in-process products. The net in-process revenue was then multiplied by the project's estimated percentage of completion as of the purchase dates to determine a forecast of net IPR&D revenues attributable to

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projects completed prior to the purchase dates. Appropriate operating expenses, cash flow adjustments and contributory asset returns were deducted from the forecast to establish a forecast of net returns on the completed portion of the in-process technology. Finally, these net returns were discounted to a present value at discount rates that incorporate both the weighted-average cost of capital (relative to the biotech industry and us) as well as the product-specific risk associated with the purchased IPR&D products. The product-specific risk factors included each product in each phase of development, type of molecule under development,

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likelihood of regulatory approval, manufacturing process capability, scientific rationale, pre-clinical safety and efficacy data, target product profile and development plan. The discount rates ranged from 16% to 19% for the 1999 valuation and 20% to 28% for the 1990 purchase valuation, all of which represent a significant risk premium to our weighted-average cost of capital.

The forecast data in the analysis was based on internal product level forecast information maintained by our management in the ordinary course of managing the business. The inputs used by us in analyzing IPR&D were based on assumptions, which we believed to be reasonable but which were inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur.

A brief description of projects that were included in the IPR&D charge is set forth below, including an estimated percentage of completion as of the Redemption date. Projects subsequently added to the research and development pipeline are not included. Except as otherwise noted below, since the Redemption date there have been no significant changes to the phase of development for the projects listed. We do not track all costs associated with research and development on a project-by-project basis. Therefore, we believe a calculation of cost incurred as a percentage of total incurred project cost as of FDA approval is not possible. We estimate, however, that the R&D expenditures required to complete the in-process projects will total at least \$240.0 million as of December 31, 2003, as compared to \$700.0 million as of the Redemption date. This estimate reflects costs incurred since the Redemption date, discontinued projects, and decreases in cost to complete estimates for other projects, partially offset by an increase in certain cost estimates related to early stage projects and changes in expected completion dates.

At the Redemption date, we estimated percentage complete data for each project based on the weighing of three indicators, as follows:

*PTS*: Probability of technical success (or PTS) is a project level statistic maintained by us on an ongoing basis, which is intended to represent the current likelihood of project success, i.e., FDA approval. This is a quantitative calculation based on the stage of development and the complexity of the project, and it is highly correlated with the project's phase of development. PTS is periodically adjusted to reflect actual experiences over a reasonable period of time.

*Status Compared to Baseline Model* We developed a baseline model, which allocated percentages of a standard development project to each major phase of the project based on our experience. We then overlaid the time-based status of each project to this baseline model, in order to calculate a percentage complete for each project.

Management's Estimate of Percentage Complete Below is a list of the projects and their estimated percentage complete included in the IPR&D charge related to the Redemption:

#### As of the Redemption Date, June 30, 1999

Product	Description/Indication	Phase of Development	Substantial Completion Date	% Complete
Nutropin Depot	long-acting dosage form of recombinant growth hormone	Awaiting regulatory approval	2000	85%
TNKase, second generation t-PA	acute myocardial infarction	Awaiting regulatory approval	2000	90%
Xolair (formerly Anti-IgE antibody)	allergic asthma, seasonal allergic rhinitis	Phase III	2001	75%

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Pulmozyme	early-stage cystic fibrosis	Phase III	2003	75%	
Dornase alfa AERx <sup>™</sup> Delivery System	cystic fibrosis	Preparing for Clinical Testing	2003	45%	
Rituxan antibody	aggressive non-Hodgkin's lymphoma	Phase III	2004	60%	
Xubix (sibrafiban) oral IIb/IIIa antagonist	orally administered inhibitor of platelet aggregation	Phase III	2000	65%	
Cathflo Activase t-PA	intravenous catheter clearance	Preparing for Phase III	1999	90%	
	psoriasis		2003	50%	

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Raptiva (formerly Anti-

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Preparing

CD11a antibody and hull24)		for Phase III		
Herceptin antibody	adjuvant therapy for breast cancer	Preparing for Phase III	2007	45%
Thrombopoietin (TPO)	thrombocytopenia related to cancer treatment	Preparing for Phase III	2002	55%
Anti-CD18 antibody	acute myocardial infarction	Phase II	2004	55%
Avastin (Anti-VEGF antibody)	colorectal and lung cancer	Phase II	2003	35-40%
Herceptin antibody	other tumors	Phase II	2004	40-45%
Lucentis (formerly rhuFab V2 AMD)	age-related macular degeneration	Preparing for Phase I	2004	20%
MLN-02 antibody (formerly LDP-02)	inflammatory bowel disease	Phase Ib/IIa	2005	30%

We also identified five additional product programs that were at different stages of IPR&D. As of June 30, 1999, the Redemption date, we estimated that these projects would be substantially complete in years 1999 through 2004. The percent completion for each of these additional programs ranged from an estimated 35% to 90%. These projects did not receive material allocations of the purchase price.

In addition, our IPR&D at the Redemption date included a process technology program. The process technology program included the R&D of ideas and techniques that could improve the bulk production of antibodies, including cell culture productivity, and streamlined and improved recovery processes, and improvements in various areas of pharmaceutical manufacturing. We estimated that the process technology program was approximately 50% complete at the Redemption date. Material cash inflows from significant projects are generally expected to commence within one to two years after the substantial completion date has been reached.

The significant changes to the projects included in the IPR&D charge since the Redemption date include:

- Nutropin Depot -- We announced on December 23, 1999, that Nutropin Depot received approval from the FDA for pediatric growth hormone deficiency (GHD).
- TNKase (tenecteplase) -- We announced on June 2, 2000, that TNKase, a single-bolus thrombolytic agent, was approved by the FDA for the treatment of acute myocardial infarction (AMI).
- Xolair (omalizumab) -- We announced on June 20, 2003, that the FDA approved Xolair for the treatment of moderate-to-severe persistent asthma in adults and adolescents. We began shipping Xolair in July 2003.

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- Pulmozyme -- Phase III trial in early stage cystic fibrosis has been completed and the study results were published in December 2001.
- Dornase alfa AERx -- This project has been discontinued.
- Rituxan (rituximab) -- We and Biogen Idec, Inc. are conducting a Phase III randomized study of Rituxan as a front-line and maintenance therapy in the treatment of newly diagnosed, diffuse, large, B-cell, or aggressive non-Hodgkin's lymphoma (NHL).
- Xubix (sibrafiban) oral IIb/IIIa antagonist -- This project has been discontinued.
- Cathflo Activase t-PA -- We announced on September 4, 2001, that Cathflo Activase was approved by the FDA for the restoration of function to central venous access devices (CVADs), as assessed by the ability to withdraw blood.
- Raptiva (efalizumab) -- We announced on May 12, 2003, in co-development with XOMA Ltd., the decision to terminate Phase II testing of Raptiva in patients with moderate-to-severe rheumatoid arthritis. We and XOMA announced on October 27, 2003, that Raptiva has been approved by the FDA for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy.
- Herceptin (trastuzumab) -- Phase III program studying Herceptin as an adjuvant therapy for breast cancer may take longer to complete than originally anticipated.
- Thrombopoietin (or TPO) -- There is an agreement with Pharmacia that development efforts will be discontinued.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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- · Anti-CD18 antibody -- This project has been discontinued.
- Avastin (bevacizumab) -- We announced on February 26, 2004, that the FDA approved Avastin to be used in combination with intravenous 5-fluorouracilbased chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum. We began shipping Avastin on February 26, 2004.
- Herceptin antibody for non-small cell lung cancer (or NSCLC) -- This project has been discontinued for this indication.
- Lucentis (ranibizumab) We have initiated two Phase III studies for patients with the wet form of age-related macular degeneration. On June 24, 2003, we announced that Novartis Ophthalmics, the eye health unit of Novartis AG, would receive an exclusive license to develop and market Lucentis outside of North America for indications related to diseases of the eye.
- MLN02 antibody -- We announced on October 8, 2003, that after a review of the Phase II ulcerative colitis data results, Genentech and Millennium Pharmaceuticals, Inc. have decided not to move forward with a Phase III study at this time. The companies are currently in discussions regarding next steps with the MLN-02 program.

Item 1 and Item 7 of this 10-K contains forward-looking statements regarding timing of completion of phases for projects in product development, costs related to the completion of in-process projects, time frame of Rituxan manufacturing by Lonza and Avastin manufacturing at Porrino, higher revenues, sales of Rituxan and Herceptin, royalties, contract revenues, R&D expenses, MG&A and collaboration profit sharing expenses, capital expenditures and impact of Medicare legislation on our sales of Rituxan and Herceptin. Actual results could differ materially. For a discussion of the risks and uncertainties associated with the time frame of Rituxan manufacturing by Lonza and Avastin manufacturing by Lonza and Avastin manufacturing at Porrino, see "The Successful Development of Biotherapeutics is Highly Uncertain and Requires Significant Expenditures," "We May Be Unable to Obtain or Maintain Regulatory Approvals for Our

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Products," "Difficulties or Delays in Product Manufacturing Could Harm Our Business," and "We May Be Unable to Manufacture Certain of Our Products If There Is BSE Contamination of Our Bovine Source Raw Material" sections of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" (or "Forward-Looking Information"); the timing of completion of product development phases, costs related to the completion of in-process projects, R&D expenses and capital expenditures, see all of the foregoing and "Protecting Our Proprietary Rights Is Difficult and Costly," "The Outcome of, and Costs Relating to, Pending Litigation or Other Legal Actions are Uncertain," and "We May Be Unable to Retain Skilled Personnel and Maintain Key Relationships"; for the impact of Medicare legislation, see "Decreases in Third Party Reimbursement Rates May Affect Our Product Sales"; for sales of Rituxan and Herceptin and MG&A and collaboration profit sharing expenses, see all of the foregoing and "We Face Competition," "Other Factors Could Affect Our Product Sales," "We May Incur Material Product Liability Costs," "Insurance Coverage is Increasingly More Difficult to Obtain or Maintain," and "We Are Subject to Environmental and Other Risks"; for royalties and contract revenues, see "Our Royalty and Contract Revenues Could Decline"; and for higher revenues, see all of the foregoing of Forward-Looking Information below. The Company has no intention and disclaims any obligation, to update or revise any forward-looking statements discussed above.

#### **RELATIONSHIP WITH ROCHE**

As a result of the Redemption of our Special Common Stock, the then-existing governance agreement between us and Roche terminated, except for provisions relating to indemnification and stock options, warrants and convertible securities. In July 1999, we entered into certain affiliation arrangements with Roche, amended our licensing and marketing agreement with Hoffmann-La Roche, and entered into a tax sharing agreement with Roche as follows:

#### Affiliation Arrangements

Our board of directors consists of two Roche directors, three independent directors nominated by a nominating committee currently controlled by Roche, and one Genentech employee. However, under our bylaws, Roche has the right to obtain proportional representation on our board at any time. Roche intends to continue to allow our current management to conduct our business and operations as we have done in the past. However, we cannot ensure that Roche will not implement a new business plan in the future.

Except as follows, the affiliation arrangements do not limit Roche's ability to buy or sell our Common Stock. If Roche and its affiliates sell their majority ownership of shares of our Common Stock to a successor, Roche has agreed that it will cause the successor to agree to purchase all shares of our Common Stock not held by Roche as follows:

- with consideration, if that consideration is composed entirely of either cash or equity traded on a U.S. national securities exchange, in the same form and
  amounts per share as received by Roche and its affiliates; and
- in all other cases, with consideration that has a value per share not less than the weighted-average value per share received by Roche and its affiliates as determined by a nationally recognized investment bank.

If Roche owns more than 90% of our Common Stock for more than two months, Roche has agreed that it will, as soon as reasonably practicable, effect a merger of Genentech with Roche or an affiliate of Roche.

Roche has agreed, as a condition to any merger of Genentech with Roche or the sale of our assets to Roche, that either:

- the merger or sale must be authorized by the favorable vote of a majority of non-Roche stockholders, provided no person will be entitled to cast more than 5% of the votes at the meeting; or
- in the event such a favorable vote is not obtained, the value of the consideration to be received by non-Roche stockholders would be equal to or greater than the average of the means of the ranges of fair values for the Common Stock as determined by two nationally recognized investment banks.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k 2003.htm

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We have agreed not to approve, without the prior approval of the directors designated by Roche:

- any acquisition, sale or other disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues;
- · any issuance of capital stock except under certain circumstances; or
- any repurchase or redemption of our capital stock other than a redemption required by the terms of any security and purchases made at fair market value in connection with any of our deferred compensation plans.

#### Licensing Agreement

We have a licensing and marketing agreement with Hoffmann-La Roche and its affiliates granting an option to license, use and sell our products in non-U.S. markets. The major provisions of that agreement include the following:

- · Hoffmann-La Roche's option expires in 2015;
- Hoffmann-La Roche may exercise its option to license our products upon the occurrence of any of the following: (1) our decision to file an IND for a
  product, (2) completion of a Phase II trial for a product or (3) if Hoffmann-La Roche previously paid us a fee of \$10.0 million to extend its option on a
  product, completion of a Phase III trial for that product;
- if Hoffmann-La Roche exercises its option to license a product, it has agreed to reimburse Genentech for development costs as follows: (1) if exercise occurs at the time an IND is filed, Hoffmann-La Roche will pay 50% of development costs incurred prior to the filing and 50% of development costs subsequently incurred, (2) if exercise occurs at the completion of a Phase II trial, Hoffmann-La Roche will pay 50% of development costs incurred through completion of the trial, 75% of development costs subsequently incurred for the initial indication, and 50% of subsequent development costs for new indications, formulations or dosing schedules, (3) if the exercise occurs at the completion of a Phase III trial, Hoffmann-La Roche will pay 50% of development costs incurred through completion of Phase II, 75% of development costs for new indications, formulations or dosing schedules, (3) if the exercise occurs at the completion of a Phase III trial, Hoffmann-La Roche will pay 50% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of the option extension fee paid by Hoffmann-La Roche to preserve its right to exercise its option at the completion of a Phase III trial will be credited against the total development costs payable to Genentech upon the exercise of the option, and (4) each of Genentech and Hoffmann-La Roche have the right to "opt-out" of developing an additional indication for a product for which Hoffmann-La Roche exercised it
- we agreed, in general, to manufacture for and supply to Hoffmann-La Roche its clinical requirements of our products at cost, and its commercial requirements at cost plus a margin of 20%; however, Hoffmann-La Roche will have the right to manufacture our products under certain circumstances, and in late September 2002, Hoffmann-La Roche received approval from the European Committee for Proprietary Medicinal Products to manufacture Herceptin at its Penzberg, Germany facility; during 2003, the Penzberg facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories;
- Hoffmann-La Roche has agreed to pay, for each product for which Hoffmann-La Roche exercises its option upon either a decision to file an IND with the
  FDA or completion of the Phase II trials, a royalty of 12.5% on the first \$100.0 million on its aggregate sales of that product and thereafter a royalty of 15%
  on its aggregate sales of that product in excess of \$100.0 million until the later in each country of the expiration of our last relevant patent or 25 years from
  the first commercial introduction of that product; and

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• Hoffmann-La Roche will pay, for each product for which Hoffmann-La Roche exercises its option after completion of the Phase III trials, a royalty of 15% on its sales of that product until the later in each country of the expiration of our relevant patent or 25 years from the first commercial introduction of that product; however, \$5.0 million of any option extension fee paid by Hoffmann-La Roche will be credited against royalties payable to us in the first calendar year of sales by Hoffmann-La Roche in which aggregate sales of that product exceed \$100.0 million.

#### Tax Sharing Agreement

Since the redemption of our Special Common Stock in June 1999, and until Roche completed its second public offering of our Common Stock in October 1999, we were included in Roche's U.S. federal consolidated group and state and local consolidated or combined income tax groups. Accordingly, we entered into a tax sharing agreement with Roche. Pursuant to the tax sharing agreement, we and Roche were to make payments such that the net amount paid by us on account of federal consolidated and state and local consolidated or combined income tax if we had filed separate, stand-alone federal, state and local income tax returns as the common parent of an affiliated group of corporations filing consolidated or combined federal, state and local returns.

Effective with the consummation of the second public offering on October 26, 1999, we ceased to be a member of the consolidated federal income tax group (and certain state and local consolidated or combined income tax groups) of which Roche is the common parent. Accordingly, our tax sharing agreement with Roche

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### Novartis Exhibit 2265.0030 Regeneron v. Novartis, IPR2021-00816

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now pertains only to the state and local tax returns in which we are consolidated or combined with Roche. We will continue to calculate our tax liability or refund with Roche for these state and local jurisdictions as if we were a stand-alone entity.

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

We expect from time to time to 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 we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. The affiliation agreement provides that we will repurchase a sufficient number of shares pursuant to this program such that, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance will be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche as well as for stock splits or stock combinations) divided by 509,194,352 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999 and October 2000. We have repurchased shares of our common stock in 2003 (see discussion below in Liquidity and Capital Resources). As long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, the affiliation agreement provides that 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 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. On December 31, 2003, Roche's percentage ownership of our common stock was 58.4%, which was 1.8% below the Minimum Percentage.

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#### RELATED PARTY TRANSACTIONS

Roche

We enter into transactions with Roche, Hoffmann-La Roche and its affiliates in the ordinary course of business. The accounting policies we apply to our transactions with Roche and its affiliates are consistent with those used in transactions with independent third-parties.

In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under its existing licensing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 75% of subsequent global development costs related to the metastatic colorectal cancer indication of Avastin and all others unless Hoffmann-La Roche specifically opts out of the development of certain other indications.

In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. (other than territory previously committed to others) under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of subsequent global development costs related to PRO70769 unless Roche opts out of the development of certain indications. We will receive royalties on net sales of Avastin and PRO70769 in countries outside of the U.S.

As part of our licensing and marketing agreement, we recognized milestone-related royalty revenue of \$20.0 million in 2003 and \$10.0 million in 2002 as a result of Hoffmann-La Roche reaching \$400.0 million and \$200.0 million, respectively, in net sales of Herceptin outside of the U.S. Contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities after the option exercise date, totaled \$66.5 million in 2003, \$7.6 million in 2002 and \$5.8 million in 2001. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled \$353.5 million in 2003, \$269.9 million in 2002 and \$164.1 million in 2001. In 2003, Hoffmann-La Roche's Penzberg, Germany facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Our ex-U.S. sales of Herceptin to Hoffmann-La Roche were \$18.8 million in 2003, \$40.3 million in 2002 and \$31.3 million in 2001. R&D expenses include amounts related to Roche of \$37.6 million in 2003, \$7.1 million in 2002, and \$2.9 million in 2001.

#### Novartis

We understand that Novartis AG (or Novartis) holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, Novartis is deemed to have an indirect beneficial ownership interest under FAS 57 "Related Party Disclosures" of more than 10% of Genentech's voting stock.

In June 2003, we entered into an agreement with Novartis Opthalmics, an affiliate of Novartis AG, under which Novartis Opthalmics licensed the exclusive right to develop and market Lucentis outside of North America for the indication of age-related macular degeneration (or AMD). As part of this agreement, Novartis Opthalmics paid an upfront milestone and R&D reimbursement fee of \$46.6 million and will pay 50% of Genentech's ongoing Phase III and related development expenses. Genentech is not responsible for any portion of the development and commercialization costs incurred by Novartis outside of North America, but we may receive additional payments for Novartis' achievement of certain clinical development and product approval milestones outside of North America. In addition, we will receive royalties on net sales of Lucentis products, which we will manufacture and supply to Novartis, outside of North America.

During 2000, we entered into an arrangement with Novartis, whereby Novartis was required to fund a portion of the cost of our Xolair inventory until the FDA approved the product for marketing. In June 2003, we received FDA approval to market Xolair. This amount was to be returned to Novartis upon the earlier of regulatory approval of Xolair in the U.S. or the European Union, and was recorded in other accrued liabilities in our financial statements beginning in 2000. The amount payable to Novartis was \$37.8 million at December 31, 2002. In June 2003, we received FDA approval to market Xolair; in July 2003, \$37.8 million of funding that had been received from Novartis was repaid. Our arrangement with Novartis allows us to record all sales and cost of sales in the U.S.

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Genentech and Novartis will co-develop and co-promote in the U.S. and both will separately make payments to Tanox; Genentech's will be in the form of royalties. We will pay Novartis a share of the U.S. operating profits and record it as collaboration profit sharing expense. Novartis will market the product in and record all sales and cost of sales in Europe. Genentech will receive a portion of the European operating profits or losses, which will be recorded as contract revenue. Genentech is currently manufacturing the product and receives cost plus a mark-up similar to other arrangements where we manufacture. Novartis plans to assume primary manufacturing responsibilities in the future. Collaboration profit sharing expenses were \$9.9 million in 2003, \$1.8 million in 2002 and not material in 2001. R&D expenses include amounts related to Novartis of \$11.1 million in 2003 and \$5.8 million in 2002. Such expense from Novartis in 2001 was not material.

Revenue from Novartis related to product sales and the associated cost of sales was not material in 2003 or in prior years. Contract revenue from Novartis, including amounts recognized under new licensing arrangements entered into in 2003 and amounts earned related to commercial and ongoing development activities, was \$24.2 million in 2003 and \$5.7 million in 2002. We had no such revenue from Novartis in 2001.

#### LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Capital Resources	2003		2002	2001
December 31:		(	in millions)	
Cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	\$ 2,934.7	\$	1,601.9	\$ 2,864.9
Working capital	1,883.8		1,436.1	1,557.6
Current ratio	3.2:1		3.2:1	3.3:1
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	1,236.9		587.7	480.6
Investing activities	(1,398.4)		(6.5)	(704.0)
Financing activities	325.5		(768.3)	67.2
Capital expenditures (included in investing activities above)	(322.0)		(322.8)	(213.4)

We use cash generated from operations, income from investments and proceeds from stock issuances to fund operations, purchase marketable securities, make capital and equity investments, make stock repurchases, and in 2002, to redeem our debentures which matured in the first quarter of 2002. In addition, in 2002, we pledged \$630.0 million in cash and investments to secure the surety bond related to the City of Hope National Medical Center (or COH) judgment. (See the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding the COH litigation and related surety bond.)

Cash flows from operations can vary significantly due to various factors including changes in accounts receivable and deferred revenues related to large opt-in and new arrangements with collaborators. The average collection period of our accounts receivable as measured in days sales outstanding (or DSO) can vary and is dependent on various factors, including the type of revenue (i.e., product sales, royalties, or contract revenue) and the payment terms related to those revenues and whether the related revenue was recorded at the beginning or at the end of a period.

Under a stock repurchase program approved by our Board of Directors on December 5, 2003, Genentech is authorized to repurchase up to \$1 billion of its common stock through December 31, 2004. In this plan, as in previous stock repurchase plans, 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 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. Under a previous stock

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repurchase program approved by our Board of Directors, Genentech was authorized to repurchase up to \$1 billion of our common stock through the period ended June 30, 2003.

Our stock repurchases under the above plans are summarized below (in thousands).

TOTAL 2003 2002 2001

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		Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts	
	Approved by Board pre-program	800	\$ 34,034	57	<b>\$</b> -	12	<b>\$</b> -	800	\$ 34,034	
	Repurchase program expired June 30, 2003	23,775	893,696	5,434	195,274	18,241	692,752	100	5,670	
1	Repurchase program expiring December 31, 2004	71	6 <mark>,071</mark>	71	6,071	5		-	( <del></del> )	
	Total repurchases	24,646	\$ 933,80 <mark>1</mark>	5,505	\$ 201,345	18,241	<b>\$ 69</b> 2,752	900	\$ 39,704	

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.

Capital expenditures in 2003 included continuing construction of and improvements to manufacturing and R&D facilities and new spending on construction of and improvements to office buildings in South San Francisco. Capital expenditures in 2002 consisted primarily of the purchase of land and the construction of and improvements to manufacturing and R&D facilities. In 2004, we expect to spend approximately \$800.0 million on property, plant and equipment. The increase over 2003 will primarily support our expected future manufacturing capacity needs, increases in property, equipment and information systems related purchases, and provide for synthetic lease repayments.

In March 2002, we redeemed in cash \$149.7 million of convertible subordinated debentures, classified as short-term debt, with interest payable at 5%.

Our total cash, cash equivalents, short-term investments and marketable securities are expected to decline over the next several years due to cash requirements for capital expenditures, share repurchases under our stock repurchase program, synthetic lease repayments and working capital. These funds, together with funds provided by operations and leasing arrangements, will be sufficient to meet our foreseeable future operating cash requirements. In addition, we believe we could access additional funds from the debt and, under certain circumstances, capital markets. See also "Our Affiliation Agreement With Roche Could Adversely Affect Our Cash Position" below for factors that could negatively affect our cash position and the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

#### OFF-BALANCE SHEET ARRANGEMENTS

We have certain contractual arrangements that create risk for the company and are not recognized in our consolidated balance sheet. Discussed below are those offbalance 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

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We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance and minimum lease payments. Some of our leases have options to renew. Four of our operating leases are commonly referred to as "synthetic leases." Prior to the issuance of FIN 46, synthetic leases represented a form of off-balance sheet financing under which they were treated as operating leases for accounting purposes and as financing leases for tax purposes. Under FIN 46, each synthetic lease is evaluated to determine if it qualifies as a VIE and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

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Under our synthetic lease structures, an unrelated third-party funds 100% of the costs of the acquisition and/or construction of the property and leases the asset to us, as the lessee, and at least 3% of the third-party funds represent at-risk equity. In addition, under our synthetic lease structures, upon termination or expiration, at our option, we must either purchase the property from the lessor at a predetermined amount that does not constitute a purchase at less than fair market value, sell the real property to a third-party, or renew the lease arrangement. If the property is sold to a third-party at an amount financed by the lessor, we have agreed under residual value guarantees to pay the lessor up to an agreed upon percentage of the amount financed by the lessor.

The most significant of our synthetic leases relates to our manufacturing facility located in Vacaville, California. In November 2001, we completed a synthetic lease transaction for this facility, which had previously been leased to us under a predecessor synthetic lease. This new synthetic lease is structured differently from our other synthetic leases. As the lessee, we lease the property from an unrelated special purpose trust (owner/lessor) under an operating lease agreement for five years ending November 2006. Third-party financing is provided in the form of a 3% at-risk equity participation from investors and 97% debt commitment. Investors' equity contributions were equal to or greater than 3% of the fair value of the property at the lease's inception and are required to remain so for the term of the lease. A bankruptcy-remote, special purpose corporation (or SPC) was formed to fund the debt portion through the issuance of commercial paper notes. The SPC lends the proceeds from the commercial paper to the owner/lessor, who issues promissory notes to the SPC. The SPC loans mature in November 2006. The SPC's commercial paper. The collateral for the SPC bans includes the leased property, and an interest in the residual value guarantee provided by us. The creditors of the SPC do not have recourse to the general credit of Genentech. As the lessee, at any time during the lease term, we have the option to purchase the property at a mount that does not constitute a purchase at less than fair market value.

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Under FIN 46, we determined that the entity from which we lease the Vacaville facility qualified as a VIE and that we are the primary beneficiary of this VIE as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46 on July 1, 2003, we consolidated the entity. See above in the "Critical Accounting Policies -- Changes in Accounting Principles" section for further information on our adoption of FIN 46.

Our three remaining leases were entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us various buildings that we occupy in South San Francisco, California. Under certain of these leases, we are required to maintain cash collateral of \$56.6 million, which we have included in our consolidated balance sheets as restricted cash and investments. We have evaluated our accounting for these leases under the provisions of FIN 46, and we determined that, as of July 1, 2003, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP leases.

Under all the synthetic leases, Genentech, as the lessee, is also required to maintain certain pre-defined financial ratios and is limited to the amount of debt it can assume. In addition, no Genentech officer or employee has any financial interest with regard to these synthetic lease arrangements or with any of the special purpose entities used in these arrangements. In the event of a default, the maximum amount payable under the residual value guarantee would equal 100% of the amount financed by the lessor, and our obligation to purchase the leased properties or pay the related residual value guarantees could be accelerated. We believed at the inception of the leases and continue to believe that the occurrence of any event of default that could trigger our purchase obligation is remote.

See the contractual obligations table below for our future minimum lease payments under all leases, exclusive of the residual value guarantees, executory costs and sublease income, at December 31, 2003. These minimum lease payments were computed based on interest rates current at that time, which are subject to fluctuation in certain market-based interest rates.

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The following summarizes the approximate initial fair values of the facilities at the inception of the related leases, lease terms and residual value guarantee amounts for each of our synthetic leases (in millions):

	í	pproximate nitial Fair Value of sed Property	Lease Expiration	Maximum Residual Value Guarantee		
Vacaville lease	\$	425.0	11/2006	\$	371.8	
South San Francisco lease 1		56.6	07/2004		48.1	
South San Francisco lease 2		160.0	06/2007		136.0	
South San Francisco lease 3		25.0	01/2004		21.3	
Total	\$	666.6		\$	577.2	

We believe that there have been no impairments in the fair value or use of the properties that we lease under synthetic leases wherein we believe that we would be required to pay amounts under any of the residual value guarantees. We will continue to assess the fair values of the underlying properties and the use of the properties for impairment at least annually.

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnifications in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses and expenses to be material. In the case of South San Francisco Lease 1, we have pledged cash collateral of \$56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

#### Commitments

In December 2003, we entered into a non-exclusive long-term manufacturing agreement with Lonza Biologics, a subsidiary of Lonza Group Ltd, under which Lonza will manufacture commercial quantities of Rituxan for us at Lonza's production facility in Portsmouth, New Hampshire. We may be obligated to make milestone payments to Lonza subject to Lonza's achievement of a series of factory preparation and process validation milestones, as well as receipt of FDA approval for the manufacturing of Rituxan bulk drug at the Lonza facility; the amounts of such payments cannot be estimated at this time. Following FDA approval at the Lonza facility, it is expected that commercial production would begin in 2005.

We have an agreement with Serono S.A.; our agreement, in addition to granting marketing rights to Serono in specific areas of the world, includes an arrangement to collaborate on co-developing additional indications of Raptiva and to share certain global development costs. We also have a supply agreement with Serono, under which we may have a loss exposure up to a maximum of \$10.0 million.

We have a manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, to provide Immunex with additional manufacturing capacity for ENBREL® (etanercept) at Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we are responsible for facility modifications needed to manufacture ENBREL, including the internal labor costs and costs of certain raw materials for development runs. The facility

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#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Payments due by period (in millions)

modification and services costs, which include engineering and equipment costs, are reimbursable by Immunex. However, if certain milestones are not met, we are required to reimburse Immunex for up to 45% of the facility modification and services costs. Costs associated with development runs are reflected in R&D expense as incurred. Shipment of the product, including pre-approval product, to Immunex would be recorded as product sales based on an agreed upon price with the associated costs reflected in cost of sales. In the fourth quarter of 2003, we determined that certain milestones, including obtaining FDA approval for the manufacturing process, would likely not be met in the pre-agreed upon timeframe. As a result, certain equipment paid for by us related to ENBREL

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manufacturing will not qualify for reimbursement by Immunex. Certain ENBREL-related equipment in our consolidated balance sheet will be depreciated over the estimated useful life of the equipment and certain of it will be depreciated over the term of the supply arrangement.

#### **Contractual Obligations**

Payments due under contractual obligations at December 31, 2003 mature as follows:

rayments due by period (in minoris)									
Total		Less than 1 year		1 to 3 years		3 to 5 years		More than 5 years	
\$	18.0	\$	6.2	\$	11.8	\$	-	\$	140
	6.4		2.7		3.7		-		340
	54.9		6.5		12.7		11.6		24.1
	73.4		62.9		10.5		-		( <del>+</del> 1)
	412.3		8 <u>4</u> 20		412.3		12		28
	649.3		-		649.3		2		-0
\$	1,214.3	\$	78.3	\$	1,100.3	\$	11.6	\$	24.1
		\$ 18.0 6.4 54.9 73.4 412.3 649.3	\$ 18.0 \$ 6.4 54.9 73.4 412.3 649.3	Total         I year           \$         18.0         \$         6.2           6.4         2.7         54.9         6.5           73.4         62.9         412.3         -           649.3         -         -         -	Total         Less than 1 year           \$ 18.0         \$ 6.2           6.4         2.7           54.9         6.5           73.4         62.9           412.3         -           649.3         -	Less than l year         l to 3 years           \$ 18.0         \$ 6.2         \$ 11.8           6.4         2.7         3.7           54.9         6.5         12.7           73.4         62.9         10.5           412.3         -         412.3           649.3         -         649.3	Less than         l to 3           Total         Less than         l to 3           \$         18.0         \$         6.2         \$         11.8         \$           6.4         2.7         3.7         54.9         6.5         12.7         73.4         62.9         10.5         412.3         -         412.3         -         412.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         649.3         -         -         649.3         -         649.3         -         649.3         -         -         649.3         - <td>Less than l year         l to 3 years         3 to 5 years           \$ 18.0         \$ 6.2         \$ 11.8         \$ -           6.4         2.7         3.7         -           54.9         6.5         12.7         11.6           73.4         62.9         10.5         -           412.3         -         412.3         -           649.3         -         649.3         -</td> <td>Less than         l to 3         3 to 5         M           Total         l year         years         years         M           \$         18.0         \$         6.2         \$         11.8         \$         -         \$           6.4         2.7         3.7         -         -         54.9         6.5         12.7         11.6           73.4         62.9         10.5         -         -         412.3         -           412.3         -         412.3         -         649.3         -         -</td>	Less than l year         l to 3 years         3 to 5 years           \$ 18.0         \$ 6.2         \$ 11.8         \$ -           6.4         2.7         3.7         -           54.9         6.5         12.7         11.6           73.4         62.9         10.5         -           412.3         -         412.3         -           649.3         -         649.3         -	Less than         l to 3         3 to 5         M           Total         l year         years         years         M           \$         18.0         \$         6.2         \$         11.8         \$         -         \$           6.4         2.7         3.7         -         -         54.9         6.5         12.7         11.6           73.4         62.9         10.5         -         -         412.3         -           412.3         -         412.3         -         649.3         -         -

(4) Other long-term liabilities include our deferred tax liabilities, litigation liabilities, noncontrolling interests in a VIE and other similar items which are reflected on our balance sheet under GAAP We have excluded our deferred revenues as they have no effect on our future liquidity

#### STOCK OPTIONS

#### **Option Program Description**

Our 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 amended and restated 1999 Stock Plan (the "Plan"), a broad-based plan under which stock options are 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 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.

We also have a stock repurchase program in place and one purpose of the program is to manage the dilutive effect generated by the exercise of stock options. All stock option grants are made after a review by, and with the approval of, the Compensation Committee of the Board of Directors. See "The Compensation Committee Report" appearing in our Proxy Statement for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

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Novartis Exhibit 2265.0035 Regeneron v. Novartis, IPR2021-00816

<sup>(1)</sup> See further discussion of our operating leases above in "Leases "

<sup>(2)</sup> Upon adoption of FIN 46, we consolidated the entity from which we lease our manufacturing facility located in Vacaville, California We also consolidated the entity's debt of \$412 3 million and noncontrolling interests of \$12 7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, at December 31, 2003

<sup>(3)</sup> Purchase obligations include commitments related to capital expenditures, clinical development, collaborations, manufacturing and research operations and other significant purchase commitments

#### **General Option Information**

#### Summary of Option Activity

		<b>Options Outstanding</b>			
(Shares in thousands)	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price		
December 31, 2001	14,509	46,640	\$ 41.06		
Grants	(12,655)	12,655	28.98		
Exercises	-	(1,673)	23.43		
Cancellations <sup>(1)</sup>	2,195	(2,203)	53.16		
Additional shares reserved	-	-	-		
December 31, 2002	4,049	55,419	38.37		
Grants	(10,890)	10,890	81.09		
Exercises	-	(16,039)	68.27		
Cancellations <sup>(1)</sup>	2,207	(2,207)	47.59		
Additional shares reserved	25,000	-	-		
December 31, 2003	20,366	48,063	\$ 50.36		

(1) We currently only grant shares under our amended and restated 1999 Stock Plan Cancellations from options granted under previous plans are not added back to the shares reserved for issuance under the 1999 Stock Plan

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

	Exer	cisable	Unexe	rcisable	Total		
As of December 31, 2003	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	
In-the-Money Out-of-the-Money <sup>(1)</sup>	23,786 18	\$ 42.81 95.66	24,256 3	\$ 57.73 95.66	48,042 21	\$ 50.34 95.66	
Total Options Outstanding	23,804		24,259		48,063		

(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, \$93 57, at the close of business on December 31, 2003

**Distribution and Dilutive Effect of Options** 

**Employee and Executive Officer Option Grants** 

2003

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Novartis Exhibit 2265.0036 Regeneron v. Novartis, IPR2021-00816

2001

2002

Net grants during the year as % of outstanding shares	1.69 %	1.98 %	1.64 %
Grants to Named Executive Officers* during the period			
as % of outstanding shares	0.18 %	0.25 %	0.22 %
Grants to Named Executive Officers during the year			
as % of total options granted	8.54 %	10.27 %	10.52 %

 "Named Executive Officers" refers to our CEO and our four other most highly compensated executive officers as defined under Item 402(a)(3) of Regulation S-K of the federal securities laws

#### **Equity Compensation Plan Information**

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

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## FORWARD-LOOKING INFORMATION AND CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-K contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forwardlooking statements made by or on behalf of Genentech, 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 and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- Preclinical and clinical trial results that may show the product to be less effective than desired (e.g., the trial failed to meet its primary objectives) 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 Biologics License
  Application (or BLA) preparation, discussions with the U.S. Food and Drug Administration (or FDA), an FDA request for additional preclinical or clinical
  data, or unexpected safety or manufacturing issues.
- · 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 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.

Factors affecting our research and development (or 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. In the
  past, some promising candidates did not yield sufficiently positive preclinical results to meet our stringent development criteria.
- Hoffmann-La Roche's decisions 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 research and development (or IPR&D), which we may record as an R&D
  expense.
- As part of our strategy, we invest in R&D. R&D as a percentage of revenues can fluctuate with the changes in future levels of revenue. Lower revenues can lead to more limited spending on R&D efforts.

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Novartis Exhibit 2265.0037 Regeneron v. Novartis, IPR2021-00816 · Future levels of revenue.

#### We May Be Unable to Obtain or Maintain Regulatory Approvals for Our Products

The biotechnology and pharmaceutical industries 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 until it has been approved by the FDA, and then can only be marketed for the indications and claims 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 NDA) or a BLA, are substantial and can require a number of years. In addition, after any of 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 a product recall.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or that we can 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.
- · 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.

Moreover, it is possible that 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.

#### Difficulties or Delays in Product Manufacturing Could Harm Our Business

We currently produce all of our products at our manufacturing facilities located in South San Francisco, California and Vacaville, California or 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 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, 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 of available product inventory. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials used for manufacture of our products, equipment malfunctions or failures, damage to a facility due to natural disasters, including earthquakes as our South San Francisco and Vacaville facilities are located in an area where earthquakes could occur, changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA or by the Company that results in the halting or slowdown of production of one or more of our products due to regulatory issues, a contract manufacture going out of business or failing to produce product as contractually required or 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 and our contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share and damage our reputation.

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We may also experience insufficient available capacity to manufacture or have manufactured for us existing or new products which could cause shortfalls of available product inventory and an inability to supply market demand of one or more of our products for either a short period of time or an extended period of time. Alternatively, we may have an excess of available capacity which could lead to an idling of a portion of our manufacturing facilities and incurring idle plant charges, resulting in an increase in our costs of sales.

#### We May Be Unable to Manufacture Certain of Our Products if There is BSE Contamination of Our Bovine Raw Material

Most biotechnology companies, including Genentech, have historically used bovine source raw materials to support cell growth in cell production processes. Bovine source raw materials from within or outside the United States are increasingly subject to greater public and regulatory scrutiny because of the perceived risk of contamination with bovine spongiform encephalopathy (or BSE). We have taken, and are continuing to take, precautions to minimize the risk of BSE contamination in our bovine source raw materials. We closely document the use of bovine source raw materials in our processes, take stringent measures to use the purest ingredients available and are working towards transitioning our processes to remove bovine source raw materials from final formulations. We are also in compliance with applicable U.S. and European guidelines on the handling and use of bovine source raw materials. Because of these efforts as well as those of the FDA, we believe that the risk of BSE contamination in our source materials is very low. However, should BSE contamination during the manufacture of any of our products that require the use of bovine source raw materials, namely Rituxan, it would negatively impact our ability to manufacture those products for an indefinite period of time (or at least until an alternative process is approved), and could result in a material adverse effect on our product sales, financial condition and results of operations.

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Novartis Exhibit 2265.0038 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

## Decreases in Third Party Reimbursement Rates May Affect Our Product Sales

The Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003, provides for, among other things, a reduction in the Medicare reimbursement rates for many drugs, including our oncology products, possibly offset to some extent by increased physician payment rates for drug administration services related to certain of our oncology products. The Congressional rationale for this legislation was that (1) the payment for drugs by the Medicare program should more closely reflect the acquisition costs for those drugs, and (2) the reimbursement for the service codes associated with the administration of drugs should be increased to better reflect practice expense costs associated with those services. The Medicare Act as well as other changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for our products may reduce or eliminate reimbursement of our products' costs to physicians. Decreases in third party reimbursement for our products, namely Rituxan and especially with respect to 2004, could reduce physician usage of the product and have a material adverse effect on our product sales, results of operations and financial condition. We are unable to predict what impact the Medicare Act or other future regulation, if any, relating to third-party reimbursement, will have on sales of Rituxan or our our our operators.

## Protecting Our Proprietary Rights Is Difficult and Costly

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material patent litigation, such as the matters discussed in the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, 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.

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.

We believe that we have strong patent protection or the potential for strong patent protection for a number of our products that generate sales and royalty revenue or that we are developing. However, it is for the courts in the U.S. and in other jurisdictions ultimately to determine the strength of that patent protection.

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## The Outcome of, and Costs Relating to, Pending Litigation or Other Legal Actions are Uncertain

Litigation to which we are currently or have been subjected relates to, among other things, our patent and other intellectual property rights, licensing arrangements with other persons, product liability and financing activities. We cannot predict with certainty the eventual outcome of pending litigation, which may include an injunction against the manufacture or sale of a product or potential product or a significant jury verdict or punitive damages award, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in defending these lawsuits.

Our activities relating to the sale and marketing of our products are subject to regulation under the Federal Food, Drug and Cosmetic Act and other federal statutes, including those relating to government program fraud and abuse. We believe our sales and marketing activities are in compliance with these laws. 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). If the government were to bring charges against or convict us of violating these laws, there could be a material adverse effect on our business, including our stock price.

## 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 attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, and on our ability to develop and maintain important relationships with leading research institutions and key distributors. Competition for these types of personnel and relationships is intense.

Roche has the right to maintain its percentage ownership interest in our common stock. Our affiliation agreement with Roche provides that, among other things, 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. This could have an effect on the number of shares we are able to grant under our stock option plans. We therefore cannot assure you that we will be able to attract or retain skilled personnel or maintain key relationships.

#### We Face Competition

We face competition in five of our therapeutic markets. First, in the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to Centocor's Retavase® (approved in 1996 for the treatment of acute myocardial infarction) and to the use of mechanical reperfusion therapies to treat acute myocardial infarction; the resulting adverse effect on sales has been and could continue to be material. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. In addition, we face potential competition in the catheter clearance market from the reintroduction of Abbott Laboratories' Abbokinase® (urokinase) in October 2002.

Second, in the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. As a result of that competition, we have experienced a loss in market share in the past. Competitors have also received approval to market their existing growth hormone products for additional indications. As a result of this competition, market share of our growth hormone products may decline. In addition, we have certain patents related to the production of growth hormone that have expired and as a consequence those patents no longer exclude others from making growth hormone using the processes claimed by those patents. Any competitive entry as a result of expiration of our patents may cause further decline in our market share.

Third, in the non-Hodgkin's lymphoma market, Corixa Corporation received FDA approval in June 2003, for Bexxar™ (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan. Biogen Idec Inc. (or Biogen Idec), formerly known as IDEC Pharmaceuticals

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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## Novartis Exhibit 2265.0039 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Corporation, received marketing approval from the FDA and began commercial shipments in late March 2002 for Zevalin<sup>™</sup> (ibritumomab tiuxetan), a product that could also potentially compete with Rituxan. Both Bexxar and Zevalin are radiolabeled molecules while Rituxan is not. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

Fourth, 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 Biogen Idec's biologic therapy Amevive® (alefacept), approved by the FDA in January 2003 for the treatment of moderate-to-severe psoriasis. Raptiva also competes with drugs approved for other indications that are used in psoriasis. Additional biologic therapies are expected to enter the psoriasis market in the next several years. ENBREL® (etanercept), marketed by Amgen and Wyeth in the U.S., is already approved for psoriatic arthritis, a condition associated with psoriasis. In 2003, Amgen announced positive phase III trial results using ENBREL for moderate-to-severe plaque psoriasis, and subsequently announced that ENBREL was filed for FDA approval to treat the condition. Other products are known to be in development for the psoriasis market.

Finally, Avastin may compete with Oxaliplatin. Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil ("5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with an irinotecan-based regimen, 5-FU/Leucovorin and CPT-11 (or "the Saltz Regimen"). In another Phase II trial, Avastin was found to provide benefit for first line patients when used in combination with 5-FU/Leucovorin alone. These regimens represent approximately 40% of all treatments used in the first-line setting. However, the use of these regimens is likely to decline as more physicians adopt Oxaliplatin-based regimens in the first-line setting. Avastin is currently being studied in combination with 5-FU/Leucovorin and Oxaliplatin (the "FOLFOX Regimen") in patients with relapsed, metastatic colorectal cancer in a large randomized study through the Eastern Cooperative Oncology Group (the "E3200 Trial"). If the results from the E3200 Trial are positive for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin or show a similar magnitude of benefit as previous colorectal cancer studies with Avastin, use of Avastin may increase as physicians increase their use of Avastin in combination of Avastin and 5-FU/Leucovorin and Oxaliplatin, potential sales of Avastin may be materially adversely affected as physicians may limit their use of Avastin to irinotecan-based regimes. Physicians may also restrict their use of Avastin to irinotecan-based regimes. Physicians may also restrict their use of Avastin to irinotecan-based regimes. Physicians may also restrict their use of Avastin to irinotecan-based regimes. Physicians may also restrict their use of Avastin to irinotecan-based regimes.

#### 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, and the pricing decisions of our competitors.
- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Negative data from new clinical studies could cause the utilization and sales of our products to decrease.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products. For example, as described in "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K, at various times other companies have filed patent infringement lawsuits against us alleging that the manufacture, use and sale of certain of our products infringe their patents.
- The increasing use and development of alternate therapies. For example, the overall size of the market for thrombolytic therapies, such as our Activase
  product, continues to decline as a result of the increasing use of mechanical reperfusion.

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• The rate of market penetration by competing products. For example, we have lost market share to new competitors in the thrombolytic and, in the past, growth hormone markets.

#### **Our Royalty and Contract Revenues Could Decline**

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.

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Novartis Exhibit 2265.0040 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

- 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 United States.
- · 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 benchmarks are achieved.
- The failure of or refusal of a licensee to pay royalties.
- · The expiration or invalidation of our patents or licensed intellectual property.
- · Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

## 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 to Obtain or Maintain

While we currently have insurance for our business, property and our products, first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policy may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

#### 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 action. 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.

## 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 United States. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.
- The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the United States and the amount and timing of sales to their respective customers, which directly impacts 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 and use of our products for approved indications and additional indications. Among other things, the rate of adoption 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.
- · The number and size of any product price increases we may issue.

## Our Stock Price, Like That of Many Biotechnology Companies, Is Highly Volatile

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0041 Regeneron v. Novartis, IPR2021-00816

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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 impact 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.
- · Developments or outcome of litigation, including litigation regarding proprietary and patent rights.
- · Regulatory developments or delays concerning our products in the United States and foreign countries.
- · Issues concerning the safety of our products or of biotechnology products generally.

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- · Economic and other external factors or a disaster or crisis.
- · Period-to-period fluctuations in our financial results.

## Future Stock Repurchases Could Adversely Affect Our Cash Position

Our Board of Directors has authorized stock repurchase programs. Generally, under these programs, Genentech can purchase its stock in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech can also engage in transactions in other Genentech securities in conjunction with the repurchase program, including derivative securities.

Under a stock repurchase program approved by our Board of Directors on December 5, 2003, Genentech is authorized to repurchase up to \$1 billion of its common stock through December 31, 2004. A total of 70,900 shares at a cost of approximately \$6.1 million has been purchased under the plan through December 31, 2003.

While the dollar amounts associated with future stock repurchase programs cannot currently be estimated, future stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access additional capital in the financial markets, and may have the effect of limiting our ability to use our capital stock as consideration for acquisitions.

## Our Affiliation Agreement with Roche 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 the "Capital Stock" note in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K. See the "Relationship With Roche -- Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock" note in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K. See the "Relationship With Roche -- Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock" note in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for information regarding the Minimum Percentage.

While the dollar amounts associated with future stock repurchase programs cannot currently be estimated, future stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access additional capital in the financial markets, and may have the effect of limiting our ability to use our capital stock as consideration for acquisitions.

## Future Sales of Our Common Stock by Roche Could Cause the Price of Our Common Stock to Decline

As of December 31, 2003, Roche owned 306,594,352 shares of our common stock or 58.4% 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 Have Interests That Are Adverse to Other Stockholders

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 two Roche directors, three independent directors nominated by a nominating committee and one Genentech employee nominated by the nominating committee. As long as Roche owns in excess of 50% of our common stock, Roche directors will comprise two of the three members of the nominating committee. However, at any time until Roche owns less than 5% of our stock, Roche will have the right to obtain proportional representation on our board. Roche intends to continue to allow our current management to conduct our business and operations as we have done in the past. However, we cannot assure stockholders that Roche will not institute a new business plan in the future. Roche's interests may conflict with minority shareholder interests.

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## Our Affiliation Agreement with Roche Could Limit Our Ability to Make Acquisitions and Could Have a Material Negative Impact on Our Liquidity

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 the "Relationship With Roche Roche's Ability to Maintain Its
  Percentage Ownership Interest in Our Stock" note in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K. For more
  information on our stock repurchase program, see the "Capital Stock" note in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form
  10-K.

These provisions may have the effect of limiting our ability to make acquisitions and while the dollar amounts associated with a stock repurchase program cannot currently be estimated, stock repurchases could have a material adverse impact on our liquidity, credit rating and ability to access additional capital in the financial markets.

## Our Stockholders May Be Unable to Prevent Transactions That Are Favorable to Roche but Adverse to Us

Our certificate of incorporation includes provisions relating to:

- · Competition by Roche with us.
- · Offering of corporate opportunities.
- · Transactions with interested parties.
- Intercompany agreements.
- · Provisions limiting the liability of specified employees.

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.

#### Potential Conflicts of Interest Could Limit Our Ability to Act on Opportunities That Are Adverse to Roche

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. Two of our directors, Dr. Franz B. Humer and Dr. Jonathan K.C. Knowles, currently serve as officers and employees of Roche Holding Ltd and its affiliates, and Dr. Humer is a director and the Chairman of Roche Holding Ltd.

#### We Are Exposed to Market Risk

We are exposed to market risk, including changes to interest rates, foreign currency exchange rates and equity investment prices. To reduce the volatility relating to these exposures, we enter into various derivative hedging transactions pursuant to our investment and risk management policies and procedures. We do not use derivatives for speculative purposes.

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We maintain risk management control systems to monitor the risks associated with interest rates, foreign currency exchange rates and equity investment price changes, and our derivative and financial instrument positions. The risk management control systems use analytical techniques, including sensitivity analysis and market values. Though we intend for our risk management control systems to be comprehensive, there are inherent risks that may only be partially offset by our hedging programs should there be unfavorable movements in interest rates, foreign currency exchange rates or equity investment prices.

The estimated exposures discussed below are intended to measure the maximum amount we could lose from adverse market movements in interest rates, foreign currency exchange rates and equity investment prices, given a specified confidence level, over a given period of time. Loss is defined in the value at risk estimation as fair market value loss. The exposures to interest rate, foreign currency exchange rate and equity investment price changes are calculated based on proprietary modeling techniques from a Monte Carlo simulation value at risk model using a 21-trading days holding period and a 95% confidence level. The value at risk model assumes non-linear financial returns and generates potential paths various market prices could take and tracks the hypothetical performance of a portfolio under each scenario to approximate its financial return. The value at risk model takes into account correlations and diversification across market factors, including interest rates, foreign currencies and equity prices. Hedge instruments are modeled as positions on the actual underlying securities. No proxies were used. Market volatilities and correlations are based on a one-year historical times-series as of December 31, 2003.

**Our Interest Income Is Subject to Fluctuations in Interest Rates** 

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0043 Regeneron v. Novartis, IPR2021-00816

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Our material interest-bearing assets, or interest-bearing portfolio, consisted of cash, cash equivalents, restricted cash and investments, short-term investments, marketable debt securities, long-term investments and interest-bearing forward contracts. The balance of our interest-bearing portfolio, including restricted and unrestricted cash and investments, was \$3,240.5 million or 37% of total assets at December 31, 2003. Interest income related to this portfolio was \$78.4 million in 2003. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest-bearing portfolio. To mitigate the impact of fluctuations in U.S. interest rates, for a portion of our portfolio, we may enter into swap transactions that involve the receipt of fixed rate interest and the payment of floating rate interest without the exchange of the underlying principal.

Based on our overall interest rate exposure at December 31, 2003, including derivative and other interest rate sensitive instruments, a near-term change in interest rates, within a 95% confidence level based on historical interest rate movements could result in a potential loss in fair value of our interest rate sensitive instruments of \$19.5 million.

## We Are Exposed to Risks Relating to Foreign Currency Exchange Rates and Foreign Economic Conditions

We receive royalty revenues from licensees selling products in countries throughout the world. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which our licensed products are sold. We are exposed to changes in exchange rates in Europe, Asia (primarily Japan) and Canada. Our exposure to foreign exchange rates primarily exists with the Swiss franc. When the dollar strengthens against the currencies in these countries, the dollar value of foreign-currency denominated revenue decreases; when the dollar weakens, the dollar value of the foreign-currency denominated revenues increases. Accordingly, changes in exchange rates, and in particular a strengthening of the dollar, may adversely affect our royalty revenues as expressed in dollars. Expenses arising from our foreign royalty revenues exceed our foreign exchange rate exposures on these royalties. Currently, our foreign royalty revenues exceed our foreign exchange rate addition, as part of our overall investment strategy, a portion of our portfolio is primarily in non-dollar denominated investments. As a result, we are exposed to changes in the exchange rates of the countries in which these non-dollar denominated investments are made.

To mitigate our net foreign exchange exposure, our policy allows us to hedge certain of our anticipated royalty revenues by purchasing option contracts with expiration dates and amounts of currency that are based on up to 90% of probable future revenues so that the potential adverse impact of movements in currency exchange rates on the non-dollar denominated revenues will be at least partly offset by an associated increase in the value of the option.

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Generally, the term of these options is one to five years. To hedge the non-dollar expenses arising from our foreign manufacturing facility, we may enter into forward contracts to lock in the dollar value of a portion of these anticipated expenses.

Based on our overall currency rate exposure at December 31, 2003, including derivative and other foreign currency sensitive instruments, a near-term change in currency rates within a 95% confidence level based on historical currency rate movements would not materially affect the fair value of our foreign currency sensitive instruments.

## Our Investments in Equity Securities Are Subject to Market Risks

As part of our strategic alliance efforts, we invest in equity instruments of biotechnology companies. Our biotechnology equity investment portfolio totaled \$380.7 million or 4% of total assets at December 31, 2003. These investments are subject to fluctuations from market value changes in stock prices. For example, in 2002, we recorded charges related to the write-down of certain equity security investments that had other-than-temporary impairments.

To mitigate the risk of market value fluctuation, certain equity securities are hedged with zero-cost collars and forward contracts. A zero-cost collar is a purchased put option and a written call option in which the cost of the purchased put and the proceeds of the written call offset each other; therefore, there is no initial cost or cash outflow for these instruments at the time of purchase. The purchased put protects us from a decline in the market value of the security below a certain minimum level (the put "strike" level), while the call effectively limits our potential to benefit from an increase in the market value of the security above a certain maximum level (the call "strike" level). A forward contract is a derivative instrument where we lock-in the termination price we receive from the sale of stock based on a pre-determined spot price. The forward contract protects us from a decline in the market value of the security below the spot price and limits our potential benefit from an increase in the market value of the security above the spot price. The forward contract protects us from a decline in the market value of the security below the spot price and limits our potential benefit from an increase in the market value of the security above the spot price. Throughout the life of the contract, we receive interest income based on the notional amount and a floating-rate index. In addition, as part of our strategic alliance efforts, we hold convertible preferred stock, including dividend-bearing convertible preferred stock, and have made interest-bearing loans that are convertible into the equity securities of the debtor or repaid in cash. Depending on market conditions, we may determine that in 2004 certain of our other unhedged equity security investments are impaired, which would result in additional write-downs of those equity security investments.

Based on our overall exposure to fluctuations from market value changes in marketable equity prices at December 31, 2003, a near-term change in equity prices within a 95% confidence level based on historic volatilities could result in a potential loss in fair value of our equity securities portfolio of \$22.4 million.

## We Are Exposed to Credit Risk of Counterparties

We could be exposed to losses related to the financial instruments described above should one of our counterparties default. We attempt to mitigate this risk through credit monitoring procedures.

## The Company's Effective Tax Rate May Vary Significantly

Various internal and external factors may have favorable or unfavorable effects on our future effective 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, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings.

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Novartis Exhibit 2265.0044 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

## New and Potential New Accounting Pronouncements May Impact Our Future Financial Position and Results of Operations

There may be potential new accounting pronouncements or regulatory rulings, which may have an impact on our future financial position and results of operations. In particular, there are a number of rule changes and proposed legislative initiatives following the recent corporate bankruptcies and failures which could result in changes in

accounting rules, including the accounting for employee stock options as an expense. These and other potential changes could materially impact our assets and liabilities, and the expenses we report under generally accepted accounting principles, and could adversely affect our operating results or financial condition.

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## Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Refer to the section labeled "Forward-Looking Information and Cautionary Factors That May Affect Future Results-We Are Exposed to Market Risk" of Part II, Item 7 of this Form 10-K.

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## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

## **REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

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

We have audited the accompanying consolidated balance sheets of Genentech, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of Genentech, Inc.'s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genentech, Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in the notes to the consolidated financial statements in 2003, the company changed its method of accounting for variable interest entities, in 2002 changed its method of accounting for goodwill and other intangible assets and in 2001 changed its method of accounting for derivative instruments and hedging activities.

/s/ ERNST & YOUNG LLP

Palo Alto, California January 13, 2004, except for the second paragraph of the note titled Subsequent Events and the twenty-first paragraph of the note titled Leases, Commitments and Contingencies, as to which the date is February 25, 2004

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Novartis Exhibit 2265.0045 Regeneron v. Novartis, IPR2021-00816

## CONSOLIDATED STATEMENTS OF INCOME (in thousands, except per share amounts)

	Year Ended December 31,					
		2003		2002		2001
Revenues						
Product sales (including amounts from related parties: 2003-\$108,078; 2002-\$117,257; 2001-\$76,290)	\$	2,621,490	\$	2,163,665	\$	1,742,897
Royalties (including amounts from related party: 2003-\$245,623; 2002-\$152,642; 2001-\$87,854)		500,903		365,550		2 <b>64</b> ,475
Contract revenue (including amounts from related parties: 2003-\$90,692; 2002-\$13,348; 2001-\$5,754)		177,934		54,443		36,660
Total operating revenues		3,300,327		2,583,658		2,044,032
Costs and expenses						
Cost of sales (including amounts for related parties: 2003-\$90,657; 2002-\$99,150; 2001-\$63,761)		480,123		441,630		354,442
Research and development (including related parties amounts of: 2003-\$37,556; 2002-\$7,092; 2001-\$2,937) (including contract related:						
2003-\$95,473; 2002-\$24,060; 2001-\$9,434)		721,970		623,482		526,230
Marketing, general and administrative		794,845		546,276		446,906
Collaboration profit sharing		457,457		350,725		246,657
Recurring charges related to redemption		154,344		155,713		321,816
Special items: litigation-related		(113,127)		543,905		121
Total costs and expenses		2,495,612	ŝ	2,661,731		1,896,051
Operating margin		804,715		<mark>(78,073)</mark>		147,981
Other income, net		92,791		107,822		135,005
Income before taxes and cumulative effect of accounting changes		897,506		29,749		282,986
Income tax provision (benefit)		287,324		(34,038)		127,112
Income before cumulative effect of accounting changes		610,182		63,787		155,874
Cumulative effect of accounting changes (net of taxes: 2003-\$31,770; 2001-\$3,759)		(47,655)		12		(5,638)
Net income	\$	562 <mark>,</mark> 527	\$	63,787	\$	150,236
Earnings per share						
Basic						
Earnings before cumulative effect of accounting changes	\$	1.18	\$	0.12	\$	0.30
Cumulative effect of accounting changes (net of taxes: 2003-\$0.06; 2001-\$0.01)	8752	(0.09)	20.85		1994	(0.01)
Net earnings per share	\$	1.09	\$	0.12	\$	0.29
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Novartis Exhibit 2265.0046 Regeneron v. Novartis, IPR2021-00816

1/17/22, 7:59 PM	Genentech, Inc Form 10-K for the period ending 12/31/2003											
Earnings before cumulative effect of accounting change		\$	1.15	\$	0.12	\$	0.29					
	Cumulative effect of accounting changes (net of taxes: 2003-\$0.06; 2001-\$0.01)		(0.09)		-		(0.01)					
	Net earnings per share	\$	1.06	\$	0.12	\$	0.28					
	Weighted-average shares used to compute basic earnings per share		517,240		519,192		527, <mark>0</mark> 22					
	Weighted-average shares used to compute diluted earnings per share		528,810		524,408		535,291					

See Notes to Consolidated Financial Statements.

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## CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

	Year Ended December 31,				
	2003	2002	2001		
Cash flows from operating activities					
Net income	\$ 562,527	\$ 63,787	\$ 150,236		
Adjustments to reconcile net income to net cash provided by operating activities:					
Cumulative effect of accounting changes, net of tax	47,655	-	5,638		
Depreciation and amortization	295,449	274,955	428,091		
Deferred income taxes	(149,001)	(196,644)	29,357		
Deferred revenue	239,145	2,001	(15,457)		
Litigation-related and other long-term liabilities	56,113	552,185	1277		
Gain on sales of securities available-for-sale and other	(23,069)	(53,710)	(39,398)		
Loss on sales of securities available-for-sale	3,137	5,868	2,011		
Write-down of securities available-for-sale	3,795	40,759	27,504		
Loss on fixed asset dispositions	10,760	15,883	4,211		
Changes in assets and liabilities:					
Receivables and other current assets	(146,107)	(107,483)	(59,512)		
Inventories	(93,264)	(36,596)	(91,116)		
Investments in trading securities	(33,825)	(121,986)	(85,712)		
Accounts payable and other current liabilities	463,622	148,681	124,774		
Net cash provided by operating activities	1,236,937	587,700	480,627		
Cash flows from investing activities					
Purchases of securities available-for-sale	(1,755,934)	(806,444)	(1,559,230)		
Proceeds from sales and maturities of securities available-for-sale	739,867	1,746,198	1,084,546		
Purchases of nonmarketable equity securities	(4,286)	(6,290)	(5,830)		
Capital expenditures	(321,955)	(322,832)	(213,351)		
Change in other assets	(56,122)	12,875	(10,105)		
Transfer to restricted cash		(630,000)	(5.)		
Net cash used in investing activities	(1,398,430)	(6,493)	(703,970)		

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0047 Regeneron v. Novartis, IPR2021-00816

Cash flows from financing activities			
Stock issuances	526,860	74,164	106,866
Stock repurchases	(201,345)	(692,752)	(39,704)
Repayment of short-term debt	( <del>7</del> 2	(149,692)	1.41
Net cash provided by (used in) financing activities	325,515	(768,280)	67,162
Net increase (decrease) in cash and cash equivalents	164,022	(187,073)	(156,181)
Cash and cash equivalents at beginning of year	208,130	395,203	551,384
Cash and cash equivalents at end of year	\$ 372,152	\$ 208,130	\$ 395,203

Supplemental cash flow data			
Cash paid during the year for:			
Interest	\$ 2,223	\$ 7,482	\$ 7,493
Income taxes	167,761	128,108	36,450
Stock received as consideration for outstanding loans	29,600		6,490

See Notes to Consolidated Financial Statements.

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## CONSOLIDATED BALANCE SHEETS (in thousands, except par value)

	December 31,			
	2003	2002		
Assets				
Current assets				
Cash and cash equivalents	\$ 372,152	\$ 208,130		
Short-term investments	1,139,620	826,442		
Accounts receivable - product sales (net of allowances: 2003-\$22,903; 2002-\$16,827; including amounts from related parties: 2003-\$16,002,\$16,0	216 007	242.007		
2003-\$16,018; 2002-\$18,564) Accounts receivable - royalties (including amounts from related party:	315,097	242,907		
2003-\$113,739; 2002-\$60,615)	184,163	116,423		
Accounts receivable - other (net of allowances: 2003-\$2,191; 2002-\$3,171; including amounts from related parties:		000000000000		
2003-\$71,863; 2002-\$27,716)	74,831	59,151		
Inventories	469,640	393,542		
Deferred tax assets	121,885	82,299		
Hedge receivable	38,485	103,148		
Prepaid expenses and other current assets	40,957	50,742		
Total current assets	2,756,830	2,082,784		
Long-term marketable debt and equity securities	1,422,886	567,286		
Property, plant and equipment, net	1,617,912	1,068,734		
Goodwill	1,315,019	1,315,019		
Other intangible assets	810,810	927,538		
Restricted cash and investments	686,600	686,600		
Other long-term assets	126,114	110,158		

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Novartis Exhibit 2265.0048 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Total assets	\$ 8,736,171	\$ 6,758,119

Liabilities and stockholders' equity			
Current liabilities			
Accounts payable	\$	59,700	\$ 51,380
Deferred revenue		47,478	20,044
Other accrued liabilities (including amounts to related parties: 2003-\$58,138; 2002-\$51,116)		765,853	575, <mark>236</mark>
Total current liabilities		873,031	646,660
Long-term debt		412,250	1070
Deferred tax liabilities		26,056	148,314
Deferred revenue		281,243	69,533
Litigation and other long-term liabilities		623,293	55 <mark>4</mark> ,728
Total liabilities		2,215,873	1,419,235
Commitments and contingencies			
Stockholders' equity			
Preferred stock, \$0.02 par value; authorized: 100,000,000 shares; none issued		-	-
Common stock, \$0.02 par value; authorized: 1,200,000,000 shares;			
outstanding: 2003-524,742,041; 2002-512,810,225		10,495	10,256
Additional paid-in capital		7,370,261	6,650,352
Accumulated deficit, since June 30, 1999	(	1,157,491)	(1,590,366)
Accumulated other comprehensive income		297,033	268,642
Total stockholders' equity		6,520,298	5,338,884
Total liabilities and stockholders' equity	\$	8,736,171	\$ 6,758,119

See Notes to Consolidated Financial Statements.

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## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands)

	Commo					Common Stock		Additional Paid-in								Paid-in		Retained Earnings (Accumulated	Accumulated Other Comprehensive													
	Shares	A	mounts		Capital	Deficit)	Income	Total																								
Balance December 31, 2000	525,477	\$	10,510	\$	6,651,428	\$ (1,319,353)	\$ 331,618	\$ 5,674,203																								
Comprehensive income																																
Net income	( <b>-</b> )				-	150,236	-	150,236																								
Changes in unrealized (loss) on securities available-for-sale, net of tax	-		-		-		(27,741)	(27,741)																								
Cumulative effect of adopting FAS 133, net of tax	-		-			-	5,020																									
Changes in fair value of cash flow hedges, net of tax	-					-	5,757																									

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Derivative gains reclassified from other comprehensive income, net of tax	51		131	74	(2,932)	7,845
Comprehensive income						130,340
Issuance of stock upon exercise of options	2,898	57	71,538	74	1 <del>7</del> 1	71,595
Issuance of stock under employee stock plan	838	17	35,254	5	( <del></del> )	35,271
Repurchase of common stock	(900)	(18)	(11,503)	(28,183)	( <del>*</del> )	(39,704)
Income tax benefits realized from employee stock option exercises	-	19. (A)	48,114		-	48,114
Balance December 31, 2001	528,313	10,566	6,794,831	(1,197,300)	311,722	5,919,819
Comprehensive income						
Net income	628	141	(2)	63,787	12.1	63,787
Changes in unrealized (loss) on securities available-for-sale, net of tax		14	-	27	(38,778)	(38,778)
Changes in fair value of cash flow hedges, net of tax	-	-	( <del>-</del> )	-	(4,302)	(4,302)
Comprehensive income						20,707
Issuance of stock upon exercise of options	1,672	34	39,018	-	14.1	39,052
Issuance of stock under employee stock plan	1,066	21	35,091	24	12-1	35,112
Repurchase of common stock	(18,241)	(365)	(235,534)	(456,853)		(692,752)
Income tax benefits realized from employee stock option exercises	829	-	16,946	23		16,946
Balance December 31, 2002	512,810	10,256	6,650,352	(1,590,366)	268,642	5,338,884
Comprehensive income						
Net income	100	10	158	562,527	1773	562,527
Changes in unrealized gain on securities available-for-sale, net of tax	<b>1</b> 33	( <b>7</b> 1	1.71	7	29,249	29,249
Changes in fair value of cash flow hedges, net of tax	10	5	125	2	(858)	(858)
Comprehensive income						590,918
Issuance of stock upon exercise of options	16,039	320	487,908	<u>2</u>	25	488,228
Issuance of stock under employee stock plan	1,398	28	38,605		17.1	38,633
Repurchase of common stock	(5,505)	(109)	(71,584)	(129,652)	( <del>.</del> .)	(201,345)
Income tax benefits realized from employee stock option exercises	171000 (75)		264,980	5	(#)	264,980
Balance December 31, 2003	524,742 \$	10,495 \$	7,370,261 \$	(1,157,491) \$	297,033 \$	6,520,298

See Notes to Consolidated Financial Statements.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In this Annual 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 putable common stock, par value \$0.02 per share, all of which was redeemed by Roche Holdings, Inc. on June 30, 1999.

## DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0050 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Genentech is a leading biotechnology company using human genetic information to discover, develop, manufacture and commercialize biotherapeutics for significant unmet medical needs. We manufacture and commercialize 13 biotechnology products directly in the United States and license several additional products to other companies.

## Principles of Consolidation

The consolidated financial statements include the accounts of Genentech and all subsidiaries. Genentech also consolidated a variable interest entity in which Genentech is the primary beneficiary pursuant to Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46) "Consolidation of Variable Interest Entities," as amended, and recorded the noncontrolling interest in the consolidated balance sheet. Material intercompany accounts and transactions have been eliminated.

## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make judgments, assumptions and estimates that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates.

## **Changes in Accounting Principles**

In January 2003, the FASB issued FIN 46, as amended, which requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE's expected losses, receives a majority of the entity's expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003. However, the FASB deferred the effective date for VIEs created before February 1, 2003 to the period ended March 31, 2004 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

We adopted FIN 46 on July 1, 2003, and consolidated the entity from which we lease our manufacturing facility located in Vacaville, California as of that date, as we determined that this entity is a VIE, as defined by FIN 46, and that we are the primary beneficiary of this entity as we absorb a majority of its expected losses. Accordingly, we consolidated assets, which consist of the Vacaville manufacturing building and related equipment, net of accumulated depreciation on July 1, 2003. Such property and equipment had a carrying value of \$348.4 million at December 31, 2003 and was included in property, plant and equipment in the accompanying consolidated balance sheet. On July 1, 2003, we also consolidated the entity's debt of \$412.3 million and the noncontrolling interests of \$12.7 million, which amounts are included in long-term debt and litigation and other long-term liabilities, respectively, in the accompanying consolidated balance sheet at December 31, 2003. We recorded a \$47.6 million charge, net of \$31.8 million in taxes, (or \$0.09 per share) as a cumulative effect of the accounting change on July 1, 2003. Due to our residual value guarantee on the property, the nonrecourse feature of the underlying debt, and certain other provisions of the lease arrangement, we do not allocate any of the entity's depreciation or interest expenses to the noncontrolling interest. We had previously accounted for our involvement with this entity as an operating lease. See also the "Leases" note below for a discussion of all of our leases.

In April 2003, the FASB issued FAS 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." FAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities." The adoption of FAS 149 did not have a material effect on our financial statements.

We adopted Statement of Financial Accounting Standards No. 133 (or FAS 133), "Accounting for Derivative Instruments and Hedging Activities," on January 1, 2001. Upon adoption, we recorded a \$5.6 million charge, net of \$3.8 million in taxes, (\$0.01 per share) as a cumulative effect of a change in accounting principle, recognized \$6.0 million in gains, net of \$4.0 million in taxes, (\$0.01 per share) in "other income, net" related to certain hedging instruments and increased other comprehensive income by \$5.0 million, net of \$3.3 million in taxes, as a result of recording derivative instruments at fair value.

#### Reclassifications

Effective January 1, 2003, we made certain classification changes to our consolidated statements of income. Comparable amounts in the prior years have been reclassified to conform to the 2003 presentation. These classification changes included:

- · a new caption titled "other income, net" (see below for the composition of this new caption),
- a change from the "contract and other" caption to the new "contract revenues" caption (the gains on sales of biotechnology equity securities, which were previously included in "contract and other," are now reflected in the new "other income, net" caption), and
- a change from including write-downs of biotechnology equity securities and changes in the recoverability of our debt securities in "marketing, general and administrative" expenses to including them in the new "other income, net" caption.

The following table summarizes the components of "other income, net" (in millions):

Other Income, Net	2003		2002		2001			
Gains on sales of biotechnology equity securities and other	\$	21.1	\$	47.9	\$	37.7		
Write-downs of biotechnology debt and equity securities		(3.8)		(40.8)		(27.5)		

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Novartis Exhibit 2265.0051 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Interest income	78.4	101.4	130.5
Interest expense	(2.9)	(0.8)	(5.7)
Total other income, net	\$ 92.8	\$ 107.7	\$ 135.0

As part of our strategic alliance efforts, we invest in debt and equity securities of certain biotechnology companies with which we have or have had collaborative agreements. The "other income, net" caption now includes realized gains and losses from the sale of certain of these biotechnology equity securities as well as changes in the recoverability of our debt securities. In addition, "other income, net" includes write-downs for other-than-temporary declines in the fair value of certain of these biotechnology debt and equity securities, interest income and interest expense, net of amounts capitalized in 2002.

Certain other reclassifications of prior years' amounts have been made to our consolidated statements of income and our consolidated balance sheets to conform to the current year presentation.

#### Cash and Cash Equivalents

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

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#### **Revenue Recognition**

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenue arrangements with 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, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated uncollectible amounts, product returns and discounts.
- 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 reliably measured and collectibility is reasonably assured. Royalty estimates are made in advance of
  amounts collected using historical and forecasted trends.
- Contract revenue generally includes upfront and continuing licensing fees, manufacturing fees, milestone payments and reimbursements of development costs and post-marketing costs.
  - 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 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.
  - Manufacturing fees are recognized as revenue as the related manufacturing services are rendered, generally on a straight-line basis over the longer of the manufacturing obligation period or the expected product life.
  - Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
  - · Reimbursements of development and post-marketing costs are recognized as revenue as the related costs are incurred.

## Accounts Receivable Allowances

Our accounts receivable allowances are based on estimates for our trade and other receivables. We make significant estimates primarily related to our trade receivables. To determine the collectibility of our trade receivables, we prepare estimates for discounts, rebates and sales returns and allowances based primarily on analysis of existing contractual obligations, historical trends and experience and changes in customer financial conditions. If actual future results vary, we may need to adjust our estimates, which could have an impact on earnings in the period of the adjustment.

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Novartis Exhibit 2265.0052 Regeneron v. Novartis, IPR2021-00816

#### Investments in Marketable and Nonmarketable Securities

We invest in short-term and long-term marketable securities, primarily corporate notes, government agencies, preferred stock, asset-backed securities and municipal bonds. As part of our strategic alliance efforts, we may also invest in equity securities, dividend bearing convertible preferred stock and interest-bearing debt of other biotechnology companies. All of our common equity investments represent less than a 20% ownership position in the investee company. Marketable equity and debt securities are accounted for as available-for-sale investments as described below. Nonmarketable equity securities are carried at cost. We periodically monitor the liquidity and financing activities of the respective issuers to determine if impairment write downs are necessary.

Marketable equity and debt securities are classified into one of three categories: held-to-maturity, available-for-sale or trading. Securities are considered held-tomaturity when we have the positive intent and ability to hold the securities to maturity. Held-to-maturity debt securities are stated at amortized cost, including adjustments for amortization of premiums and accretion of discounts. Securities are considered trading when purchased principally for the purpose of selling in the near term. These securities are recorded as short-term investments and are carried at market value. Unrealized holding gains and losses on trading securities are included in interest income. Securities not classified as held-to-maturity or as trading are considered available-for-sale. These securities are recorded as either shortterm or long-term investments and are carried at fair value with unrealized gains and losses included in accumulated other comprehensive income in stockholders' equity. Nonmarketable equity securities are carried at cost, less write-downs for impairments. If the fair value of a security is below its carrying value for each trading day for six consecutive months or if its decline is due to a significant adverse event, the impairment is considered to be other-than-temporary and the security is written down to its estimated fair value. Other-than-temporary declines in fair value of all marketable securities are charged to "other income, net." Some of the factors we consider in determining whether a significant adverse event has occurred with an issuer include, among other things, unfavorable clinical trial results and the diminished prospect for new products, failure to receive product approval from a regulatory body, the termination of a major collaborative relationship and the liquidity position and financing activities of the issuer. The cost of all securities sold is based on the specific identification method. We recognized charges of \$3.8 million in 2003, \$40.8 million in 2002 and \$27.5 million in 2001 as a result of charges related to other-than-temporary declines in the fair values of certain of our marketable equity and debt securities.

## **Derivative Instruments**

We use derivatives to manage our market exposure to fluctuations in foreign currencies, U.S. interest rates and marketable equity investments. We record all derivatives on the balance sheet at fair value. For derivative instruments that are designated and qualify as a fair value hedge (i.e., hedging the exposure to changes in the fair value of an asset or a liability or an identified portion thereof that is attributable to a particular risk), the gain or loss on the derivative instrument, as well as the offsetting loss or gain on the hedged item attributable to the hedged risk, is recognized in current earnings during the period of the change in fair values. For derivative instruments that are designated and qualify as a cash flow hedge (i.e., hedging the exposure to variability in expected future cash flows that is attributable to a particular risk), the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. The gain or loss on the derivative instruments in excess of the cumulative change in the present value of future cash flows of the hedged transaction, if any, is recognized in current earnings during the period of change. We do not use derivative instruments for speculative purposes. See the "Derivative Financial Instruments" note below for further information on our accounting for derivatives

#### Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in first-out method. If inventory costs exceed expected market value due to obsolescence or lack of demand, reserves are recorded for the difference between the cost and the market value. These reserves are determined based on significant estimates. Inventories consist of currently marketed products, products manufactured under contract and product candidates awaiting regulatory approval (i.e. pre-launch inventories), which were capitalized based on management's judgment of probable near term commercialization.

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In anticipation of the launch of Avastin in 2004, we produced approximately \$86.7 million of inventory, net of reserves. The Avastin inventory was included in work in process at December 31, 2003. Avastin was approved by the U.S. Food and Drug Administration (or FDA) on February 26, 2004 and we began shipping Avastin on that date. Inventories at December 31 are summarized below (in thousands):

	2003	2002
Raw materials and supplies	\$ 37,069	\$ 30,181
Work in process	383,850	329,819
Finished goods	48,721	33,542
Total	\$ 469,640	\$ 393,542

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Novartis Exhibit 2265.0053 Regeneron v. Novartis, IPR2021-00816

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## Property, Plant and Equipment

The costs of buildings and equipment are depreciated using the straight-line method over the following estimated useful lives of the assets:

	Userui Lives
Buildings	25 years
Certain manufacturing equipment	15 years
Other equipment	4 or 8 years
Leasehold improvements	length of applicable lease

The costs of repairs and maintenance are expensed as incurred and were \$65.6 million in 2003, \$51.2 million in 2002 and \$52.8 million in 2001.

Property, plant and equipment balances at December 31, 2003 and 2002 are summarized below (in thousands):

	2003	2002
At cost:		
Land	\$ 153,265	\$ 149,533
Buildings	442,157	422,790
Equipment	924,303	880,624
Leasehold improvements	58,512	53,589
Construction-in-progress	498,231	289,810
Vacaville capitalized lease assets	425,000	-
	2,501,468	1,796,346
Less: accumulated depreciation and amortization	883,556	727,612
Net property, plant and equipment	\$ 1,617,912	\$ 1,068,734

Depreciation expense was \$124.7 million in 2003, \$104.6 million in 2002 and \$96.3 million in 2001.

## FDA Validation Costs

FDA validation costs are capitalized as part of the effort required to acquire and construct long-lived assets, including readying them for their intended use, and are amortized over the estimated useful life of the asset or the term of the lease, whichever is shorter.

## Restricted Cash and Investments

On October 3, 2002, we entered into an arrangement with third-party insurance companies to post a \$600 million bond in connection with the City of Hope trial judgment that was issued in the second quarter of 2002. As part of this arrangement, we were required to pledge \$630 million in cash and investments to secure this bond. Further, under certain lease agreements, we may be required from time to time to set aside cash as collateral. At December 31, 2003 and 2002, we had \$56.6 million of restricted cash and investments related to such lease agreements. These amounts are classified as restricted cash and investments on our consolidated balance sheet at December 31, 2003 and 2002.

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## Impairment of Long-Lived Assets

Long-lived assets and certain identifiable intangible assets to be held and used are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Goodwill and Other Intangible Assets

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0054 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Goodwill represents the difference between the purchase price and the fair value of the net assets acquired when accounted for by the purchase method of accounting arising from Roche's purchases of our Special Common Stock and push-down accounting (refer to the "Redemption of Our Special Common Stock" note below). On January 1, 2002, we adopted FAS 141, "Business Combinations" and FAS 142, "Goodwill and Other Intangible Assets." FAS 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001, and also specifies the criteria for the recognition of intangible assets separately from goodwill. Under the new rules, goodwill is no longer amortized but is subject to an impairment test at least annually. Prior to 2002, goodwill was amortized using the straight-line method over 15 years. We performed an impairment test of goodwill upon transition to FAS 142 on January 1, 2002, and perform an annual impairment test every September, and have found no impairment. We will continue to evaluate our goodwill for impairment annually and whenever events and changes in circumstances suggest that the carrying amount may not be recoverable. FAS 141 specifically identified assembled workforce as an intangible asset that is not to be recognized apart from goodwill and it was subsumed into goodwill on January 1, 2002. Other intangible assets that meet the new criteria continue to be amortized over their useful lives.

In accordance with FAS 141 and 142, we discontinued the amortization of goodwill and our trained and assembled workforce intangible asset, which resulted in an increase in reported net income by approximately \$157.6 million (or \$0.30 per share) in 2002, as compared to the accounting prior to the adoption of FAS 141 and 142.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from five to 15 years, and review for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We capitalize costs of patents and patent applications related to products and processes of significant importance to us and amortize these on a straight-line basis over their estimated useful lives of approximately 12 years.

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

Research and development (or R&D) expenses include salaries, benefits and other headcount related costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees, and facilities and overhead costs. R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. In addition, we fund R&D at other companies and research institutions under agreements, which we can generally terminate at will. R&D expenses also include post-marketing activities such as Phase IV and investigator-sponsored trials and product registries. R&D costs, including upfront fees and milestones paid to collaborative partners, are generally expensed as incurred.

## **Collaboration Profit Sharing**

Collaboration profit sharing primarily includes the net operating profit sharing with Biogen Idec Inc. (or Biogen Idec), formerly known as IDEC Pharmaceuticals Corporation, on Rituxan sales and with Novartis on Xolair sales, and the sharing of costs with these collaborators related to the commercialization of future products. See "Related Party Transactions" discussion below regarding Novartis related collaboration profit sharing expenses.

## **Royalty Expenses**

Royalty expenses directly related to product sales are classified in cost of sales. Other royalty expenses, relating to royalty revenue, are classified in marketing, general and administrative expenses and totaled \$114.3 million in 2003, \$92.0 million in 2002 and \$59.5 million in 2001.

#### Advertising Expenses

We expense the costs of advertising, which also includes promotional expenses, as incurred. Advertising expenses were \$197.8 million in 2003, \$111.7 million in 2002 and \$91.9 million in 2001.

## Stock Award Plans

We have elected to continue to follow Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options because the alternative fair value method of accounting prescribed by Statement of Financial Accounting Standards (or FAS) No. 123, "Accounting for Stock-Based Compensation," requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, the intrinsic value method of accounting, no compensation expense is recognized because the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant. We apply FAS 123 for disclosure purposes only. The FAS 123 disclosures include pro forma net income and earnings per share as if the fair value method of accounting had been used. We are currently evaluating our option valuation methodologies and assumptions in light of evolving accounting standards related to employee stock options.

The following information regarding net income and earnings per share has been determined as if we had accounted for our employee stock options and employee stock plan under the fair value method prescribed by FAS 123. The resulting effect on net income and earnings per share pursuant to FAS 123 is not likely to be representative of the effects in future periods, due to subsequent additional option grants and periods of vesting.

		2003		2002		2001
Net income as reported	\$	562,527	\$	63,787	\$	150,236
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards,						
net of related tax effects		172,045		166,624		152,799
	٠	200 100	*	(100 007)	•	(0.500)

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# Novartis Exhibit 2265.0055 Regeneron v. Novartis, IPR2021-00816

/17/22, 7:59 PM		Genentech, Inc Form 10-K for the period ending 12/31/2003									
Pro forma net income (loss)	Pro forma net income (loss)	\$	<mark>390,48</mark> 2	\$ ()	102,837)	\$	(2,363)				
	Earnings (loss) per share: Basic-as reported	\$	1.09	\$	0.12	\$	0.29				
	Basic-pro forma	\$	0.76	\$	(0.20)	\$	0.00				
	Diluted-as reported	\$	1.06	\$	0.12	\$	0.28				
	Diluted-pro forma	\$	0.7 <mark>6</mark>	\$	(0.20)	\$	0.00				

The fair value of options was estimated at the date of grant using a Black-Scholes option valuation model with the following weighted-average assumptions:

	2003	2002	2001
Risk-free interest rate	2.8 %	2.6 %	3.9%
Dividend yield	0%	0%	0 %
Volatility factors of the expected market price of our Common Stock	44.7 %	43.0 %	63.0 %
Weighted-average expected life of option (years)	5	5	5

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The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not provide a reliable single measure of the fair value of our employee stock options.

## 401(k) Plan

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Our 401(k) Plan (or the Plan) covers substantially all of our employees. For 2003 and earlier, we matched a portion of employee contributions, up to a maximum of 4% of each employee's eligible compensation. This match increases to 5% beginning in 2004. The match is effective December 31 of each year and is fully vested when made. Also beginning in 2004, we will annually contribute to every employee's account 1% of his or her eligible compensation, regardless of whether or not the employee participates actively in the Plan. We provided \$15.9 million in 2003, \$13.6 million in 2002 and \$11.9 million in 2001 for our match under the Plan.

## Income Taxes

Income tax provision (benefit) is based on pretax financial accounting income under 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 enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provisions (benefit) for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. We believe that our estimates are reasonable and that our reserves for income tax related uncertainties are adequate. Various internal and external factors may have favorable or unfavorable effects on our future effective 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, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings.

Effective with the consummation of the second public offering by Roche on October 26, 1999, we ceased to be a member of the consolidated federal income tax group (and certain consolidated or combined state and local income tax groups) of which Roche is the common parent. Accordingly, our tax sharing agreement with Roche now pertains only to the state and local tax returns in which we are consolidated or combined with Roche. We will continue to calculate our tax liability or refund with Roche for these state and local jurisdictions as if we were a stand-alone entity.

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0056 Regeneron v. Novartis, IPR2021-00816

## Earnings Per Share

Basic earnings per share is computed based on the weighted-average number of shares of our common stock outstanding. Diluted earnings per share is computed based on the weighted-average number of shares of our common stock and other dilutive securities. See also "Earnings Per Share" note below.

#### **Comprehensive** Income

Comprehensive income is comprised of net income and other comprehensive income (or OCI). OCI includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in OCI changes in the fair value of derivatives designated as effective cash flow hedges and unrealized gains and losses on our available-for-sale securities. Comprehensive income for the years ended December 31, 2003, 2002 and 2001 has been reflected in the consolidated statements of stockholders' equity.

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

	2003	2002
Net unrealized gains on securities available-for-sale	\$ 294.3	\$ 265.1
Net gains on cash flow hedges	2.7	3.5
Accumulated other comprehensive income	\$ 297.0	\$ 268.6

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The activity in OCI related to our available-for-sale securities was as follows (in millions):

		2003	2002	2001
Unrealized gains (losses) on securities available-for-sale (net of tax	¢	20.0	¢ (24.0)	¢ (21.0)
effect of \$ 25.9 in 2003, (\$23.1) in 2002, (\$14.5) in 2001) Reclassification adjustment for net gains included in net income	\$	38.9	\$ (34.6)	\$ (21.8)
(net of tax effect of (\$6.5) in 2003, (\$2.8) in 2002, (\$4.0) in 2001)		(9.7)	(4.2)	(5.9)
Change in net unrealized gains (losses) on securities available-for-sale	\$	29.2	\$ (38.8)	\$ (27.7)

The activity in OCI related to our cash flow hedges held during the years ended December 31, 2003, 2002 and 2001 was not material.

## REDEMPTION OF OUR SPECIAL COMMON STOCK

On June 30, 1999, Roche exercised its option to cause us to redeem all of our Special Common Stock held by stockholders other than Roche (the Redemption). The Redemption was reflected as a purchase of a business, which under U.S. generally accepted accounting principles required push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value. As a result, we were required to push down the effect of the Redemption and Roche's 1990 through 1997 purchases of our Common and Special Common Stock into our consolidated financial statements at the date of the Redemption. In 1990 and 1991 through 1997 Roche purchased 60% and 5%, respectively, of the outstanding stock of Genentech. In June 1999, we redeemed all of our Special Common Stock held by stockholders other than Roche resulting in Roche owning 100% of our Common Stock. The push-down effect of Roche's aggregate purchase price and the Redemption price in our consolidated balance sheet as of June 30, 1999 was allocated based on Roche's ownership percentages as if the purchases occurred at the original purchase for the 1990 and 1991 through 1997 purchases, and at June 30, 1999 for the Redemption. Management of Genentech determined the values of tangible and intangible assets, including in-process research and development (or IPR&D) used in allocating the purchase prices. The aggregate purchase price for the acquisition of all of Genentech's outstanding shares, including Roche's estimated transaction costs of \$10.0 million, was \$6,604.9 million, consisting of approximately \$2,843.5 million for the 1990 and 1991 through 1997 purchases and approximately \$3,761.4 million for the Redemption.

## GOODWILL AND OTHER INTANGIBLE ASSETS

The components of our acquisition-related intangible assets arising from the Redemption and push-down accounting at December 31, 2003 and 2002, are as follows (*in millions*):

2003

2002

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https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0057 Regeneron v. Novartis, IPR2021-00816

1/17/22, 7:59 PM	Genentech, Inc Form 10-K for the period ending 12/31/2003										
				Accumulated Amortization		Net arrying mount	Gross Carrying Amount		ccumulated mortization		Net arrying mount
	Developed product technology	\$ 1,194.1	\$	769.5	\$	424.6	\$ 1,194.1	\$	690.4	\$	503.7
	Core technology	443.5		329.8		113.7	443.5		308.0		135.5
	Developed license technology	467.5		423.8		43.7	467.5		394.6		72.9
	Tradenames	144.0		65.1		78.9	144.0		55.5		88.5
	Key distributor relationships	80.0		72.6		7.4	80.0		58.0		22.0
	Patents	116.6		44.5		72.1	100.0		36.2		63.8
	Other intangible assets	114.3		43.9		70.4	77.3		36.2		41.1
	Total	\$ 2,560.0	\$	1,749.2	\$	810.8	\$ 2,506.4	\$	1,578.9	\$	927.5

The \$29.3 million increase in net other intangible assets was primarily due to purchased licenses related to our Xolair and Rituxan products.

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Amortization expense of our goodwill and other intangible assets are as follows (in millions):

		2003	2002	2001	
Acquisition-related intangible assets amortization	\$	154.3	\$ 155.7	\$ 164.3	
Goodwill amortization			-	153.3	
Patents amortization		8.3	6.5	5.5	
Other intangible assets amortization		8.1	8.2	8.7	
Total amortization expense	\$	170.7	\$ 170.4	\$ 331.8	

The expected future annual amortization expense of our other intangible assets is as follows (in millions):

For the Year Ending December 31,	ortization xpense
2004	\$ 165.9
2005	142.9
2006	121.7
2007	120.5
2008	118.5
Thereafter	141.3
Total expected future annual amortization	\$ 810.8

## SEGMENT, SIGNIFICANT CUSTOMER AND GEOGRAPHIC INFORMATION

Our operations are treated as one operating segment as we only report profit and loss information on an aggregate basis to our executive committee. Information about our product sales, major customers and material foreign sources of revenues is as follows (in millions):

Product Sales	2003	2002	2001
Rituxan	\$ 1,489.1	\$ 1,162.9	\$ 818.6

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Novartis Exhibit 2265.0058 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Herceptin	424.8	385.2	346.7
Growth Hormone	321.9	297.2	250.2
Thrombolytic	185.2	180.2	197.1
Pulmozyme	167.2	138.1	123.0
Xolair	25.3	945	2
Raptiva	1.4	121	<u>_</u>
Product manufactured under contract	6.5	15.0	5
Actimmune	=	-	7.3
Total product sales	\$ 2,621.4	\$ 2,163.6	\$ 1,742.9

Three major customers, Amerisource/Bergen, Corp., Cardinal Health, Inc. and McKesson, Inc. each contributed 10% or more of our total operating revenues in each of the last three years. Amerisource/Bergen, a national wholesale distributor of all of our products, contributed 23% in 2003 and 2002, and 22% in 2001 of our total operating revenues. Cardinal Health, a national wholesale distributor of all our products, contributed 18% in 2003, and 19% in 2002 and 2001 of our total operating revenues. McKesson, a national wholesale distributor of all of our products, contributed 18% in 2003 and 2002, and 16% in 2001 of our total operating revenues

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Net foreign revenues by country were as follows (in millions):

	20	2002	2001	
Europe:				
Switzerland	\$ 2	210.3	\$ 118.4	\$ 74.9
Germany		33.0	31.7	39.2
France		21.0	13.5	8.9
Italy		15.4	23.0	18.0
Great Britain		13.7	20.9	24.5
Others		35.9	27.9	16.6
Asia Pacific		95.0	46.3	23.9
Canada		22.5	24.3	24.0
Other		30.6	10.0	3.7
Total net foreign revenues	\$ 4	477 <mark>.4</mark>	\$ 316.0	\$ 233.7

We currently sell primarily to distributors and health care companies throughout the U.S., perform ongoing credit evaluations of our customers' financial condition and extend credit, generally without collateral, and give discounts for prompt payment. In 2003, 2002 and 2001, we did not record any material additions to, or losses against, our allowance for bad debts.

## RESEARCH AND DEVELOPMENT ARRANGEMENTS

To gain access to potential new products and technologies and to utilize other companies to help develop our potential new products, we establish strategic alliances with various companies. These strategic alliances often include the acquisition of marketable and nonmarketable equity investments or debt of companies developing technologies that complement or fall outside our research focus and include companies having the potential to generate new products through technology exchanges and investments. Potential future payments may be due to certain collaborative partners achieving certain benchmarks as defined in the collaborative agreements. We also entered into product-specific collaborations to acquire development and marketing rights for products. See the "Leases, Commitments and Contingencies" and the "Related Party Transactions" notes below for a discussion of our more significant collaborations.

R&D in-licensing expense includes \$13.6 million in 2003, \$4.0 million in 2002 and \$19.0 million in 2001 of upfront payments to collaborators under in-licensing arrangements for the purchase of in-process research and development (or IPR&D). We have determined that the acquired IPR&D was not yet technologically feasible and that the acquired technology had no future alternative uses. The IPR&D purchases in 2001 included a \$15.0 million upfront payment to OSI

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## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Pharmaceuticals, Inc. (or OSI) under an agreement with us, OSI and Hoffmann-La Roche for the global co-development and commercialization of Tarceva for the potential treatment of solid tumor cancers. One of the members of the Board of Directors of OSI is also a member of the Board of Directors of Genentech.

## INCOME TAXES

The income tax provision (benefit) consists of the following amounts (in thousands):

2003		2003	2002	2001	
Current:					
Federal	\$	389,354	\$ 148,419	\$ 72,731	
State		46,971	14,187	25,024	
Total current		436,325	162,606	97,755	
Deferred:					
Federal		(133,085)	(166,008)	47,043	
State		(15,916)	(30,636)	(17,686)	
Total deferred		(149,001)	(196,644)	29,357	
Total income tax provision (benefit)	\$	287,324	\$ (34,038)	\$ 127,112	

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Tax benefits of \$265.0 million in 2003, \$16.9 million in 2002 and \$48.1 million in 2001 related to employee stock options and stock purchase plans. These amounts reduced current income taxes payable and were credited to stockholders' equity.

A reconciliation between our income tax provision (benefit) and the U.S. statutory tax rate follows (in thousands):

	2003	2002	2001
Tax at U.S. statutory rate of 35%	\$ 314,127	<b>\$ 10,412</b>	\$ 99,045
Research and other credits	(23,531)	(31,192)	(24,114)
Prior years' items	(34,819)	(9,545)	(14,000)
Export sales benefit	(10,325)	(1,393)	(305)
State taxes	44,842	837	16,219
Goodwill amortization	2	<u>_</u> 2	53,649
Tax-exempt investment income	(3,680)	(4,057)	(3,630)
Other	710	900	248
Income tax provision (benefit)	\$ 287,324	\$ (34,038)	\$ 127,112

Prior years' items in 2003 include additional research credits resulting from the settlement of IRS examinations in 2003. Other prior years' items relate principally to changes in estimates resulting from events in 2003, 2002 and 2001 that provided greater certainty as to the expected outcome of prior years' matters.

The components of deferred taxes consist of the following at December 31 (in thousands):

	2003	2002
Deferred tax liabilities:		
Depreciation	\$ (208,114)	\$ (209,144)
Unrealized gain on securities available-for-sale	(204,661)	(188,636)

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Novartis Exhibit 2265.0060 Regeneron v. Novartis, IPR2021-00816

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Intangibles - Roche transaction	(267,361)		(329,099)					
Other	(20,852)		(22,500)					
Total deferred tax liabilities	(700,988)		(749,379)					
Deferred tax assets:								
Capitalized R&D costs	38,227		58,983					
Federal credit carryforwards	43,429		43,429					
Expenses not currently deductib	le 294,148		258,213					
Deferred revenue	131,193		35,231					
Investment basis difference	213,222		202,876					
State credit carryforwards	76,598		78,052					
Other	-		6,580					
Total deferred tax assets	796,817		683,364					
Total net deferred taxes	\$ 95,829	\$	(66,015)					

Total tax credit carryforwards of \$120.0 million have no expiration date.

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## EARNINGS PER SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations for the years ended December 31, 2003, 2002, and 2001 (in thousands):

	2003	2002	2001
Numerator:			
Net income	\$ 562,527	\$ 63,787	\$ 150,236
Denominator:			
Weighted-average shares outstanding used for basic earnings			
per share	517,240	519,192	527,022
Effect of dilutive securities:			
Stock options	11,570	5,216	8,269
Weighted-average shares outstanding and dilutive securities			
used for diluted earnings per share	528,810	524,408	535,291

Options to purchase 17.4 million shares of our Common Stock with exercise prices ranging from \$63.63 to \$95.66 per share were outstanding during 2003, but were excluded from the computation of diluted earnings per share as their effect would have been antidilutive. See the "Capital Stock" note below for information on option expiration dates.

## FAIR VALUES OF INVESTMENT SECURITIES AND FINANCIAL INSTRUMENTS

## **Investment Securities**

Securities classified as trading and available-for-sale at December 31, 2003 and 2002 are summarized below *(in thousands)*. Estimated fair value is based on quoted market prices for these or similar investments.

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Novartis Exhibit 2265.0061 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

December 31, 2003		Amortized		Gross Unrealized Gains		Gross Unrealized Losses		Estimated Fair Value
TOTAL TRADING SECURITIES	\$	481,336	\$	38,862	\$	(848)	\$	519,350
SECURITIES AVAILABLE-FOR-SALE Equity securities	\$	45.192	\$	335,595	\$	(65)	\$	380,722
Preferred stock		157,108		14,510		(24)		171,594
Debt securities maturing:								
within 1 year		697,067		1,213		(881)		697,399
between 1-5 years		1,180,764		14,262		(2,783)		1,192,243
between 5-10 years		342,119		20,016		(2,534)		359,601
TOTAL SECURITIES AVAILABLE-FOR-SALE	\$	2, <mark>42</mark> 2,250	\$	385,596	\$	(6,287)	\$	2,801,559

December 31, 2002	Gross Amortized Unrealized Jber 31, 2002 Cost Gains		nrealized	Gross arealized Losses	1	Estimated Fair Value	
TOTAL TRADING SECURITIES	\$	466,417	\$	<mark>19,9</mark> 52	\$ (844)	\$	485,525

SECURITIES AVAILABLE-FOR-SALE					
Equity securities	\$ 37,788	\$ 242,172	\$ (3,315)	\$ 276,645	
Preferred stock	150,271	7,114	(573)	156,812	
Debt securities maturing::					
within 1 year	420,105	1,295	(425)	420,975	
between 1-5 years	432,422	16,567	(64)	448,925	
between 5-10 years	285,064	21,937	2	307,001	
TOTAL SECURITIES AVAILABLE-FOR-SALE	\$ 1,325,650	\$ 289,085	\$ (4,377)	\$ 1,610,358	

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## The carrying value of all cash and investment securities held at December 31, 2003 and 2002 is summarized below (in thousands):

2003		2002
\$ 243,145	\$	135,271
129,007		72,859
\$ 372,152	\$	208,130
	\$ 243,145 129,007	\$ 243,145 <b>\$</b> 129,007

Trading securities

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0062 Regeneron v. Novartis, IPR2021-00816

\$ 519,350 \$ 485,525

#### Genentech, Inc. - Form 10-K for the period ending 12/31/2003 Securities available-for-sale maturing within one year 448,676 184,105 Preferred stock 171,594 156,812 Total short-term investments \$ 1,139,620 \$ 826,442 Securities available-for-sale maturing after one year \$ 1,042,164 290,641 Equity securities 380 722 276,645 Total long-term marketable debt and equity securities \$ 1,422,886 \$ 567,286 Cash 57,204 57,304 Securities available-for-sale maturing within one year 119,716 164,011 Securities available-for-sale maturing between 1-10 years 509,680 465,285

In 2003, proceeds from the sales of available-for-sale securities totaled \$739.9 million; gross realized gains totaled \$2.1 million and gross realized losses totaled \$3.1 million. In 2002, proceeds from the sales of available-for-sale securities totaled \$1,746.2 million; gross realized gains totaled \$53.7 million and gross realized losses totaled \$5.9 million. In 2001, proceeds from the sales of available-for-sale securities totaled \$1,084.5 million; gross realized gains totaled \$30.0 million and gross realized losses totaled \$2.0 million. We recorded charges of \$3.8 million in 2003, \$40.8 million in 2002 and \$27.5 million in 2001 to write down certain available-for-sale biotechnology equity securities for which the decline in fair value below carrying value was deemed other-than-temporary.

Net change in unrealized holding gains (losses) on trading securities included in net income totaled \$18.9 million in 2003, \$21.2 million in 2002 and \$0.2 million in 2001.

The marketable debt securities we hold are issued by a diversified selection of corporate and financial institutions with strong credit ratings. Our investment policy limits the amount of credit exposure with any one institution. Other than asset-backed and mortgage-backed securities, these debt securities are generally not collateralized. In 2003, 2002 and 2001, we did not have charges for credit impairment on marketable debt securities.

#### **Financial Instruments**

The fair value of the foreign exchange put options was based on the forward exchange rates as of December 31, 2003 and 2002. The fair value of the equity forwards and collars was determined based on the closing market prices of the underlying securities at each year-end. The fair value of our long-term debt is estimated based on the current rates offered to us for debt of the same remaining maturities. The table below summarizes the fair value, which is also the carrying value, of our financial instruments at December 31, 2003 and 2002 (*in thousands*):

		2003	2002
Assets:			
Purchased foreign exchange put options	\$	3,347	\$ 6,404
Equity forwards		107,407	154,101
Equity collars		14,526	13,160
Liabilities:			
Purchased foreign exchange forward contracts		σ	5,402
Long-term debt	2	412,250	9 <del>0</del>

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The financial instruments we hold are entered into with a diversified selection of institutions with strong credit ratings, which minimizes the risk of loss due to nonpayment from the counterparty. Credit exposure is limited to the unrealized gains on our contracts. We have not experienced any material losses due to credit impairment of our financial instruments.

## DERIVATIVE FINANCIAL INSTRUMENTS

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

Total restricted cash and investments

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Novartis Exhibit 2265.0063 Regeneron v. Novartis, IPR2021-00816

686,600

686,600

## Foreign Currency Instruments

To protect against currency exchange risks on forecasted foreign currency cash flows from royalties to be received from licensees' foreign product sales over the next one to five years and expenses related to our foreign facility and our collaboration development expenses denominated in foreign currencies, we have instituted a foreign currency cash flow hedging program. We hedge portions of our forecasted foreign currency revenues with option contracts and we hedge our foreign currency expenses from our foreign facility with forward contracts. When the dollar strengthens significantly against the foreign currencies, the decline in value of future foreign currency revenues or expenses is offset by gains or losses, respectively, in the value of the option or forward contracts designated as hedges. Conversely, when the dollar weakens, the increase in the value of future foreign currency expenses is offset by gains are designated and documented at the hedge's inception as cash flow hedges and evaluated for hedge effectiveness at least quarterly.

During the years ended December 31, 2003 and 2002, the ineffective portions of our foreign currency hedging instruments were not material. Gains and losses related to option and forward contracts that hedge future cash flows are recorded against the hedged revenues or expenses in the statements of income.

At December 31, 2003, net losses on derivative instruments expected to be reclassified from accumulated other comprehensive income to earnings during the next twelve months due to the receipt of the related net revenues denominated in foreign currencies were \$4.3 million.

## Interest Rate Swaps

We enter into interest-rate swap agreements to limit our exposure to fluctuations in U.S. interest rates. Our material interest-bearing assets, or interest-bearing portfolio, consisted of cash, cash equivalents, restricted cash and investments, short-term investments, marketable debt securities and long-term investments as of December 31, 2003 and 2002. Our interest-rate swap agreements effectively convert a portion of our short-term investments in our interest-bearing portfolio to a fixed-rate basis, thus reducing the impact of interest rate changes on future interest income. In 2002, we recognized gains of \$10.7 million in earnings related to the early termination of certain of our swap agreements when we determined that the forecasted transaction was not likely to occur. We had no such gains in 2003 and we have no interest rate swaps outstanding as of December 31, 2003.

#### Equity Instruments

Our marketable equity securities portfolio consists primarily of investments in biotechnology companies whose risk of market fluctuations is greater than the stock market in general. To manage a portion of this risk, we enter into derivative instruments such as zero-cost collar instruments and equity forward contracts to hedge equity securities against changes in market value. We have zero-cost collars that expire in 2005 through 2007 and will require settlement in equity securities. A zero-cost collar is a purchased put option and a written call option on a specific equity security such that the cost of the purchased put and the proceeds of the written call offset each other; therefore, there is no initial cost or cash outflow for these instruments. At December 31, 2003, our zero-cost collars were designated and qualified as cash flow hedges.

As part of our fair value hedging strategy, we have also entered into equity forwards that mature in 2004 through 2008. An equity forward is a derivative instrument where we pay the counterparty the total return of the security above the current spot price and receive interest income on the notional amount for the term of the equity forward. A forward contract is a derivative instrument where we lock-in the termination price we receive from the sale of stock

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based on a pre-determined spot price. The forward contract protects us from a decline in the market value of the security below the spot price and limits our potential benefit from an increase in the market value of the security above the spot price. Throughout the life of the contract, we receive interest income based on the notional amount and a floating-rate index.

As part of our hedging transactions, we have entered and may in the future enter into security lending agreements with our counterparties. For an equity forward contract, in exchange for lending the hedged shares to the counterparty, we receive additional interest income throughout the life of the agreement based on the notional amount and a floating-rate index. For an equity collar, the benefit is embedded in the call strike price. The total fair value of the securities lent under these agreements was \$89.8 million at December 31, 2003 and \$76.5 million at December 31, 2002.

In 2003 and 2002, our recognized gains and losses related to certain derivative instruments as a result of FAS 133 were not material. We record gains and losses in "other income, net."

## OTHER ACCRUED LIABILITIES

Other accrued liabilities at December 31 are as follows (in thousands):

	2003	2002	
Accrued compensation	\$ 139,392	\$ 77,238	
Accrued royalties	105,366	87,082	
Accrued clinical and other studies (including to related parties: 2003-\$21,934; 2002-\$13,364)	88,064	59,330	
Accrued marketing and promotion costs	82,204	39,101	
Taxes payable	88,988	85,405	

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Accrued collaborations (including to related parties:		
2003-\$9,499; 2002-\$0)	141,551	103,432
Other (including to related parties:		
2003-\$26,705; 2002-\$37,752)	120,288	123,648
Total other accrued liabilities	\$ 765,853	\$ 575,236

## DEBT OBLIGATIONS

Our short-term debt at December 31, 2001 consisted of \$149.7 million of convertible subordinated debentures, with interest payable at 5%, due in March 2002. We redeemed the debentures in cash at maturity.

Our long-term debt at December 31, 2003 consisted of \$412.3 million of debt related to a variable interest entity (or VIE), which we consolidated on July 1, 2003, with minimum interest payable at 1.2%, due in November 2006. See discussion on this VIE below in "Leases."

#### LEASES, COMMITMENTS AND CONTINGENCIES

#### Leases

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance and minimum lease payments. Some of our leases have options to renew. Four of our operating leases are commonly referred to as "synthetic leases." Prior to the issuance of FIN 46, synthetic leases represented a form of off-balance sheet financing under which they were treated as operating leases for accounting purposes and as financing leases for tax purposes. Under FIN 46, each synthetic lease is evaluated to determine if it qualifies as a VIE and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

Under our synthetic lease structures, an unrelated third-party funds 100% of the costs of the acquisition and/or construction of the property and leases the asset to us, as the lessee, and at least 3% of the third-party funds represent

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at-risk equity. In addition, under our synthetic lease structures, upon termination or expiration, at our option, we must either purchase the property from the lessor at a predetermined amount that does not constitute a purchase at less than fair market value, sell the real property to a third-party, or renew the lease arrangement. If the property is sold to a third-party at an amount less than the amount financed by the lessor, we have agreed under residual value guarantees to pay the lessor up to an agreed upon percentage of the amount financed by the lessor.

The most significant of our synthetic leases relates to our manufacturing facility located in Vacaville, California. In November 2001, we completed a synthetic lease transaction for this facility, which had previously been leased to us under a predecessor synthetic lease. This new synthetic lease is structured differently from our other synthetic leases. As the lessee, we lease the property from an unrelated special purpose trust (owner/lessor) under an operating lease agreement for five years ending November 2006. Third-party financing is provided in the form of a 3% at-risk equity participation from investors and 97% debt commitment. Investors' equity contributions were equal to or greater than 3% of the fair value of the property at the lease's inception and are required to remain so for the term of the lease. A bankruptcy-remote, special purpose corporation (or SPC) was formed to fund the debt portion through the issuance of commercial paper notes. The SPC lends the proceeds from the commercial paper to the owner/lessor, who issues promissory notes to the SPC. The SPC loans mature in November 2006. The SPC lends the proceeds from the collectral facility provided by financing institutions and draws are generally available under that credit facility to repay the SPC's commercial paper. The collateral for the SPC loans includes the leased property, and an interest in the residual value guarantee provided by us. The creditors of the SPC do not have recourse to the general credit of Genentech. As the lessee, at any time during the lease term, we have the option to purchase the property at a mount that does not constitute a purchase at less than fair market value.

Under FIN 46, we determined that the entity from which we lease the Vacaville facility qualified as a VIE and that we are the primary beneficiary of this VIE as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46 on July 1, 2003, we consolidated the entity. See above in the "Changes in Accounting Principles" note for further information on our adoption of FIN 46.

Our three remaining leases were entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us various buildings that we occupy in South San Francisco, California. Under certain of these leases, we are required to maintain cash collateral of \$56.6 million, which we have included in our consolidated balance sheets as restricted cash and investments. We have evaluated our accounting for these leases under the provisions of FIN 46, and we determined that, as of July 1, 2003, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP leases.

Under all the synthetic leases, Genentech, as the lessee, is also required to maintain certain pre-defined financial ratios and is limited to the amount of debt it can assume. In addition, no Genentech officer or employee has any financial interest with regard to these synthetic lease arrangements or with any of the special purpose entities used in these arrangements. In the event of a default, the maximum amount payable under the residual value guarantee would equal 100% of the amount financed by the lessor, and our obligation to purchase the leased properties or pay the related residual value guarantees could be accelerated. We believed at the inception of the leases and continue to believe that the occurrence of any event of default that could trigger our purchase obligation is remote.

Future minimum lease payments under all leases, exclusive of the residual value guarantees, executory costs and sublease income, at December 31, 2003, are as follows *(in millions)*. These minimum lease payments were computed based on interest rates current at that time, which are subject to fluctuations in certain

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Novartis Exhibit 2265.0065 Regeneron v. Novartis, IPR2021-00816

# 1/17/22, 7:59 PM Genentech, Inc. - Form 10-K for the period ending 12/31/2003 market-based interest rates: Genentech, Inc. - Form 10-K for the period ending 12/31/2003

	2004	0	2005	2006	2	007	2	008	The	ereafter	8	Total
Vacaville synthetic lease <sup>(1)</sup>	\$ 6.2	\$	6.2	\$ 5.6	\$	5	\$	5	\$	73	\$	18.0
South San Francisco synthetic leases	2.7		2.6	1.1		a		2		<u>.</u>		6.4
Other operating leases	6.5		6.9	5.8		5.8		5.8		24.1		54.9
Total	\$ 15.4	\$	15.7	\$ 12.5	\$	5.8	\$	5.8	\$	24.1	\$	79.3

(1) Represents a VIE, which we consolidated effective July 1, 2003, as we are the primary beneficiary of this VIE

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Rental expenses for our operating leases were \$9.1 million in 2003 and 2002, and \$12.7 million in 2001.

The following summarizes the approximate initial fair values of the facilities at the inception of the related leases, lease terms and residual value guarantee amounts for each of our synthetic leases (in millions):

	Í	pproximate nitial Fair Value of sed Property	Lease Expiration	R	aximum Lesidual Value Larantee
Vacaville lease	\$	425.0	11/2006	\$	371.8
South San Francisco lease 1		56.6	07/2004		48.1
South San Francisco lease 2		160.0	06/2007		136.0
South San Francisco lease 3		25.0	01/2004		21.3
Total	\$	666.6		\$	577.2

We believe that there have been no impairments in the fair value or use of the properties that we lease under synthetic leases wherein we would be required to pay amounts under any of the residual value guarantees. We will continue to assess the fair values of the underlying properties and the use of the properties for impairment at least annually.

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnifications in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses and expenses to be material. In the case of South San Francisco Lease 1, we have pledged cash collateral of \$56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

## Commitments

In December 2003, we entered into a non-exclusive long-term manufacturing agreement with Lonza Biologics, a subsidiary of Lonza Group Ltd, under which Lonza will manufacture commercial quantities of Rituxan for us at Lonza's production facility in Portsmouth, New Hampshire. We may be obligated to make milestone payments to Lonza subject to Lonza's achievement of a series of factory preparation and process validation milestones, as well as receipt of FDA approval for the manufacturing of Rituxan bulk drug at the Lonza facility; the amounts of such payments cannot be estimated at this time. Following FDA approval at the Lonza facility, it is expected that commercial production would begin in 2005.

In August 2002, we entered into an agreement with Serono S.A., which, in addition to granting Serono marketing rights in specific areas of the world, includes an arrangement to collaborate on co-developing additional indications of Raptiva and to share certain global development costs. We also have a supply agreement with Serono, under which we may have a loss exposure up to a maximum of \$10.0 million.

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Novartis Exhibit 2265.0066 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

In the second quarter of 2002, we entered into a manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, to provide Immunex with additional manufacturing capacity for ENBREL® (etanercept) at Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we are responsible for facility modifications needed to manufacture ENBREL, including the internal labor costs and costs of certain raw materials for development runs. The facility modification and services costs, which include engineering and equipment costs, are reimbursable by Immunex. However, if certain milestones are not met, we are required to reimburse Immunex for up to 45% of the facility modification and services costs. Costs associated with development runs are reflected in R&D expense as incurred. Shipment of the product, including pre-approval product, to Immunex would be recorded as product sales based on an agreed upon price with the associated costs

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reflected in cost of sales. In the fourth quarter of 2003, we determined that certain milestones, including obtaining FDA approval for the manufacturing process, would likely not be met in the pre-agreed upon timeframe. As a result, certain equipment paid for by us related to ENBREL manufacturing will not qualify for reimbursement by Immunex. Certain ENBREL-related equipment in our consolidated balance sheet will be depreciated over the estimated useful life of the equipment and certain of it will be depreciated over the term of the supply arrangement.

In April 1996, we entered into a research collaboration agreement with XOMA to develop and commercialize Raptiva. The agreement was subsequently modified in the first quarter of 2003 to provide a convertible equity loan to XOMA of up to \$80.0 million (outstanding at any one time) to fund XOMA's share of development costs for Raptiva through FDA approval, and a cash loan of up to \$15.0 million to fund XOMA's share of U.S. marketing and sales costs prior to the date of regulatory approval of Raptiva. On October 27, 2003, the FDA approved Raptiva for the treatment of chronic moderate-to-severe plaque psoriasis. Under the provisions of the agreement, XOMA elected to defer payment of \$40.0 million of the development loan, of which we had previously recognized \$11.9 million as an other-than-temporary impairment charge, as an offset against the proceeds from its share of U.S. operating profits on Raptiva. XOMA repaid the remaining development loan balance of approximately \$29.6 million, of which we had previously recognized \$8.8 million as an other-than-temporary impairment charge, with Series B preference shares. The Series B preference shares are convertible at our option into XOMA common shares at \$7.75 per share. As of December 31, 2003, the commercial loan balance was \$13.5 million, which will be repaid in cash through April 2004.

## Contingencies

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

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, Genentech has 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. The first trial of this suit began on August 28, 2001. On October 24, 2001, the jury hearing the lawsuit announced that it was unable to reach a verdict and on that basis the Court declared a mistrial. COH requested a retrial, and the retrial began on March 20, 2002. On June 10, 2002, the jury voted to award the COH approximately \$300 million in compensatory damages. On June 24, 2002, the 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 were included in litigation and other long-term liabilities in the consolidated balance sheets at December 31, 2003 and 2002. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. The appeal process is ongoing. The amount of cash paid, if any, in connection with the COH matter will depend on the outcome of the appeal.

On June 7, 2000, Chiron Corporation filed a patent infringement suit against us in the U.S. District Court in the Eastern District of California (Sacramento), alleging that the manufacture, use, sale and offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 6,054,561. This patent was granted on April 25, 2000, and will expire on June 28, 2005, and it relates to certain antibodies that bind to breast cancer cells and/or other cells. Chiron is seeking compensatory damages for the alleged infringement, additional damages (e.g., for willful infringement), and attorneys' fees and costs. On April 22, 2002, the Court issued its decision ("Markman Order") construing certain aspects of the patent claims that are in dispute. On June 25, 2002, the Court issued several decisions regarding summary judgment motions that previously had been filed by Chiron and us. In those decisions, the Court ruled as a matter of law that Herceptin infringes claims 1 to 25 of Chiron's patent, and also ruled as a matter of law in favor of Chiron on some but not all of Genentech's defenses and counterclaims regarding the alleged invalidity and/or unenforceability of the patent. The trial of this suit began on August 6, 2002. Following the first phase of the trial, which related to Genentech's remaining defenses and counterclaims regarding the alleged invalidity of the patent segarding the alleged invalidity of the patent claims is regarding the alleged invalidity of that claims 1 to 25 of Chiron's patent were invalid, and on that

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basis the Court entered judgment in favor of Genentech. Chiron filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit, and Genentech filed a notice of cross-appeal. The appeal process is ongoing and therefore the outcome of this matter cannot be determined at this time.

On August 12, 2002, the U.S. Patent and Trademark Office (or Patent Office) declared an interference between the Chiron patent involved in the above-mentioned lawsuit (U.S. Patent No. 6,054,561) and a patent application exclusively licensed by Genentech from a university relating to anti-HER2 antibodies. An interference proceeding is declared to decide who first made a particular invention where two or more parties claim the same invention, whether the parties' claims are

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# Novartis Exhibit 2265.0067 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

patentable, and consequently who is or is not entitled to a patent on the invention. In declaring this interference, the Patent Office has determined that there is a substantial question as to whether the inventors of the Chiron patent were first to invent and are entitled to this patent. If the Patent Office were to decide that the inventors of the university's patent application were first to invent and that their claims are patentable, a new patent would be issued to the university and the Chiron patent would be revoked. On October 24, 2002, the Patent Office redeclared the interference to include, in addition to the above-referenced Chiron patent and university patent application, a number of patents and patent applications owned by either Chiron or Genentech, including Chiron's U.S. Patent No. 4,753,894 that is also at issue in the separate patent infringement lawsuit described below. The interference proceeding is ongoing and therefore the outcome of this matter cannot be determined at this time.

On March 13, 2001, Chiron filed another patent infringement lawsuit against us in the U.S. District Court in the Eastern District of California, alleging that the manufacture, use, sale and/or offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 4,753,894. Chiron is seeking compensatory damages for the alleged infringement, additional damages, and attorneys' fees and costs. Genentech filed a motion to dismiss this second lawsuit, which was denied. On November 1, 2002, the parties filed a proposed stipulation to stay all proceedings in this lawsuit until (1) the interference involving U.S. Patent No. 4,753,894 is resolved or (2) two years from entry of the proposed stipulation, whichever is sooner. On or about November 13, 2002, the Court entered the stipulation, staying the proceedings as requested by the parties. This lawsuit is separate from and in addition to the Chiron suit mentioned above.

We and Tanox Biosystems, Inc. (or Tanox) are parties to a July 1996 Settlement and Cross-Licensing Agreement relating to the development and manufacture of certain antibody products directed towards immunoglobin E, including Xolair and Hu-901. On February 20, 2002, Tanox filed an amended demand in an ongoing arbitration proceeding between Genentech and Tanox that is being conducted by the American Arbitration Association in San Francisco. In its amended demand, Tanox has claimed breach of the July 1996 Agreement, conversion, tortious interference, unjust enrichment, and unfair competition by Genentech, and requests injunctive relief as well as monetary damages "many times in excess of \$100,000,000." On March 14, 2002, Genentech denied all of Tanox's claims, and counterclaimed for breach of contract, theft of trade secrets, misappropriation, breach of confidence, interference with contract, and interference with economic expectancies by Tanox. Genentech requested injunctive relief and monetary damages. On October 16, 2002, Tanox announced that in a dispute between it and Novartis, an arbitration panel ruled that Tanox is not entitled to develop independently the Hu-901 antibody product. The Novartis/Tanox panel also ruled that Tanox is entitled to receive certain know-how from Novartis. Tanox contends in its dispute against Genentech that it is entitled to similar information from Genentech. The effect of the October 16 ruling from the Novartis/Tanox arbitration, if any, on Tanox's claims against Genentech cannot be determined since the arbitrators in the Tanox/Genentech and Novartis, and (2) additional royalties on future sales. On February 25, 2004, the parties settled and agreed to dismiss with prejudice all claims from the arbitration that began on January 13, 2003.

On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, City of Hope National Medical Center (or COH), and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 ("the '415 patent") that is co-owned by Genentech and COH and under which MedImmune and other companies have been licensed and are paying royalties to Genentech. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking to have the '415 patent declared 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 Genentech from enforcing the '415 patent, an award of actual and exemplary damages, and other relief. Genentech intends to vigorously defend itself

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against all of the allegations and claims in this lawsuit. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in Genentech's favor on all of MedImmune's antitrust and unfair competition claims. MedImmune is seeking to amend its complaint to reallege certain claims for antitrust and unfair competition and the Court has not yet ruled on this issue. Discovery in the case on the remaining claims is ongoing and trial is currently set to begin on August 30, 2004. An estimate of any potential loss or range of loss cannot be made at this time.

We recorded \$53.9 million in 2003 for accrued interest and bond costs related to the COH trial judgment. In 2002, we recognized \$543.9 million of litigationrelated special charges, which included the COH trial judgment, including accrued interest and bond costs, and certain other litigation-related matters. In conjunction with the City of Hope judgment, we arranged to post a \$600.0 million surety bond and as part of this arrangement, we were required to pledge \$630.0 million in cash and investments to secure the bond. In addition, we accrued \$4.7 million in 2003 and \$9.1 million in 2002 of royalty expenses related to the City of Hope judgment, which was reflected in marketing, general and administrative expenses. 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 City of Hope trial results. These special charges represent our estimate of the costs for the current resolution of these matters and are included in litigation and other long-term liabilities in the consolidated balance sheet at December 31, 2002 and 2003. We developed this estimate in consultation with outside counsel handling our defense in these matters and it is based upon the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. The amount of cash, if any, paid in connection with the City of Hope matter will depend on the outcome of the appeal.

#### Litigation Settlement

In August 2003, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately \$0.19 in earnings per diluted share for 2003 and was reported as a litigation-related special item in our consolidated statements of income. In November 2003, we received a settlement payment from Bayer, one of our licensees, in connection with the settlement of a breach of contract action which resulted in an increase of approximately \$0.03 in earnings per diluted share for 2003 and was reported as a litigation-related special item.

## RELATIONSHIP WITH ROCHE

As a result of the Redemption of our Special Common Stock, the then-existing governance agreement between us and Roche terminated, except for provisions relating to indemnification and stock options, warrants and convertible securities. In July 1999, we entered into certain affiliation arrangements with Roche, amended our licensing and marketing agreement with Hoffmann-La Roche, and entered into a tax sharing agreement with Roche as follows:

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# Novartis Exhibit 2265.0068 Regeneron v. Novartis, IPR2021-00816

## Affiliation Arrangements

Our board of directors consists of two Roche directors, three independent directors nominated by a nominating committee currently controlled by Roche, and one Genentech employee. However, under our bylaws, Roche has the right to obtain proportional representation on our board at any time. Roche intends to continue to allow our current management to conduct our business and operations as we have done in the past. However, we cannot ensure that Roche will not implement a new business plan in the future.

#### Tax Sharing Agreement

Since the redemption of our Special Common Stock in June 1999, and until Roche completed its second public offering of our Common Stock in October 1999, we were included in Roche's U.S. federal consolidated group and state and local consolidated or combined income tax groups. Accordingly, we entered into a tax sharing agreement with Roche. Pursuant to the tax sharing agreement, we and Roche were to make payments such that the net amount paid by us on account of federal consolidated and state and local consolidated or combined income taxes was determined as if we had filed separate, stand-alone federal, state and local income tax returns.

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Effective with the consummation of Roche's second public offering of Genentech Common Stock on October 26, 1999, we ceased to be a member of the consolidated federal income tax group (and certain state and local consolidated or combined income tax groups) of which Roche is the common parent. Accordingly, our tax sharing agreement with Roche now pertains only to the state and local tax returns in which we are consolidated or combined with Roche. We will continue to calculate our tax liability or refund with Roche for these state and local jurisdictions as if we were a stand-alone entity.

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

We expect from time to time to 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 we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. The affiliation agreement provides that we will repurchase a sufficient number of shares pursuant to this program such that, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance will be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche as well as for stock splits or stock combinations) divided by 509,194,352 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999 and October 2000. We have repurchased shares of our common stock in 2003 (see discussion below in Stock Repurchase Program). As long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, the affiliation agreement provides that 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 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. On December 31, 2003, Roche's percentage ownership of our common stock was 58.4%, which was 1.8% below the Minimum Percentage.

## **RELATED PARTY TRANSACTIONS**

## Roche

We enter into transactions with Roche, Hoffmann-La Roche and its affiliates in the ordinary course of business. The accounting policies we apply to our transactions with Roche and its affiliates are consistent with those used in transactions with independent third-parties.

In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under its existing licensing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately \$188.0 million and will pay 75% of subsequent global development costs related to the metastatic colorectal cancer indication of Avastin and all others unless Hoffmann-La Roche specifically opts out of the development of certain other indications.

In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. (other than territory previously licensed to others) under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us \$8.4 million and will pay 50% of subsequent global development costs related to PRO70769 unless Roche opts out of the development of certain other indications. We will receive royalties on net sales of Avastin and PRO70769 in countries outside of the U.S.

As part of our licensing and marketing agreement, we recognized milestone-related royalty revenue of \$20.0 million in 2003 and \$10.0 million in 2002 as a result of Hoffmann-La Roche reaching \$400.0 million and \$200.0 million, respectively, in net sales of Herceptin outside of the U.S. Contract revenue from Hoffmann-La Roche, including

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Novartis Exhibit 2265.0069 Regeneron v. Novartis, IPR2021-00816 amounts earned related to ongoing development activities after the option exercise date, totaled \$66.5 million in 2003, \$7.6 million in 2002 and \$5.8 million in 2001. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled \$353.5 million in 2003, \$269.9 million in 2002 and \$164.1 million in 2001. In 2003, Hoffmann-La Roche's Penzberg, Germany facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Our ex-U.S. sales of Herceptin to Hoffmann-La Roche were \$18.8 million in 2003, \$40.3 million in 2002 and \$31.3 million in 2001. R&D expenses include amounts related to Roche of \$37.6 million in 2003, \$7.1 million in 2002, and \$2.9 million in 2001.

## Novartis

We understand that Novartis AG (or Novartis) holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, Novartis is deemed to have an indirect beneficial ownership interest under FAS 57 "Related Party Disclosures" of more than 10% of Genentech's voting stock.

In June 2003, we entered into an agreement with Novartis Opthalmics, an affiliate of Novartis AG, under which Novartis Opthalmics licensed the exclusive right to develop and market Lucentis outside of North America for the indication of age-related macular degeneration (or AMD). As part of this agreement, Novartis Opthalmics paid an upfront milestone and R&D reimbursement fee of \$46.6 million and will pay 50% of Genentech's ongoing Phase III and related development expenses. Genentech is not responsible for any portion of the development and commercialization costs incurred by Novartis outside of North America, but we may receive additional payments for Novartis' achievement of certain clinical development and product approval milestones outside of North America. In addition, we will receive royalties on net sales of Lucentis products, which we will manufacture and supply to Novartis, outside of North America.

During 2000, we entered into an arrangement with Novartis, whereby Novartis was required to fund a portion of the cost of our Xolair inventory until the FDA approved the product for marketing. In June 2003, we received FDA approval to market Xolair. This amount was to be returned to Novartis upon the earlier of regulatory approval of Xolair in the U.S. or the European Union, and was recorded in other accrued liabilities in our financial statements beginning in 2000. The amount payable to Novartis was \$37.8 million at December 31, 2002. In June 2003, we received FDA approval to market Xolair; in July 2003, \$37.8 million of funding that had been received from Novartis was repaid. Our arrangement with Novartis allows us to record all sales and cost of sales in the U.S. Genentech and Novartis will co-develop and co-promote in the U.S. and both will separately make payments to Tanox; Genentech's will be in the form of royalties. We will pay Novartis a share of the U.S. operating profits and record it as collaboration profit sharing expense. Novartis will market the product in and record all sales and cost of sales and cost of sales in cervel of sales in the U.S. Genentech is currently manufacturing the product and receives cost plus a mark-up similar to other arrangements where we manufacture. Novartis plans to assume primary manufacturing responsibilities in the future. Collaboration profit sharing expenses were \$9.9 million in 2003, \$1.8 million in 2001. R&D expenses include amounts related to Novartis of \$11.1 million in 2003 and \$5.8 million in 2002. Such expenses from Novartis in 2001 was not material.

Revenue from Novartis related to product sales and the associated cost of sales was not material in 2003 or in prior years. Contract revenue from Novartis, including amounts recognized under new licensing arrangements entered into in 2003 and amounts earned related to commercial and ongoing development activities, was \$24.2 million in 2003 and \$5.7 million in 2002. We had no such revenues from Novartis in 2001.

## CAPITAL STOCK

## **Common Stock and Special Common Stock**

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche. Subsequently, in July and October 1999, and March 2000, Roche consummated public offerings of our Common Stock. On January 19, 2000, Roche completed an offering of zero-coupon notes that are exchangeable for an aggregate of approximately 13.0 million shares of our Common Stock held by Roche. See "Redemption of Our Special Common Stock" and "Relationship With Roche" notes above for a discussion of our Redemption and the related transactions.

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#### Stock Repurchase Program

Under a stock repurchase program approved by our Board of Directors on December 5, 2003, Genentech is authorized to repurchase up to \$1 billion of its common stock through December 31, 2004. In this plan, as in previous stock repurchase plans, 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 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. Under a previous stock through the period ended June 30, 2003.

Our stock repurchases under the above plans are summarized below (in thousands).

	TOTAL		2003			2002				2001					
	Shares		Amounts	Shares		Amount	s	Shares		Ашо	ints		Shares		Amounts
 roved by Board pre-program Irchase program expired	800	\$	34,034		-	\$	2		2	\$	-	20	800	\$	<mark>34,03</mark> 4

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k 2003.htm

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# Novartis Exhibit 2265.0070 Regeneron v. Novartis, IPR2021-00816

1/17/22, 7:59 PM		Genentech, Inc Form 10-K for the period ending 12/31/2003											
	June 30, 2003	23,775	893,696	5,434	195,274	18,241	692,752	100	5,670				
I	Repurchase program expiring December 31, 2004	71	6,071	71	<mark>6,071</mark>	-	1960	( <b>1</b> )					
	Total repurchases	24,646	\$ 933,801	5,505	\$ 201,345	18,241	\$ 692,752	900	\$ <mark>39,70</mark> 4				

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

## Stock Plans

1/

We currently have an employee stock 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 are limited to 15% of each employee's eligible compensation and subject to certain Internal Revenue Service restrictions. All full-time employees of Genentech are eligible to participate in the 1991 Plan. Of the 23.2 million shares of Common Stock reserved for issuance under the 1991 Plan, 20.8 million shares have been issued as of December 31, 2003. During 2003, 4,990 of the eligible employees participated in the 1991 Plan.

We currently grant options under a stock option plan adopted in 1999 and amended thereafter (or the 1999 Plan), that allows for the granting of non-qualified stock options, incentive stock options and stock purchase rights to employees, directors and consultants of Genentech. Incentive stock options may only be granted to employees under this plan. Generally, non-qualified options and incentive options have a maximum term of 10 years. In general, options vest in increments over four years from the date of grant, although we may grant options with different vesting terms from time to time. No stock purchase rights or incentive stock options have been granted under the 1999 Plan to date.

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A summary of our stock option activity and related information is as follows:

	Shares	ighted-Average xercise Price	
Options outstanding at December 31, 2000	40,944,862	\$ 39.84	
Grants	10,740,689	42.58	
Exercises	(2,899,135)	24.69	
Cancellations	(2,146,446)	45.84	
Options outstanding at December 31, 2001	46,639,970	41.06	
Grants	12,655,875	28.98	
Exercises	(1,672,772)	23.43	
Cancellations	(2,203,658)	53.16	
Options outstanding at December 31, 2002	55,419,415	38.37	
Grants	10,890,520	81.09	
Exercises	(16,039,322)	68.27	
Cancellations	(2,207,504)	47.59	
Options outstanding at December 31, 2003	48,063,109	\$ 50.36	

The following table summarizes information concerning currently outstanding and exercisable options:

As of December 31, 2003

**Options Outstanding** 

**Options Exercisable** 

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Novartis Exhibit 2265.0071 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

Range of Exercise Prices	Number Outstanding	Weighted- Average Years Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
\$12.53 - \$17.78	893,205	6.19	\$14.91	893,205	\$14.91
\$20.00 - \$28.70	17,646,638	7.44	\$26.77	10,017,070	\$25.42
\$30.07 - \$44.77	11,561,689	7.27	\$41.67	7,123,060	\$42.22
\$45.75 - \$66.00	777,874	7.19	\$56.00	413,299	\$57.97
\$71.25 - \$95.66	17,183,703	8.54	\$82.01	5,356,716	\$79.75
	48,063,109			23,803,350	

Using the Black-Scholes option valuation model, the weighted-average fair value of options granted was \$34.95 in 2003, \$12.54 in 2002 and \$24.00 in 2001. Shares of Common Stock available for future grants under all stock option plans were 20,365,697 at December 31, 2003. We have reserved a sufficient number of shares of our Common Stock in connection with these stock option programs.

## SUBSEQUENT EVENTS

On January 2, 2004, one of our synthetic leases related to an office building we occupy in South San Francisco expired (refer to "South San Francisco Lease 3" in "Leases, Commitments and Contingencies" note above). Under the terms and conditions of the lease agreement, we must either purchase the property from the lessor at a predetermined amount that does not constitute a purchase at less than fair market value, sell the real property to a third-party, or renew the lease arrangement. At the expiration of the lease, we purchased the related land and office building from our lessor at a cost of \$25.0 million.

To accommodate our growth, we purchased on February 4, 2004, an additional building in the research and industrial park in South San Francisco at a cost of \$18.0 million.

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## QUARTERLY FINANCIAL DATA (UNAUDITED) (in thousands, except per share amounts)

	2003 Quarter Ended											
	December 31		Sep	September 30		June 30		March 31				
Total operating revenues	\$	933,899	\$	817,044	\$	799,712	\$	749,672				
Product sales		723,736		654,948		644,324		598,482				
Gross margin from product sales		597,534		539,275		520,917		483,640				
Income before cumulative effect of accounting changes		126,730		199,636		132,345		151,471				
Cumulative effect of accounting changes, net of tax		æ		47,655		-		-				
Net income <sup>(1)</sup>		126,730		151,981		132,345		151,471				
Earnings per share:												
Basic		0.24		0.29		0.26		0.30				
Diluted		0.24		0.29		0.25		0.29				
				2002 Quart	er End	led						

	De	cember 31	Sep	otember 30	June 30	1	March 31
Total operating revenues	\$	743,195	\$	650,138	\$ 622,243	\$	568,082
Product sales		611,766		551,823	523,527		476,549
Gross margin from product sales		491,928		439,342	416,660		374,105
Net income (loss) <sup>(2)</sup>		92,828		89,304	(213,648)		95,303

Earnings (loss) per share:

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0072 Regeneron v. Novartis, IPR2021-00816

Genentech, Inc Form 10-K for the period ending 12/31/2003							
0.18	0.17	(0.41)	0.18				
0.18	0.17	(0.41)	0.18				
	0.18	0.18 0.17	0.18 0.17 (0.41)				

(1) Net income in 2003 includes recurring charges of \$154 3 million related to the Redemption and amounts received related to our litigation settlements with Amgen, Inc and Bayer The settlements were both reported as litigation-related special items in our consolidated statements of income The settlement of our complaint against Amgen, originally filed in 1996, resulted in a one-time payment from Amgen to us and an increase of approximately \$0 17 in earnings per diluted share for the third quarter of 2003 Net income in 2003 also reflects our adoption of FIN 46, "Consolidation of Variable Interest Entities," an interpretation of Accounting Research Bulletin No 51, on July 1, 2003, which resulted in a \$47.6 million charge, net of \$31.8 million in taxes, (or \$0.09 per share) as a cumulative effect of the accounting change in the third quarter of 2003

(2) Net income (loss) in 2002 reflects litigation-related special charges of \$518.0 million in the second quarter for the City of Hope judgment and other litigation-related matters, \$12.5 million in the third quarter for accrued interest related to the City of Hope judgment, and \$13.4 million in the fourth quarter for accrued interest and costs related to obtaining a surely bond in conjunction with the City of Hope judgment. Net income (loss) in 2002 As a result of our adoption of FAS 141 and 142 on January 1, 2002, reported net income increased in each quarter of 2002 As a result of our adoption of FAS 141 and 142 on January 1, 2002, reported net income increased in each quarter of 2002 by approximately \$39.4 million (or \$0.08 per share) due to the cessation of goodwill amortization and the amortization of our trained and assembled workforce intangible asset

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Item 9.

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

(a) 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-K. 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.

(b) *Changes in Internal Controls*: There were no significant changes in the Company's internal controls or other factors that could significantly affect those controls subsequent to the date of the Company's evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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## PART III

#### Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY

(a) The sections labeled "Nominees for Directors," "Board Committees and Meetings," "Audit Committee Report," and "Section 16(a) Beneficial Ownership Reporting Compliance" of our Proxy Statement in connection with the 2004 Annual Meeting of Stockholders are incorporated herein by reference.

(b) Information concerning our Executive Officers is set forth in Part I of this Form 10-K.

## Item 11. EXECUTIVE COMPENSATION

The sections labeled "Compensation of Directors," "Compensation of Executive Officers," "Summary of Compensation," "Summary Compensation Table," "Stock Option Grants and Exercises," "Option Grants in Last Fiscal Year," "Aggregated Option Exercises in Last Fiscal Year and FY-End Option Values," "Change-In-Control Agreements," "Loans and Other Compensation" and "Compensation Committee Interlocks and Insider Participation" of our Proxy Statement in connection with the 2004 Annual Meeting of Stockholders are incorporated herein by reference.

#### Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The sections labeled "Relationship With Roche," "Equity Compensation Plans" and "Beneficial Ownership of Principal Stockholders, Directors and Management" of our Proxy Statement in connection with the 2004 Annual Meeting of Stockholders are incorporated herein by reference.

## Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The sections labeled "Relationship With Roche," "Loans and Other Compensation" and "Certain Relationships and Related Transactions" of our Proxy Statement in connection with the 2004 Annual Meeting of Stockholders is incorporated herein by reference.

## Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The sub-section labeled "Principal Accounting Fees and Services" of our Proxy Statement in connection with the 2004 Annual Meeting of Stockholders is incorporated herein by reference.

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https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k 2003.htm

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Novartis Exhibit 2265.0073 Regeneron v. Novartis, IPR2021-00816

## PART IV

## Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are included as part of this Annual Report on Form 10-K.

## 1. Index to Financial Statements

Report of Ernst & Young LLP, Independent Auditors

Consolidated Statements of Income for the years ended December 31, 2003, 2002 and 2001

Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001

Consolidated Balance Sheets at December 31, 2003 and 2002

Consolidated Statements of Stockholders' Equity for the year ended December 31, 2003, 2002 and 2001

Notes to Consolidated Financial Statements

Quarterly Financial Data (unaudited)

## 2. Financial Statement Schedule

The following schedule is filed as part of this Form 10-K:

Schedule II- Valuation and Qualifying Accounts for the years ended December 31, 2003, 2002 and 2001

All other schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

## 3. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation. <sup>(1)</sup>
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation. <sup>(6)</sup>
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation. <sup>(8)</sup>
3.4	Restated Bylaws. <sup>(10)</sup>
4.4	Form of Common Stock Certificate. <sup>(2)</sup>
10.1	Form of Affiliation Agreement, dated as of July 22, 1999, between Genentech, Inc. and Roche Holdings, Inc. <sup>(2)</sup>
10.2	Amendment No. 1, dated October 22, 1999, to Affiliation Agreement between Genentech, Inc. and Roche Holdings, Inc. <sup>(5)</sup>
10.3	Form of Amended and Restated Agreement, restated as of July 1, 1999, between Genentech, Inc. and F. Hoffmann-La Roche Ltd regarding Commercialization of Genentech's Products outside the United States. <sup>(2)</sup>
10.4	Form of Tax Sharing Agreement, dated as of July 22, 1999, between Genentech, Inc. and Roche Holdings, Inc. <sup>(2)</sup>
10.5	Genentech, Inc. Tax Reduction Investment Plan, as amended and restated as of January 1, 2002. <sup>(10)</sup>
10.6	1990 Stock Option/Stock Incentive Plan, as amended effective October 16, 1996. <sup>(4)</sup>
10.7	1994 Stock Option Plan, as amended effective October 16, 1996. <sup>(4)</sup>
10.8	1996 Stock Option/Stock Incentive Plan, as amended effective October 16, 1996. <sup>(4)</sup>

10.8 1996 Stock Option/Stock Incentive Plan, as amended effective October 16, 1996.<sup>(4)</sup>

10.9 1999 Stock Plan, as amended and restated as of February 13, 2003.<sup>(11)</sup>

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10.10 1991 Employee Stock Plan, as amended on April 23, 2003.

10.11 Long-Term Key Employee Incentive Program effective as of July 1 1999 <sup>(5)</sup> https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0074 Regeneron v. Novartis, IPR2021-00816 one remarcy employee meanine roogani, encente as or say 1, 1999.

- 10.12 Promissory Note, dated as of December 22, 2000, issued to Genentech, Inc. by Myrtle S. Potter.<sup>(7)</sup>
- 10.13 Change in Control Agreement, dated as of January 20, 2001, between Genentech, Inc. and Myrtle S. Potter.<sup>(7)</sup>
- 10.14 Lease, dated as of October 26, 2001, between Genentech, Inc. and Vacaville Real Estate Trust 2001.<sup>(9)</sup>
- 10.15 Participation Agreement, dated as of October 26, 2001, among Genentech, Inc., Vacaville Real Estate Trust 2001, Wilmington Trust Company, The Chase Manhattan Bank, J.P. Morgan Securities, Inc., BNP Paribas, Credit Suisse First Boston, UBS AG, Stamford Branch, Wachovia Bank and various financial institutions named therein <sup>(9)</sup>
- 10.16 Amended and Restated Backup Facility Agreement and Amendment to Other Operative Agreements, dated as of November 6, 2003, among DNA Finance Corp, JP Morgan Bank and various financial institutions named therein.
- 10.17 Guarantee, dated as of October 26, 2001, between Genentech, Inc., DNA Finance Corp and the investors named therein.<sup>(9)</sup>
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.
- 24.1 Power of Attorney. Reference is made to the signature page.
- 28.1 Description of the Company's capital stock.<sup>(3)</sup>
- 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.
- 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.
- 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.

- (2) Filed as an exhibit to Amendment No 3 to our Registration Statement (No 333-80601) on Form S-3 filed with the Commission on July 16, 1999 and incorporated herein by reference
- (3) Incorporated by reference to the description under the heading "Description of Capital Stock" relating to our Common Stock in the prospectus included in our Amendment No 2 to the Registration Statement on Form S-3 (No 333-88651) filed with the Commission on October 20, 1999, and the description under the heading "Description of Capital Stock" relating to the Common Stock in our final prospectus filed with the Commission on October 21, 1999 pursuant to Rule 424(b)(1) under the Securities Act of 1933, as amended, including any amendment or report filed for the purpose of updating that description
- (4) Filed as an exhibit to our Registration Statement (No 333-83157) on Form S-8 filed with the Commission on July 19, 1999 and incorporated herein by reference
- (5) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 1999 filed with the Commission and incorporated herein by reference
- (6) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2000
- (7) Filed as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001 filed with the Commission and incorporated herein by reference This is an agreement between the Company and an executive officer
- (8) Filed as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 filed with the Commission and incorporated herein by reference
- (9) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2001 filed with the Commission and incorporated herein by reference
- (10) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2002 filed with the Commission and incorporated herein by reference
- (11) Filed as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003 filed with the Commission and incorporated herein by reference

#### (b) Reports on Form 8-K:

On October 8, 2003, we filed a Report on Form 8-K under Item 5 - Other Events, reporting the issuance of a press release, announcing our earnings for the quarter ended September 30, 2003.

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## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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. Registrant

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Novartis Exhibit 2265.0075 Regeneron v. Novartis, IPR2021-00816

<sup>(1)</sup> Filed as an exhibit to our Current Report on Form 8-K filed with the Commission on July 28, 1999 and incorporated herein by reference

Date: February 27, 2004

By:

/s/ JOHN M. WHITING

John M. Whiting Vice President, Controller, and Chief Accounting Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Louis J. Lavigne, Jr., Executive Vice President and Chief Financial Officer, and John M. Whiting, Vice President, Controller and Chief Accounting Officer, and each of them, his true and lawful attorneys-in-fact and agents, with the full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date	
Principal Executive Officer:			
/s/ ARTHUR D. LEVINSON	Chairman, President and Chief Executive Officer	February 27, 2004	
Arthur D. Levinson	Chief Executive Officer		
Principal Financial Officer:			
/s/ LOUIS J. LAVIGNE, JR.	Executive Vice President and	February 27, 2004	
Louis J. Lavigne, Jr.	Chief Financial Officer		
Principal Accounting Officer:			
/s/ JOHN M. WHITING	Vice President, Controller, and	February 27, 2004	
John M. Whiting	Chief Accounting Officer		
	Page 92		
<u>Signature</u> Directors:	<u>Tide</u>	Date	
/s/ HERBERT W. BOYER Herbert W. Boyer	Director	February 27, 2004	

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0076 Regeneron v. Novartis, IPR2021-00816

## Genentech, Inc. - Form 10-K for the period ending 12/31/2003

/s/ JONATHAN K.C. KNOWLES	Director	February 27, 2004
Jonathan K.C. Knowles		
/s/ FRANZ B. HUMER	Director	February 27, 2004
Franz B. Humer		THE SAME AND A CONTRACT OF
/s/ MARK RICHMOND	Director	F 1 27 2004
/s/ MARK RICHMOND	Director	February 27, 2004
Mark Richmond		
/s/ CHARLES A. SANDERS	Director	February 27, 2004
Charles A. Sanders		
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	rage 35	

SCHEDULE II

## GENENTECH, INC. VALUATION AND QUALIFYING ACCOUNTS Years Ended December 31, 2003, 2002 and 2001 (in thousands)

	Sector Address	Sector Anno						
		alance at eginning f Period	Addition Charged to Cost and Expenses		Deductions <sup>(1)</sup>		Balance at End of Period	
Allowance for doubtful accounts and returns:								
Year Ended December 31, 2003:	\$	19,998	\$	<mark>29,39</mark> 3	\$	(24,297)	\$	25,094
Year Ended December 31, 2002:	\$	20,509	\$	16,5 <mark>6</mark> 3	\$	(17,074)	\$	19,99 <mark>8</mark>
Year Ended December 31, 2001:	\$	15,477	\$	16,287	\$	(11,255)	\$	20,509
Inventory reserves: Year Ended December 31, 2003:	\$	20,975	\$	<b>16</b> ,232	\$	(16,524)	\$	20,683
Year Ended December 31, 2002:	\$	25,589	\$	18,588	\$	(23,202)	\$	20,975

https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k\_2003.htm

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Novartis Exhibit 2265.0077 Regeneron v. Novartis, IPR2021-00816

1/17/22, 7:59 PM	Genentech, Inc Form 10-K for the period ending 12/31/2003								
	Year Ended December 31, 2001:	\$	11,817	\$	16,354	\$	(2,582)	\$	25,589
	Reserves for nonmarketable debt and equity securities: Year Ended December 31, 2003:	\$	23,862	\$	-	\$	(8,812)	\$	15,050
	Year Ended December 31, 2002:	\$	36,137	\$	1,465	\$	(13,740)	\$	23,862
	Year Ended December 31, 2001:	\$	32,785	\$	3,352	\$	-	\$	36,137

(1) Represents amounts written off or returned against the allowance or reserves, or returned against earnings

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Novartis Exhibit 2265.0078 Regeneron v. Novartis, IPR2021-00816