

GENENTECH INC  
Form 10-K  
February 28, 2005

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 SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

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

94-2347624

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

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

(650) 225-1000

(Address of principal executive offices and zip code)

(Telephone Number)

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.02 par value	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  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.

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

The approximate aggregate market value of voting stock held by non-affiliates of the registrant is \$26,401,075,180 as of June 30, 2004.<sup>(A)</sup>

Number of shares of Common Stock outstanding as of February 14, 2005: 1,046,299,857

Documents incorporated by reference:

Definitive Proxy Statement with respect to the 2005 Annual Meeting of Stockholders to be filed by Genentech, Inc. with the Securities and Exchange Commission (hereinafter referred to as "Proxy Statement") Part III

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(A) Excludes 587,259,934 shares of Common Stock held by directors and executive officers of Genentech and Roche Holdings, Inc.

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GENENTECH, INC.

2004 Form 10-K Annual Report

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### SIGNATURES

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

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin™ (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis™ (ranibizumab, rhuFab V2) anti-VEGF antibody fragment; Nutropin® (somatropin (rDNA origin) for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen® (somatropin (rDNA origin) for injection) liquid formulation growth hormone; Nutropin Depot® (somatropin (rDNA origin) for injectable suspension) encapsulated sustained-release growth hormone; Omnitarg™ (pertuzumab) HER dimerization inhibitor; Protropin® (somatrem for injection) growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva® (efalizumab)

anti-CD11a antibody; and TNKase™ (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva™ (erlotinib) is a trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a trademark of Novartis AG. This report also includes other trademarks, service marks and trade names of other companies.

## PART I

### Item 1. BUSINESS

#### Overview

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products directly in the United States (or U.S.), and receives royalties from companies that are licensed to market products based on our technology. 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

At December 31, 2004, Roche's percentage ownership of our outstanding common stock was 56.1%. On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche Holdings, Inc. (or Roche) at a price of \$10.31 per share in cash with funds deposited by Roche for that purpose. We refer to this event as the "Redemption." As a result, on that date, Roche's percentage ownership of our outstanding Common Stock increased from 65% to 100%. Consequently, under 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 on our balance sheet on June 30, 1999. For more information about push-down accounting, please read Note 1, "Description of Business" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Annual Report on Form 10-K (or Form 10-K).

Roche subsequently completed public offerings of our Common Stock in 1999 and 2000. 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 commercialize in the United States the biotechnology products listed below.

#### Oncology

Herceptin (trastuzumab) anti-HER2 antibody is a 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 as a single agent in second- and third-line therapy in patients with metastatic breast cancer who have tumors that overexpress the HER2 protein.

#### Rituxan

(rituximab) anti-CD20 antibody, which we commercialize with Biogen Idec Inc. (or Biogen Idec), is approved 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 licensed Rituxan from and co-developed Rituxan with Biogen Idec (and one of its predecessor companies, IDEC Pharmaceuticals Corporation).

#### Avastin

(bevacizumab) is a humanized antibody that binds to and inhibits vascular endothelial growth factor (or VEGF). It was approved by the U.S. Food and Drug Administration (or FDA) on February 26, 2004 for use in

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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.

#### Tarceva

(erlotinib), co-developed with OSI Pharmaceuticals, Inc. (or OSI) and Hoffmann-La Roche, is a small molecule designed to block tumor cell growth by inhibiting the tyrosine kinase activity of HER1/epidermal growth factor receptor (or EGFR) signaling pathway inside the cell, which is one of the factors critical to cell growth in non-small cell lung cancer (or NSCLC). On November 18, 2004 the FDA approved Tarceva for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. We began shipping Tarceva on November 22, 2004.

#### Specialty Biotherapeutics

##### Raptiva

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

##### Xolair

(omalizumab) is a humanized anti-IgE antibody, which we commercialize with Novartis AG (or Novartis) in the United States, approved for the treatment of moderate-to-severe persistent asthma in adults and adolescents.

##### 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 t-PA approved for the restoration of function to central venous access devices that have become occluded due to a blood clot in adult and pediatric patients.

#### TNKase

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

#### Nutropin

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

#### Nutropin AQ

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

#### 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. On June 1, 2004, we and our collaborator Alkermes made a decision to discontinue commercialization of Nutropin Depot. We expect sales of Nutropin Depot to cease in 2005.

#### 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. Protropin sales ended upon inventory depletion at the end of 2004.

#### Pulmozyme

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

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.

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#### 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 2004, are presented in the following table:

<u>Product</u>	<u>Trade Name</u>	<u>Licensee</u>	<u>Licensed Territory</u>
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D2E7/adalimumab	Humira	Abbott	Worldwide
Factor VIII	Kogenate/Helixate	Bayer Corporation	Worldwide
Recombinant tissue plasminogen activator	Actilyse	Boehringer Ingelheim	A number of countries outside of U.S., Canada and Japan
Tenecteplase	Metalyse	Boehringer Ingelheim	A number of countries outside of U.S., Canada and Japan
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
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 Tenecteplase	Activase and TNKase	Hoffmann-La Roche	Canada
Etanercept	ENBREL	Immunex Corporation	Worldwide
Palivizumab	Synagis	MedImmune, Inc.	Worldwide

We will receive royalties from Hoffmann-La Roche on net sales of Avastin in countries outside of the U.S. Hoffmann-La Roche received approval for Avastin in Israel in September 2004, in Switzerland in December 2004 and from the European Union in January 2005 for the treatment of patients with previously untreated metastatic cancer of the colon or rectum.

In January 2005, we entered into a patent license agreement with ImClone Systems Inc. (or ImClone) under which, beginning in 2005, we will receive certain royalties from ImClone on sales of ERBITUX by ImClone and its commercialization partners.

We have granted a license to Zenyaku Kogyo Co., Ltd., a Japanese pharmaceutical company, for the manufacture, use and sale of rituximab in Japan. We record net sales of rituximab from Zenyaku, who co-promotes rituximab in Japan under the trademark MabThera with Chugai, a Japanese subsidiary of Hoffmann-La Roche.

## Products in Development

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

Product	Description	Estimate of Completion of Phase*
Awaiting Regulatory Approval Nutropin and Nutropin AQ	We filed a supplemental New Drug Application for the indication of long-term treatment of idiopathic short stature in December 2003.	2005
Preparing for Filing Avastin	We announced that results of a Phase III trial in advanced colorectal cancer patients who had previously received treatment achieved its primary endpoint in improving overall survival. We are preparing to submit a supplemental Biologics License Application (or sBLA) to the FDA for the treatment of relapsed (or previously treated) metastatic cancer of the colon or rectum. This product is being developed in collaboration with Hoffmann-La Roche.	2006
Herceptin	We are preparing to submit a sBLA to the FDA for the use of Herceptin in the metastatic setting in combination with Taxotere® (docetaxel). This product is being developed in collaboration with Hoffmann-La Roche.	2005-2006
Rituxan Hematology/Oncology	We are preparing to submit a sBLA to the FDA for the use of Rituxan as a treatment of front-line aggressive non-Hodgkin's lymphoma (or NHL). In the front-line indolent NHL setting, we are currently in filing discussions with the FDA. This product is being developed in collaboration with Hoffmann-La Roche and Biogen Idec.	2005-2006
Phase III Avastin	Phase III programs in renal cell carcinoma, advanced non-small cell lung cancer, metastatic and locally advanced pancreatic cancer, adjuvant colon cancer, and metastatic breast cancer are being conducted. This product is being developed in collaboration with Hoffmann-La Roche.	2006-2011
Herceptin		2007



	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.	
Lucentis AMD (formerly rhuFab V2 AMD)	A customized fragment of an anti-VEGF antibody for the potential treatment of the wet form 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
Rituxan Hematology/Oncology	We are conducting a Phase III clinical trial for the potential treatment of relapsed chronic lymphocytic leukemia. This product is being developed in collaboration with Hoffmann-La Roche and Biogen Idec.	2009

Rituxan Immunology	Rituxan is being evaluated in Phase III clinical trials for anti-TNF (tumor necrosis factor) refractory rheumatoid arthritis, primary progressive multiple sclerosis, and ANCA-associated vasculitis. This product is being developed in collaboration with Hoffmann-La Roche and Biogen Idec.	2005-2009
Tarceva	We have announced that results from a randomized Phase III clinical study of the investigational drug Tarceva, in combination with gemcitabine chemotherapy, met its primary endpoint of improving overall survival for patients with locally advanced or metastatic pancreatic cancer. We and our collaborators OSI and Hoffmann-La Roche will discuss these data with the FDA and other regulatory agencies to determine the next steps for Tarceva in pancreatic cancer. This product is being developed in collaboration with OSI and Hoffmann-La Roche.	2005-2006
Xolair	Xolair is currently in Phase III clinical trials in pediatric asthma. This product is being developed in collaboration with Novartis and Tanox.	2006
Preparing for Phase III Avastin	We are currently planning for Phase III clinical trials in front-line ovarian cancer. This product is being developed in collaboration with Hoffmann-La Roche.	2005
Rituxan Immunology	We are currently planning for Phase III clinical trials in	2005-2006

moderate-to-severe rheumatoid arthritis, systemic lupus eruthematosus, and lupus nephritis. This product is being developed in collaboration with Biogen Idec and Hoffmann-La Roche.

## Phase II

Humanized Anti-CD20	A Phase I/II U.S. clinical trial in patients with rheumatoid arthritis was initiated in 2004. A Phase I/II ex-U.S. trial in patients with non-Hodgkin's lymphoma is being planned. This product is being developed in collaboration with Biogen Idec and Hoffmann-La Roche.	2005-2006
Omnitarg (formerly 2C4 antibody)	An antibody directed against HER2 as a potential treatment for cancer. We are in Phase II clinical trials for HER2 negative metastatic breast cancer, ovarian cancer, and non-small cell lung cancer. This product is being developed in collaboration with Hoffmann-La Roche.	2005-2007
Avastin	A Phase II clinical trial in relapsed ovarian cancer was initiated in 2005. This product is being developed in collaboration with Hoffmann-La Roche.	2007
Rituxan Immunology	A Phase II clinical trial in relapsing remitting multiple sclerosis was initiated in 2004. This product is being developed in collaboration with Biogen Idec and Hoffmann-La Roche.	2006-2007
Xolair	A Phase II clinical trial in peanut allergy was initiated in 2004. This product is being developed in collaboration with Novartis and Tanox.	2007

## Preparing for Phase II

VEGF	VEGF is a recombinant vascular endothelial growth factor. VEGF is a naturally occurring protein secreted by tissues lacking oxygen. Vascular endothelial growth factor is being evaluated in diabetic foot ulcers.	2006
Phase I and Earlier Stage Projects	Apo2L/TRAIL for cancer therapy, Anti-nerve growth factor (or NGF) for acute and chronic pain, BR3-Fc for rheumatoid arthritis, and Topical Hedgehog Antagonist for Basal Cell Carcinoma are projects in Phase I or earlier stages of development.	2005-2006

\* 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

See "Relationship with Roche" and "Related Party Transactions" sections below in Part II, Item 7 of this Form 10-K for information on our collaboration arrangements with Roche, Hoffmann-La Roche and Novartis.

In November 2004, we exercised an option under an agreement with Rinat Neuroscience, a privately held biotechnology company, to co-develop and commercialize RI 624 on a worldwide basis. RI 624 is a novel humanized antibody that blocks NGF, a key mediator of acute and chronic pain, and is currently in Phase I/II clinical trials. Under the terms of our opt-in on RI 624, Genentech and Rinat will share worldwide costs and profits for the development and commercialization of RI 624. As part of this opt-in, we expensed upfront payments and made a minority equity investment in Rinat. We and Rinat will jointly participate in the development and commercialization responsibilities for RI 624. Also as part of our opt-in, we have a commitment to provide, under certain conditions, a loan of up to \$40.0 million to Rinat to support Rinat's own financing of the product development and commercialization costs of RI 624. As of December 31, 2004, no loan amounts were outstanding.

In September 2004, we entered into a non-exclusive long-term manufacturing agreement for Herceptin with Wyeth Pharmaceuticals, a division of Wyeth, (or Wyeth). Under this agreement, Wyeth will manufacture Herceptin bulk drug substance for Genentech at Wyeth's production facility in Andover, Massachusetts. We may be obligated to make milestone payments to Wyeth subject to Wyeth's achievement of a series of factory preparation and process validation milestones, as well as receipt of FDA approval for the manufacturing of Herceptin bulk drug at the Wyeth facility. Technology transfer activities have begun and we anticipate that Wyeth will receive FDA approval and begin commercial production of Herceptin in 2006.

In December 2003, we entered into a non-exclusive long-term manufacturing agreement with Lonza Biologics, a subsidiary of Lonza Group Ltd (or Lonza), 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. We anticipate FDA approval and initiation of commercial production at the Lonza facility in 2005.

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

We have a fixed price manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, (or Immunex), to provide Immunex with additional manufacturing capacity for ENBREL® (etanercept) at

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Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we made facility modifications needed to manufacture ENBREL. Certain of these modification costs which included engineering and equipment costs were reimbursed by Immunex. In addition, costs of certain raw materials for development runs were reimbursed by Immunex.

In April 1996, we entered into a research collaboration agreement with XOMA to develop and commercialize Raptiva. This agreement, as modified in 2003, provided 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. 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. The development loan balance was approximately \$29.2 million at December 31, 2004 and \$28.1 million at December 31, 2003. The fair value of the Series B preferred shares was \$9.9 million at December 31, 2004 and \$25.2 million at December 31, 2003. During 2004, we recognized an other-than-temporary charge of \$12.0 million related to the value of the Series B preferred shares. On January 12, 2005, we and XOMA restructured our financial arrangement related to Raptiva, which became effective January 1, 2005. See Note 11, "Subsequent Events" in the Notes to Consolidated Financial statements of Part II, Item 8 of this Annual Report on Form 10-K for further information.

#### Distribution and Commercialization

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 pharmacies. 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 available at no charge to qualified patients under our uninsured or underinsured 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 also provide certain customer service programs relating to our products. We maintain a comprehensive patient-related product wastage replacement program for Rituxan, Avastin, Herceptin, 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, provide customers the right to return products to us for replacement or credit at the price in effect on the date of the return. We maintain the right to renew, modify or discontinue any of the patient programs described above.

As discussed in Note 10, "Segment, Significant Customer And Geographic Information" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K, we had three major customers who each 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 2004, 2003, and 2002.

#### 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 attempt, to the extent feasible, 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 commitment of our resources in the future and, depending on their outcome, may adversely affect the validity and scope of certain of our patent or other proprietary rights. We cannot assure you that the patents we obtain or the unpatented proprietary technology 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, 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.

Our royalty income for patent licenses, know-how and other related rights amounted to \$641.1 million in 2004, \$500.9 million in 2003, and \$365.6 million in 2002. Royalty expenses were \$355.0 million in 2004, \$244.6 million in 2003, and \$204.4 million in 2002.

#### 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 follow-on biologics 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 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 payors.

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 certain of our therapeutic markets. In the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to competing thrombolytic therapies and to the use of mechanical reperfusion therapies to treat acute myocardial infarction. 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 the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. Competitors have also received approval to market their existing growth hormone products for additional indications beyond those that are currently approved for our products. As a result of that competition, we have experienced and may continue to experience a loss in market share.

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 Amgen's ENBREL® (etanercept), co-marketed by Wyeth, which was approved for adult patients with moderate-to-severe psoriasis in April 2004.

Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil (or "5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with intravenous 5-FU/Leucovorin and CPT-11 (or "the Saltz Regimen"). In a Phase II trial, Avastin was found to provide benefit for first-line patients when used in combination with intravenous 5-FU/Leucovorin alone. The use of the intravenous 5-FU/Leucovorin and Saltz regimens in the first-line is likely to decline as more physicians adopt 5-FU/Leucovorin/Oxaliplatin (or "FOLFOX") regimen. In November 2004, we and Hoffmann-La Roche announced the preliminary results of a Phase III trial of Avastin in patients with advanced colorectal cancer who had previously received treatments. The trial achieved its primary endpoint of improving overall survival. With this positive data (assuming a sBLA is approved), Avastin may compete with ImClone/Bristol-Myers Squibb's ERBITUX®, an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer patients. In addition, an oral VEGF-inhibitor from Novartis, PTK-787, is currently in Phase III clinical trials in combination with FOLFOX in both the first-line and relapsed settings. Results from these studies are expected to be announced in 2005. If those results are successful, there is the potential for that product, if approved by the FDA, to compete with Avastin.

Tarceva faces competition from Iressa, the only other EGFR tyrosine kinase inhibitor indicated for NSCLC, although recent negative survival data about Iressa's efficacy in relapsed NSCLC (i.e., the ISEL trial) may substantially lessen that competition. Tarceva also faces competition from new and established chemotherapy regimens. Specifically, Tarceva competes with the chemotherapeutic products Taxotere® and Alimta®, both of which are indicated for the treatment of relapsed NSCLC.

## 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 required 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 in humans 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 evaluate the preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large scale, multicenter clinical trials are conducted with patients afflicted with a target disease in order to provide enough data to statistically evaluate the efficacy and safety of the product, as required by the FDA. The results of the preclinical and clinical testing of a chemical pharmaceutical product are then submitted to 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 commence 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 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 usually perform a preapproval inspection of the facility to determine its compliance with GMP and other rules and regulations. Manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. 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 at our facilities or the facilities of third parties who manufacture for us 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 applying to our business 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 payors 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 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 (or 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."

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

#### 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 \$947.5 million in 2004, \$722.0 million in 2003, and \$623.5 million in 2002. We intend to maintain our strong commitment to R&D. Biotechnology products generally take 10 to 15 years to research, develop and bring to market in the United States. As



discussed above, 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. Product completion dates and completion costs vary significantly by product and are difficult to predict.

#### Human Resources

As of December 31, 2004, we had 7,646 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.

#### Corporate Governance

The Board of Directors (the "Board") of the Company adopted the Principles of Corporate Governance (the "Principles"). These Principles, together with the Company's amended and restated Certificate of Incorporation, the bylaws, the Affiliation Agreement between the Company and Roche Holdings, Inc. and the charters of Board committees, provide the framework for the governance of Genentech.

The Board is committed to legal and ethical conduct in fulfilling its responsibilities. The Board expects all directors, as well as officers and employees, to act ethically at all times and to adhere to the policies comprising the Company's

Good Operating Principles. The Board also expects the Chief Executive Officer (or CEO), the Chief Financial Officer (or CFO) and all senior financial officials to adhere to the Company's Code of Ethics especially in matters of public disclosure relating to Genentech.

#### Available Information

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

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;
- our policies related to corporate governance, including Genentech's Principles of Corporate Governance, 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 CEO, CFO and senior financial officials; and

- the charter of the Audit Committee of our Board of Directors.

## Item 2. PROPERTIES

Our primary facilities are located in a research and industrial park in South San Francisco, California as both leased and owned properties. In South San Francisco, we currently own 41 and lease seven buildings which house our research and development, manufacturing, marketing and administrative activities. We have made and will continue to make improvements to these properties to accommodate our growth. We also have a lease with a third party for property adjacent to our South San Francisco campus to be developed into eight buildings and two parking structures. The lease of this property will take place beginning in 2006. In addition, we own vacant property in South San Francisco for future expansion. The South San Francisco properties include manufacturing facilities licensed to produce commercial quantities of our products, a fill and finish facility and a warehouse.

We also lease a manufacturing facility in Vacaville, California, which is licensed to produce commercial quantities of our products. We are currently expanding our Vacaville site by constructing an additional manufacturing facility adjacent to the existing facility as well as office buildings to support the added manufacturing capacity.

Outside of North America, we own a warehouse and a cell culture manufacturing facility currently licensed for the manufacture of Avastin for clinical trials in Porriño, Spain.

We also lease additional office facilities as regional sales and marketing offices in several locations throughout the United States.

In general, our existing facilities owned or leased are in good condition and adequate for all present and near term uses and we believe our capital resources are sufficient to purchase, lease 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.

On October 4, 2004, we received a subpoena from the United States (or U.S.) Department of Justice, requesting documents related to the promotion of Rituxan, a prescription treatment approved for the treatment of relapsed or

refractory, low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma. We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. The potential outcome of this matter cannot be determined at this time.

We and the City of Hope National Medical Center (or COH) are parties to a 1976 agreement relating to work conducted by two COH employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, 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. On June 10, 2002, a jury voted to award the COH approximately \$300.0 million in compensatory damages. On June 24, 2002, a jury voted to award the COH an additional \$200.0 million in punitive damages. Such amounts were accrued as an expense in the second quarter of 2002 and were included in the consolidated balance sheets in "litigation-related and other long-term liabilities" at December 31, 2004 and 2003. Genentech filed a notice of appeal of the verdict and damages awards with the California Court of Appeal. On October 21, 2004 the California Court of Appeal affirmed the verdict and damages awards in all respects. On November 22, 2004, the California Court of Appeal modified its opinion without changing the verdict and denied Genentech's request for rehearing. On November 24, 2004, Genentech filed a petition seeking review by the California Supreme Court. On February 2, 2005, the California Supreme Court granted that petition. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter, however, we do expect that it will take longer than one year to further resolve the matter.

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. 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, 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 ("Court of Appeals"), and Genentech filed a notice of cross-appeal. On April 6, 2004, we announced that a three-judge panel of the Court of Appeals unanimously affirmed the 2002 judgment of the U.S. District Court that found in favor of Genentech that all claims of Chiron's patent asserted against Genentech are invalid. On or about April 15, 2004, Chiron filed a Petition for Rehearing with the Court of Appeals seeking further review and reconsideration of that Court's decision. The Court of Appeals denied the Petition in its entirety on June 8, 2004. On October 4, 2004, Chiron filed a petition with the United States Supreme Court seeking review of the judgment in favor of Genentech. On January 10, 2005, the Supreme Court denied Chiron's petition. All proceedings in this matter are now concluded.

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. 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. On November 30, 2004, the Patent Office's Board of Patent Appeals and Interferences issued rulings on several preliminary motions. These rulings terminated both interferences involving the patent application referenced above

that Genentech licensed from a university, redeclared interferences between the Genentech and Chiron patents and patent applications, and made several determinations which could affect the validity of the Genentech and Chiron

patents and patent applications involved in the remaining interferences. On January 28, 2005, Genentech filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. Because the appeal process and further interference proceedings are ongoing, the final 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 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. On November 10, 2004, the Court extended the stay until the resolution of all proceedings before the United States Supreme Court in the Chiron suit mentioned above. This lawsuit is separate from and in addition to the Chiron suit mentioned above. The final outcome of this matter cannot be determined at this time.

On April 11, 2003, MedImmune, Inc. filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 ("the '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. 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 sought to amend its complaint to reallege certain claims for antitrust and unfair competition. On February 19, 2004, the Court denied this motion in its entirety and final judgment was entered in favor of Genentech and Celltech and against MedImmune on March 15, 2004 on all antitrust and unfair competition claims. MedImmune filed a notice of appeal of this judgment with the U.S. Court of Appeals for the Federal Circuit. Concurrently, in the District Court litigation, Genentech filed a motion to dismiss all remaining claims in the case. On April 23, 2004, the District Court granted Genentech's motion and dismissed all remaining claims. Final judgment was entered in Genentech's favor on May 3, 2004, thus concluding proceedings in the District Court. MedImmune filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. Oral argument of MedImmune's appeal was held on February 10, 2005. Because the appeal process is ongoing, the final outcome of this matter cannot be determined at this time.

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

Not applicable.

The executive officers of the Company and their respective ages (ages as of December 31, 2004) and positions with the Company are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Arthur D. Levinson, Ph.D.*	54	Chairman and Chief Executive Officer
Susan D. Desmond-Hellmann, M.D., M.P.H.*	47	President, Product Development
Myrtle S. Potter*	46	President, Commercial Operations
Stephen G. Juelsgaard, J.D.*	56	Executive Vice President, General Counsel and Secretary
Louis J. Lavigne, Jr.*	56	Executive Vice President and Chief Financial Officer
Richard H. Scheller, Ph.D.*	51	Executive Vice President, Research
David A. Ebersman*	35	Senior Vice President, Product Operations through January 4, 2005; Senior Vice President, Finance effective January 5, 2005
Robert L. Garnick, Ph.D.	55	Senior Vice President, Regulatory, Quality and Compliance
Patrick Y. Yang, Ph.D.	56	Senior Vice President, Product Operations effective January 5, 2005
John M. Whiting	49	Vice President, Controller and Chief Accounting Officer

\* Members of the Executive Committee of the Company.

On November 10, 2004, we announced that Executive Vice President and Chief Financial Officer Louis Lavigne will retire on March 5, 2005. On December 7, 2004, the Board of Directors elected David Ebersman to serve as Senior Vice President, Finance effective January 5, 2005 through March 5, 2005, at which time he will become Chief Financial Officer, and elected Patrick Yang, formerly Vice President, South San Francisco Manufacturing and Engineering, as Senior Vice President, Product Operations, effective January 5, 2005.

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

#### Business Experience

##### Arthur D. Levinson, Ph.D.

was appointed Chairman of the Board of Directors of Genentech in September 1999 and was elected its 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, Senior Vice President of Research in December 1992 and Senior Vice President of Research and Development in March 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.

**Susan D. Desmond-Hellmann, M.D., M.P.H.**

was appointed President, Product Development of Genentech in March 2004. She previously served as Executive Vice President, Development and Product Operations from September 1999 to March 2004, Chief Medical Officer from December 1996 to March 2004, and as Senior Vice President, Development from December 1997 to 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.

**Myrtle S. Potter**

was appointed President, Commercial Operations of Genentech in March 2004. She previously served as Executive Vice President, Commercial Operations and Chief Operating Officer from May 2000 to March 2004. 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.

**Stephen G. Juelsgaard, J.D.**

was appointed Executive Vice President of Genentech 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 and plans to retire on March 5, 2005. 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.

**Richard H. Scheller, Ph.D.**

was appointed Executive Vice President, Research of Genentech 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, Finance of Genentech in January 2005 and will serve in that role through March 5, 2005 at which time he will become Chief Financial Officer. Previously, he served as Senior Vice President, Product Operations from May 2001 through January 2005. 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 of Genentech 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.

Patrick Y. Yang, Ph.D.

was appointed Senior Vice President, Product Operations of Genentech in January 2005. Previously, he served as Vice President, South San Francisco Manufacturing and Engineering from December 2003

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to January 2005. Prior to joining Genentech, he worked for General Electric from 1980 to 1992 in manufacturing and technology and for Merck & Co. Inc. from 1992 to 2003 in manufacturing. At Merck, he held several executive positions including Vice President, Supply Chain Management from 2001 to 2003 and Vice President, Asia/Pacific Manufacturing Operations from 1997 to 2000.

John M. Whiting

was appointed Vice President of Genentech 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, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

See Note 1, "Description of Business -- Redemption of Our Special Common Stock," Note 7, "Relationship with Roche and Related Party Transactions" and Note 8, "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, 2004, there were approximately 2,327 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 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			
	2004		2003	
	High	Low	High	Low
4th Quarter	\$ 55.98	\$ 41.00	\$ 47.68	\$ 38.15
3rd Quarter	56.61	43.00	44.00	35.15
2nd Quarter	68.25	50.11	38.75	16.90
1st Quarter	56.98	44.74	19.88	15.77

All information in this report relating to the number of shares, price per share and per share amounts of common stock give effect to the May 2004 two-for-one stock split of our common stock.

## Stock Repurchases

See Note 8, "Capital Stock" 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.



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SELECTED CONSOLIDATED FINANCIAL DATA

(in millions, except per share amounts)

	2004	2003	2002	2001	2000
Total operating revenues	\$ 4,621.2	\$ 3,300.2	\$ 2,583.7	\$ 2,044.1	\$ 1,514.2
Product sales	3,748.9	2,621.4	2,163.6	1,742.9	1,278.3
Royalties	641.1	500.9	365.6	264.5	207.3
Contract revenue	231.2	177.9	54.5	36.7	28.6
Income (loss) before cumulative effect of accounting changes	\$ 784.8	\$ 610.1	\$ 63.8	\$ 155.9	\$ (16.4)
Cumulative effect of accounting changes, net of tax	-	(47.6) <sup>(3)</sup>	-	(5.6) <sup>(6)</sup>	(57.8) <sup>(8)</sup>
Net income (loss) <sup>(2)</sup>	\$ 784.8 <sup>(1)</sup>	\$ 562.5 <sup>(3)</sup>	\$ 63.8 <sup>(5)</sup>	\$ 150.3 <sup>(6)</sup>	\$ (74.2) <sup>(8)</sup>
Basic earnings (loss) per share	\$ 0.74	\$ 0.54	\$ 0.06	\$ 0.14	\$ (0.07)
Diluted earnings (loss) per share	0.73	0.53	0.06	0.14	(0.07)
Total assets	\$ 9,403.4 <sup>(4)</sup>	\$ 8,759.5 <sup>(4)</sup>	\$ 6,775.5	\$ 7,161.5	\$ 6,738.8
Long-term debt	412.3 <sup>(4)</sup>	412.3 <sup>(4)</sup>	- <sup>(7)</sup>	- <sup>(7)</sup>	149.7
Stockholders' equity	6,782.2	6,520.3	5,338.9	5,919.8	5,674.2

We have paid no dividends.

All per share amounts reflect two-for-one stock splits that were effected in 2004 and 2000.

Certain prior year amounts have been reclassified to conform with the current year presentation.

- (1) Net income in 2004 includes accrued interest and bond costs related to the City of Hope (or COH) trial judgment, net of a released accrual on a separate litigation matter.
- (2) Net income (loss) includes recurring charges of \$145.5 million in 2004, \$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).
- (3) Net income in 2003 includes litigation settlements with Amgen, Inc. and Bayer, net of accrued interest and bond costs related to the COH 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 \$0.05 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 in property, plant and equipment assets with net book values of \$325.9 million at December 31, 2004 and \$348.4 million 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 litigation-related and other long-term liabilities, respectively, at December 31, 2004 and 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 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 \$0.15 per share) due to the cessation of goodwill amortization and the amortization of our trained and assembled workforce intangible asset.
- (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.

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

### Overview

Genentech primarily earns revenues from product sales, royalties, and contract revenues. We also generate other income from interest on our investment portfolio and gains on sales of stocks in our biotechnology equity portfolio. In 2004, we experienced significant revenue growth, driven by sales of our new products, Avastin, Xolair and Raptiva and continued strong sales of our established oncology products, Rituxan and Herceptin. Our legacy products, royalties and contract revenues continue to contribute to the bottom-line. Operating revenues for 2004 increased 40% to more than \$4.6 billion, compared to \$3.3 billion for 2003. Net income for 2004 increased 40% to \$784.8 million compared to \$562.5 million for 2003. We ended 2004 with approximately \$2.8 billion in unrestricted cash and marketable securities.

We have now entered the final year of our 5x5 plan. We expect to exceed our most important goal of average annual non-GAAP EPS growth of 25% while we are uncertain if we will meet our net income as a percent of total operating revenues goal due to the success of Rituxan and the associated profit split. We are well positioned to exceed our goal of five significant products/indications in late stage development and have already exceeded our goal of five new products or indications approved through 2005. We expect to have substantive revenue progress on our goal of \$500 million in new revenue from alliances and/or acquisitions, but we are uncertain if we will meet this goal since we have changed our strategic focus to pursue earlier stage opportunities. Information on our 5x5 plan can be found on our website at <http://www.gene.com>.

Our long-term business objectives are reflected in our Horizon 2010 strategy and goals set forth below.

- To aim to become the number one United States (or U.S.) oncology company (measured by U.S. sales) by 2010. We recognize that this goal is highly ambitious and that there will be formidable competition from other companies, particularly given the rate of new business consolidations in our industry. We face many challenges in meeting this goal, such as U.S. Food and Drug Administration (or FDA) approvals, clinical trial successes, and levels of government reimbursement rates, which recognize the innovation of our products to patients.
- To position ourselves for continued leadership in our oncology business by bringing five new oncology products or indications for existing products into clinical development and into the market by 2010.
- To build a leading immunology business by expanding the fundamental understanding of immune disorders, bringing at least five new immunology products or indications into clinical development, and obtaining FDA approval of at least five new indications or products by 2010.
- To increase our leadership in developing biotherapeutics for disorders of tissue growth and repair, with a major focus on angiogenic disorders, and to move at least three new projects into late-stage research or developmental research and three or more new projects into clinical development by 2010.
- To achieve average annual non-GAAP EPS growth rates through 2010 sufficient to be considered a growth company.

Achieving these goals depends on our ability to quickly capitalize on advances in basic research, to balance speed in clinical development with designing high-quality trials, to shape the markets for our products, to increase our manufacturing capability and to maintain our unique corporate culture during a period of rapid growth.

As a business in a highly regulated and competitive industry, we face many risks and challenges and we also have opportunities. There are many economic and industry-wide factors that affect our business. Some of the most important industry factors are discussed below:

- The Medicare Act was enacted into law in December 2003. On November 3, 2004, the 2005 Physician Fee Schedule and Hospital Outpatient Prospective Payment System Final Rules were announced and were in-line with our expectations. We will be monitoring the situation closely and, in 2005, we continue to anticipate minimal additional impact to our revenues.
- With respect to follow-on biologics, we believe that current technology cannot prove a follow-on biotechnology product to be safe and effective outside the New Drug Application (or NDA) and Biologics License Application (or BLA) process. We filed a Citizen Petition with the FDA in April 2004 requesting that the agency re-assess its approach to approvals of follow-on biologics and put processes in place to protect trade secrets and confidential commercial data and information from use and disclosure by others. The FDA initiated a public process to discuss the complex scientific issues surrounding follow-on biologics and we participated in the FDA Stakeholder meeting in September 2004. Following this meeting, the FDA and Drug Information Association held a scientific workshop scheduled in February 2005, which we hope will be followed by a similar public discussion of the critical legal issues involved with establishing an approval pathway for follow-on biologics.

- We place a high priority on ensuring that clinical trial information is available to physicians and other interested parties. We currently submit protocol information to the Clinical Trial Data Bank (or CTDB) for trials in serious and life-threatening conditions, according to FDA guidance. To provide more transparency and in line with the proposed requirement by the International Committee of Medical Journal Editors, we also plan to register protocol information for all of our sponsored Phase II, III and IV trials with the CTDB. In addition, we are planning to post clinical trial results for our marketed drugs to the CTDB and are currently finalizing our internal guidelines for this process.
- In the current FDA safety debate, we are well placed given our innovative products for unmet medical needs, use of diagnostics when appropriate and our standards for safety monitoring, including the use of patient post marketing registries.
- In regards to employee stock compensation, the Financial Accounting Standards Board (or FASB) has issued a final rule to expense costs related to share-based payments including employee stock options and stock issued under our employee stock purchase plans, effective July 1, 2005. We believe the FASB's new rule requiring companies to expense these options may have unintended negative consequences. Our adoption of the new rule is expected to have a material adverse impact on our consolidated financial results.
- Our success is predicated on our ability to recruit and retain highly qualified and talented people in all areas of the company. This past year we experienced a 23% growth in the number of employees. This significant growth in employees is challenging to manage, especially given our work environment where our culture is important for our success. We are working hard across the company to make sure that we successfully hire, train and integrate new employees into the Genentech culture and environment.
- On October 4, 2004, we received a subpoena from the U.S. Department of Justice, requesting documents related to the promotion of Rituxan. We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. The potential outcome of this matter cannot be determined at this time.
- Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection on one or more products could result in lost sales to competing products and negatively affect our sales, royalty revenues and operating results. We are often involved in disputes over contracts

and intellectual property and we work to resolve these disputes in confidential negotiations or litigations. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position. The resources required to do this are significant.

On the operations front, we continue to plan for manufacturing needs in both the short- and long-term. We have increased manufacturing efforts in both our South San Francisco and Vacaville facilities in an effort to meet growing product demand. We received FDA approval in August 2004 for the manufacture of Avastin bulk drug substance at our Vacaville facility; this additional capacity will supplement our Avastin bulk drug substance manufactured in South San Francisco. We announced a decision to expand our Vacaville facility which is expected to cost approximately \$600 million over the next several years. That additional capacity is planned to be available in 2009. In addition, we have 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. We anticipate FDA approval and

initiation of commercial production at the Lonza facility in 2005. We also have a manufacturing agreement with Wyeth Pharmaceuticals, a division of Wyeth, (or Wyeth), under which Wyeth will manufacture Herceptin bulk drug substance at Wyeth's production facility in Andover, Massachusetts. Technology transfer activities have begun and we anticipate that Wyeth will receive FDA approval and begin commercial production of Herceptin in 2006. Our facility in Porriño, Spain (Genentech España), is currently producing Avastin bulk drug substance for clinical trials. Finally, as part of our capacity planning to support our growth and expansion, and efforts to add additional capacity, we will continue to have ongoing dialogue with third-party manufacturers and evaluate potential sites with existing manufacturing capabilities, as well as sites where we can build new facilities. We recognize that there are some inherent uncertainties associated with forecasting future demand, especially for newly introduced products, and that manufacturing of biologics is a complex process and as a consequence we may have inadequate bulk capacity to meet demands or we may have an excess of bulk capacity. In 2004, we had equipment malfunctions in our filling facility, due in part to the aging nature of some equipment in one of the two filling lines in that facility, and, consequently, several product lots were not able to be released and a scheduled facility maintenance shut-down was extended. These events resulted in decreased target inventory levels for certain of our products. We are working to rebuild our inventory to target levels. In addition, we are undertaking efforts to secure additional licensed filling capacity in order to mitigate the current risk associated with having a single licensed filling facility for many of our products but establishing that additional capacity is likely to take at least 12 months and could be substantially longer. Until that process is completed, we have potential supply risk for many of our products that are single-sourced from our own filling facility or from a single contract filling site.

In 2004, operating revenue growth was driven by product sales which totaled \$3.7 billion, a 43% increase over 2003, primarily due to the launch of Avastin, a full year of Xolair and Raptiva sales and higher Rituxan and Herceptin sales. In 2004, we launched two new targeted bio-oncology products, Avastin and Tarceva. In the 10 months since Avastin approval and launch, Avastin sales reached \$554.5 million. We believe Avastin will continue to grow in the metastatic colorectal cancer market in 2005, driven by additional penetration of the first-line market, adoption in relapsed disease (an unapproved use), and other longer durations of treatment. Tarceva was approved on November 18, 2004 and generated net product sales of \$13.3 million in the six weeks following launch. Tarceva faces competition from Iressa, the only other epidermal growth factor receptor (or EGFR) tyrosine kinase inhibitor indicated for non-small cell lung cancer (or NSCLC), although recent negative survival data about Iressa's efficacy in relapsed NSCLC (i.e., the ISEL trial) may substantially lessen that competition. Sales of Xolair were \$188.5 million in 2004 compared to \$25.3 million in 2003. This growth reflects ongoing market penetration and high patient compliance. Sales of Raptiva were \$56.3 million in 2004 and \$57.7 million since launch. The rate of growth in prescriptions for Raptiva has been affected by the recent approval of ENBREL for psoriasis. Specifically, a significant ENBREL trial that was launched earlier in the year took several thousand patients out of the market and impacted our revenues for the year. Rituxan sales increased 15% in 2004 as compared to a 28% increase in 2003. This trend reflects a slowing of the Rituxan growth rate. We believe the opportunities for long-term Rituxan sales growth lie in potential new FDA approved indications, for which we have conducted or are conducting label-enabling clinical trials, particularly in immunology, and in the potential use of Rituxan in the maintenance setting in treating non-Hodgkin's lymphoma. Sales of Herceptin increased 14% in 2004 as compared to a 10% increase in 2003. We believe the potential for long-term Herceptin sales growth lies in the adjuvant setting for HER2 positive breast cancer, for which label-enabling clinical studies are still ongoing.

Operating expenses increased significantly over 2003 as a result of higher marketing, general and administrative (or MG&A) and research and development (or R&D) expenses and we expect this trend to continue in 2005, but at a more modest pace. Cost of sales as a percentage of sales in 2004 was comparable to the rate in 2003, reflecting

favorable product mix changes offset by production and inventory related charges.

To monitor and potentially mitigate our risks, in 2004, we are beginning to implement an Enterprise Risk Management (or ERM) process, which is a systematic annual process used to help identify, analyze, finance and mitigate critical risks that could impact us. ERM provides management awareness of the critical risks across the company to our Executive Committee and Board of Directors, and facilitates the prioritization of mitigation efforts and financial resources.

#### 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 (or GAAP). The preparation of these consolidated 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 Note 6, "Leases, Commitments and Contingencies" 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, 2004, we have accrued \$626.0 million in "litigation-related and other long-term liabilities," which represents our estimate of the costs for the current resolution of these matters. The nature of these matters is highly uncertain and subject to change, as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters different than previously estimated could 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, title passes, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated discounts, product returns, bad debts, and rebates.

- 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, post-marketing and certain commercial 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.
  - ◆ Upfront 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. Manufacturing profit is recognized when the product is shipped and title passes.
  - ◆ Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
  - ◆ Reimbursements of development, post-marketing and certain commercial 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, 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,

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among other potential factors, a denial or delay of approval by the necessary regulatory bodies. In the event that a pre-approval product candidate receives regulatory approval, subsequent sales of previously reserved inventory will result in increased gross margins.

#### 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 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.

#### Business Development Collaborations

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

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#### Results of Operations

*(in millions, except per share amounts)*

<u>Annual Percent Change</u>				
<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004/2003</u>	<u>2003/2002</u>



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Product sales	3,748.9	2,521.4	2,163.6	43 %	21 %
Royalties	641.1	500.9	365.6	28	37
Contract revenue	231.2	177.9	54.5	30	226
Total operating revenues	<u>4,621.2</u>	<u>3,300.2</u>	<u>2,583.7</u>	40	28
Cost of sales (or COS)	672.5	480.1	441.6	40	9
Research and development	947.5	722.0	623.5	31	16
Marketing, general and administrative	1,088.2	794.8	546.2	37	46
Collaboration profit sharing	593.6	457.5	350.7	30	30
Recurring charges related to redemption	145.5	154.3	155.7	(6)	(1)
Special items: litigation-related	37.1	(113.1)	543.9	*	*
Total costs and expenses	<u>3,484.4</u>	<u>2,495.6</u>	<u>2,661.6</u>	40	(6)
Operating margin	1,136.8	804.6	(77.9)	41	*
Other income, net	82.6	92.8	107.7	(11)	(14)
Income before taxes and cumulative effect of accounting change	1,219.4	897.4	29.8	36	2,911
Income tax provision (benefit)	434.6	287.3	(34.0)	51	*
Income before cumulative effect of accounting change	784.8	610.1	63.8	29	856
Cumulative effect of accounting change, net of tax	-	(47.6)	-	*	*
Net income (or NI)	<u>\$84.8</u>	<u>\$62.5</u>	<u>\$63.8</u>	40	782
Earnings per share:					
Basic:					
Earnings before cumulative effect of accounting change	\$ 0.74	\$ 0.59	\$ 0.06	25	883
Cumulative effect of accounting change, net of tax	-	(0.05)	-	*	*
Net earnings per share	<u>\$ 0.74</u>	<u>\$ 0.54</u>	<u>\$ 0.06</u>	37	800
Diluted:					
Earnings before cumulative effect of accounting change	\$ 0.73	\$ 0.58	\$ 0.06	26	867
Cumulative effect of					

accounting change, net of tax	-	(0.05)	-	*	*
Net earnings per share	<u>\$ 0.73</u>	<u>\$ 0.53</u>	<u>\$ 0.06</u>	38 %	783 %
Operating margin as a % of operating revenues	25 %	24 %	(3) %		
COS as a % of product sales	18	18	20		
R&D as a % of operating revenues	21	22	24		
MG&A as a % of operating revenues	24	24	21		
NI as a % of operating revenues	17	17	2		

\* Calculation not meaningful.

### Total Operating Revenues

Total operating revenues increased 40% to \$4,621.2 million in 2004 and 28% to \$3,300.2 million in 2003. Increases in both years were driven by increases in all components of operating revenues, in particular, higher product sales and royalty income. These revenue increases are further discussed below (*in millions*).

Product Sales	2004	2003	2002	Annual Percent Change	
				2004/2003	2003/2002
Rituxan	\$ 1,711.2	\$ 1,489.1	\$ 1,162.9	15 %	28 %
Herceptin	483.2	424.8	385.2	14	10
Avastin	554.5	-	-	-	-
Tarceva	13.3	-	-	-	-
Growth Hormone	353.6	321.9	297.2	10	8
Thrombolytics	200.0	185.2	180.2	8	3
Pulmozyme	177.7	167.2	138.1	6	21
Xolair	188.5	25.3	-	645	-
Raptiva	56.3	1.4	-	3,921	-
Other	10.6	6.5	-	63	-
Total product sales	<u>\$ 3,748.9</u>	<u>\$ 2,621.4</u>	<u>\$ 2,163.6</u>	43 %	21 %
Product sales as a % of total	81 %	79 %	84 %		

operating revenues

#### Total Product Sales

Total net product sales increased 43% to \$3,748.9 million in 2004 and 21% to \$2,621.4 million in 2003. In both years, the increases were due to higher sales across all products, in particular Avastin, Rituxan, Xolair, Herceptin and Raptiva in 2004 and Rituxan in 2003. Combined sales of our bio-oncology products (Rituxan and Herceptin, as well as Avastin and Tarceva in 2004), represented 74% of total product sales in 2004, 73% in 2003, and 72% in 2002. Increased sales volume for our products accounted for 96% of the product sales increase, or \$1,078.8 million in 2004, and higher sales prices accounted for the remainder of the increase. Increased sales volume for our products accounted for 74% of the product sales increase, or \$337.9 million in 2003, 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 F. Hoffmann-La Roche Ltd (or Hoffmann-La Roche).

#### Rituxan

Net sales of Rituxan increased 15% to \$1,711.2 million in 2004 and 28% to \$1,489.1 million in 2003. The 2004 growth was driven by increased adoption in indolent non-Hodgkin's lymphoma (or NHL) maintenance, front-line chronic lymphocytic leukemia (or CLL) and relapsed aggressive NHL, which are all unapproved uses of Rituxan. This trend reflects a slowing of the Rituxan growth rate and limited reaction to the Medicare legislation. However, we believe opportunities remain for long-term Rituxan sales growth (albeit, slower) in potential new FDA approved indications, for which we have conducted or are conducting label-enabling clinical trials. The 2003 sales increases were primarily driven by higher worldwide sales volume due to increased use of the product for the treatment of B-cell NHL in indolent and aggressive NHL, as well as 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, a price increase in 2003 also contributed, to a lesser extent, to the increase.

In the recently published 2005 Centers for Medicare and Medicaid Services Final Rules for Medicare reimbursement, there is minimal change in the overall reimbursement for Rituxan in 2005 when compared to that in 2004. Therefore, we anticipate limited additional impact on Rituxan usage in 2005.

Hoffmann-La Roche announced earlier in 2004 the positive opinion of the European Union's Committee for Human Medicinal Products, for the front-line use of Rituxan in combination with CVP (cyclophosphamide, vincristine, prednisone) chemotherapy for the treatment of indolent NHL. In the aggressive NHL setting, Genentech and Biogen Idec Inc. (or Biogen Idec) have agreed upon a filing strategy with the FDA that includes both the Eastern Cooperative Oncology Group (or ECOG) 4494 data and the GELA (Groupe d'Etude des Lymphomes de l'Adulte) study, and now anticipate this filing to occur in 2005. In the indolent NHL setting, we are also in discussions with the FDA to file the Rituxan CVP and ECOG 1496 maintenance studies. We are also in discussions with the FDA about additional data requirements needed to file a supplemental Biologics License Application (or sBLA) for the use of Rituxan in front-line indolent NHL.

#### Herceptin

Net sales of Herceptin increased 14% to \$483.2 million in 2004 and 10% to \$424.8 million in 2003. The growth in the past two years was driven by multiple factors, including physicians' extension of the average treatment duration and increased first-line penetration. In unapproved uses, there continues to be growing adoption by physicians of the combination of Herceptin, carboplatin and taxane, a combination otherwise known as TCH. The TCH regimen has demonstrated an improved time to disease progression and may therefore lead to a longer treatment duration. In addition to the above factors, we implemented price increases in 2004 and 2003, which contributed, to a lesser extent, to the increases. We currently believe there will be limited impact on Herceptin's usage under the new Medicare Act. We believe the potential for long-term Herceptin sales growth lies in the adjuvant setting for HER2 positive breast cancer, for which label-enabling clinical studies are still ongoing.

#### Avastin

Avastin achieved total net sales of \$554.5 million after launch in February 2004. Our sales have been driven primarily by use in colorectal cancer, which represents more than 95% of current Avastin use. In both the first-line (our approved indication) and relapsed/refractory (an unapproved use) settings, Avastin is being combined with a wide range of 5FU-based chemotherapies, reflecting Avastin's broad indication. In November 2004, we and Hoffmann-La Roche announced the preliminary results of a Phase III trial of Avastin in patients with advanced colorectal cancer who had previously received treatments. The trial achieved its primary endpoint of improving overall survival. We believe Avastin will continue to grow in the metastatic colorectal cancer market in 2005, driven by additional penetration of the first-line market, adoption in relapsed disease (an unapproved use), and other longer durations of treatment.

At present, all Medicare carriers and all of our targeted commercial payers are covering Avastin and reimbursement has proceeded as expected. On September 1, 2004, the Centers for Medicare and Medicaid Services added Avastin to its ongoing National Coverage Analysis (or NCA) of colorectal cancer therapies. We do not anticipate any interruption of Medicare coverage of Avastin during the NCA assessment period.

On January 28, 2005, the Centers for Medicare and Medicaid Services published its final National Coverage Decision which had a positive outcome for Avastin. Specifically, the final decision provides Medicare coverage of drugs used in nine specified clinical trials, seven of which include Avastin.

We have now completed discussions with the FDA, and have updated our package insert to include information about the risk of arterial thrombolytic events. We do not anticipate that these data will negatively impact long-term prescribing habits.

Our collaborator Hoffmann-La Roche received approval for Avastin in Israel in September 2004, in Switzerland in December 2004 and from the European Union in January 2005 for the treatment of patients with previously untreated metastatic cancer of the colon or rectum.

#### Tarceva

On November 18, 2004, the FDA approved Tarceva™. Net sales in 2004 were \$13.3 million from launch reflecting distribution of the product into the supply channel and positive physician adoption rates.

In September 2004, Genentech and its collaborators OSI Pharmaceuticals, Inc. (or OSI) and Hoffmann-La Roche announced that results from a randomized Phase III clinical study of Tarceva, in combination with gemcitabine chemotherapy, met its primary endpoint of improving survival for patients with locally advanced or metastatic pancreatic cancer. Genentech and its collaborators are discussing these data with the FDA and other regulatory agencies to determine the next steps for Tarceva in pancreatic cancer.

#### Growth Hormone

Combined net sales of our four growth hormone products, Nutropin AQ, Nutropin, Nutropin Depot, and Protropin, increased 10% to \$353.6 million in 2004 and 8% to \$321.9 million in 2003. The net sales growth in both years resulted from price increases and continued demand for the Nutropin products. On June 1, 2004, we and our collaborator Alkermes made a decision to discontinue commercialization of Nutropin Depot, a long-acting dosage form of recombinant growth hormone. Nutropin Depot sales continued through 2004 and are expected to cease in 2005. At the end of 2002, manufacture of Protropin was discontinued as physicians had shifted their therapy preference toward other Nutropin family products. Protropin sales ended following inventory depletion at the end of 2004.

In December 2003, we filed a supplemental New Drug Application for the additional indication of Nutropin® [somatotropin (rDNA origin) for injection]/Nutropin AQ® [somatotropin (rDNA origin) injection] for the long-term treatment of idiopathic short stature.

#### Thrombolytics

Combined net sales of our three thrombolytic products, Activase, TNKase and Cathflo Activase, increased 8% to \$200.0 million in 2004 and 3% to \$185.2 million in 2003. The sales increase in 2004 was driven by a price increase on Activase and growth in our catheter clearance and stroke markets. Sales of our thrombolytic products used to treat acute myocardial infarction continue to be impacted by the adoption by physicians of mechanical reperfusion strategies; however, the decline in the use of thrombolytics in acute myocardial infarction market has been offset by growth in our other markets. The higher sales in 2003 were primarily due to Cathflo Activase for catheter clearance. Cathflo Activase was launched in September 2001 and 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.

Our sales in 2004 and 2003 were also impacted by continued competition from Centocor, Inc.'s Retavase® (reteplase) and its aggressive price discounting.

On January 4, 2005, Cathflo Activase received approval from the FDA for catheter clearance in pediatric patients. With this new indication, Cathflo Activase is the only thrombolytic approved for use in pediatric patients with dysfunctional central venous access devices.

#### Pulmozyme

Net sales of Pulmozyme increased 6% to \$177.7 million in 2004 and increased 21% to \$167.2 million in 2003. These increases primarily reflect an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and a price increase in 2004 and to a lesser extent, a price increase in 2003.

## Xolair

Xolair total net sales were \$188.5 million in 2004 and \$25.3 million in 2003, due to ongoing market penetration reflected by continued acceptance of the product, strong growth in our prescriber base and strong patient compliance. Payer coverage and perceived clinical response remain high. A price increase on September 1, 2004 also positively impacted sales. In 2003, net sales reflected distribution of product into the supply channel and positive physician adoption rates. The impact of the Medicare Act on Xolair is expected to be minimal given that Xolair has a small Medicare patient population.

In the second half of 2004, Xolair received regulatory approval in Canada, Brazil, New Zealand, and Venezuela. Our collaborator, Novartis AG (or Novartis), is preparing for Xolair's launch in Canada, Brazil and Venezuela during the first half of 2005.

## Raptiva

Net sales of Raptiva were \$56.3 million in 2004 and \$1.4 million in 2003, reflecting continued acceptance of the product and effective reimbursement processing and, to a lesser extent, a price increase in September 2004. The rate of growth in prescriptions and resulting revenue for Raptiva was affected by the approval of ENBREL for psoriasis and the initiation of a significant patient experience trial with that product that took several thousand patients out of the market.

In September 2004, Serono S.A., which has rights to market Raptiva in certain areas of the world, announced that it had received European Commission Marketing Authorization for Raptiva. As of the end of January 2005, Raptiva is registered in the European Union and 12 other countries, and is already available in 15 of these countries through our collaborator, Serono.

Net sales in 2003 reflected initial distribution of product into the supply channel and initial reorders. We worked with a network of specialty pharmacies in processing reimbursements and the model was received positively.

## Royalties

Royalty income increased 28% to \$641.1 million in 2004 and 37% to \$500.9 million in 2003. The increases in both 2004 and 2003 were due to higher third-party sales by various licensees, primarily Hoffmann-La Roche (see "Related Party Transactions" below) for higher sales of Rituxan and Herceptin products. Also contributing to the increase in 2003 were gains related to foreign currency exchange rates on third-party sales by Hoffmann-La Roche. We expect that in 2005, the rate of increase in royalty income will be somewhat comparable to the rate in 2004.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase simple foreign currency put option (or option) and forward contracts to hedge these foreign royalty cash flows. The terms of these contracts are generally one to five years. See "Foreign Currency Exchange and Foreign Economic Conditions Risk" under Quantitative and Qualitative Disclosures about Market Risk in Part II, Item 7A of this Form 10-K for a discussion of market risks related to these financial instruments.

## Contract Revenue

Contract revenue increased 30% to \$231.2 million in 2004 and 226% to \$177.9 million in 2003. The increase in 2004 was primarily driven by revenues from our collaborators for amounts earned on development efforts related to Lucentis, Rituxan Immunology and commercialization of Tarceva, partially offset by lower revenues related to commercialization of Raptiva. 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 the humanized anti-CD20 antibody. See "Related

Party Transactions" below for more information on contract revenue from Hoffmann-La Roche and Novartis.

We expect that contract revenues will have a modest increase in 2005. 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 40% to \$672.5 million in 2004 and 9% to \$480.1 million in 2003. COS as a percentage of product sales in 2004 and 2003 was 18%. In 2004, we had higher sales of products with more favorable margins (primarily new sales of Avastin and higher U.S. sales of Rituxan) offset by higher 2004 production and inventory charges, including a charge of \$18.8 million related to Nutropin Depot inventory and our decision to discontinue its commercialization and reserve related expenses of \$34.7 million related to filling failures for certain other products.

As discussed in Part I, Item 1, "Collaboration Arrangements," we have an agreement with Lonza Biologics, a subsidiary of Lonza Group Ltd, to provide additional manufacturing capacity for Rituxan. We anticipate FDA approval and initiation of commercial production at the Lonza facility in 2005. We also have an agreement with Wyeth for the manufacture of Herceptin. We anticipate FDA approval and initiation of commercial production at the Wyeth facility in 2006. We do not expect the Lonza or the Wyeth arrangements to have a significant impact on our overall cost of sales as a percentage of product sales in the future.

We expect our COS as a percentage of sales for 2005 to be comparable to the rate in 2004.

#### Research and Development

Research and development (or R&D) expenses increased 31% to \$947.5 million in 2004 and 16% to \$722.0 million in 2003. R&D as a percentage of operating revenues in 2004 was 21%, a decrease from 22% in 2003. R&D expenses are expected to increase in 2005 in support of products in our clinical development pipeline, later-stage development of Avastin, Rituxan Immunology and Lucentis products and the related clinical material costs, and also increases in research and in-licensing expenses. Coupled with our expectations for higher revenues, R&D as a percentage of operating revenues in 2005 is expected to be comparable to the rate in 2004. Over the longer term, we expect the percentage rate will likely decline, but R&D expenses (as absolute dollars) will continue to increase. We manage our R&D expenses within each of the categories listed in the following table and described in more detail below (*in millions*).

Research and Development	2004	2003	2002	Annual Percent Change	
				2003/2002	2002/2001
Product development	\$ 545.7	\$ 449.0	\$ 417.1	22 %	8 %
Post-marketing	127.5	81.0	45.5	57	78
Total development	\$ 673.2	\$ 530.0	\$ 462.6	27	15

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Research	212.7	149.0	131.9	43	13
In-licensing	61.6	43.0	29.0	43	48
Total	\$ 947.5	\$ 722.0	\$ 623.5	31 %	16 %

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 27% to \$673.2 million in 2004, and 15% to \$530.0 million in 2003.

The increase in 2004 was primarily driven by (i) \$96.7 million higher clinical development of our pipeline products, including Lucentis, Rituxan Immunology and BR3-Fc for rheumatoid arthritis and higher development product production costs, including costs related to Rituxan development runs at Lonza, ramp-up of our facility in Porriño,

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Spain, increased headcount and related expenses and higher depreciation and facility expenses; and (ii) \$46.5 million increased post-marketing studies of Avastin, Xolair and Raptiva.

The increase in 2003 was primarily 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 post-marketing trials for products, including Raptiva, Avastin and Xolair.

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 43% to \$212.7 million in 2004 and 13% to \$149.0 million in 2003. The primary driver of the increase in both years was an increase in internal personnel and related expenses and outside contractors for research and testing of product candidates. The increase in 2004 also included expenses related to our chemical compound library.

In-licensing:

In-licensing includes costs paid upfront to acquire licenses to develop and commercialize various technologies and molecules. In-licensing expenses increased 43% to \$61.6 million in 2004 and 48% to \$43.0 million in 2003. The increases in 2004 and 2003 primarily relate to new collaborations.

Marketing, General and Administrative

Marketing, general and administrative (or MG&A) expenses increased 37% to \$1,088.2 million in 2004 and 46% to \$794.8 million in 2003. The increase in 2004 was due to: (i) an increase of \$66.5 million in marketing activities for the launches of Tarceva and Avastin; (ii) an increase of \$72.0 million in marketing activities for Raptiva and Xolair, preparations for the potential launch of our pipeline products, Rituxan Immunology and Lucentis, and higher managed care expenses; (iii) an increase of \$64.7 million related to headcount growth, market development and increased



commercial training programs to support all products, including increases in field sales force and sales incentive compensation and related expenses; (iv) an increase of \$70.7 million in royalty expenses, primarily to Biogen Idec related to royalties on ex-US sales of Rituxan; and (v) a charge of \$18.6 million in 2004 related to an impairment of a recorded Nutropin Depot license as a result of our decision to discontinue commercializing Nutropin Depot; partially offset by lower net loss on fixed asset disposal as compared to prior year (see also Note 2 and Note 5 "Other Intangible Assets" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on this charge).

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; and (iii) a \$43.6 million increase in corporate bonus and corporate functional expenses (primarily related to information systems technologies), and increased headcount and related expenses across most corporate functions, partially offset by lower net loss on fixed asset disposals as compared to the prior year, and (iv) an \$18.2 million increase in royalty expenses, primarily to Biogen Idec related to royalties on ex-US sales of Rituxan.

MG&A expenses are expected to rise in the near term, in particular, the marketing and sales component as we expand the commercialization of our new product, Tarceva, and continue marketing our recently launched products, Avastin, Xolair and Raptiva. 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 the sharing of the commercial net operating results of Xolair with Novartis.

Collaboration profit sharing expenses increased 30% to \$593.6 million in 2004 and 30% to \$457.5 million in 2003. These increases were driven by increased Rituxan profit sharing with Biogen Idec due to higher Rituxan sales and Xolair cost and profit sharing with Novartis primarily associated with Xolair sales, which began in July 2003.

We expect that any profit sharing with OSI on commercial activities related to 2005 U.S. sales of Tarceva will be reflected in this line. Collaboration profit sharing expense is expected to increase in 2005 consistent with the expected collaboration operating results associated with increased Rituxan and Xolair sales and new sales of Tarceva.

#### Recurring Charges Related to Redemption

In 2004, 2003 and 2002, this line is comprised of the amortization of our Redemption-related intangible assets. We began recording recurring charges for the amortization of our acquired intangible assets resulting from the Redemption and push-down accounting in the third quarter of 1999. See also Note 1, "Description of Business" 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 \$0.15 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, 2004, 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 Note 5, "Other Intangible Assets" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

#### Special Items: Litigation-Related

We recorded \$53.8 million in 2004 and \$53.9 million in 2003 for accrued interest and bond costs related to the City of Hope National Medical Center (or COH) trial judgment. In 2002, we recognized \$543.9 million of litigation-related special charges, which included the COH trial judgment, accrued interest and bond costs, and certain other litigation-related matters. In conjunction with the City of Hope judgment, we posted a surety bond and were required to pledge cash and investments of \$630.0 million at December 31, 2003 and \$682.0 million at December 31, 2004 to secure the bond. These amounts are reflected in the consolidated balance sheets in "restricted cash and investments" at December 31, 2004 and 2003. 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. As of December 31, 2004, we have classified approximately \$626.0 million in recorded liabilities as "litigation-related and other long-term liabilities," and the associated deferred tax assets of \$250.4 million and pledged assets of \$682.0 million as long-term assets in our consolidated balance sheet. This classification of the COH trial judgment-related assets and liabilities is updated from that previously presented in the unaudited condensed consolidated balance sheet filed on Form 8-K on January 10, 2005 in conjunction with the filing of our press release announcing earnings for the three and twelve months ended December 31, 2004. The presentation of these assets and liabilities in our unaudited condensed consolidated balance sheet filed on that Form 8-K was based on our then evaluation of the likelihood that the California Supreme Court would review the California Court of Appeal's November 2004 decision in this matter. The February 2, 2005 decision by the California Supreme Court has caused us to re-evaluate our assumptions as to the classification of these assets and liabilities. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter, however, we do expect that it will take longer than one year to further resolve this matter. Also included in this line in 2004 is a released accrual as a result of the resolution of a separate litigation matter.

In 2003, this line also includes litigation settlements as follows: (i) 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 \$0.09 in earnings per diluted share for 2003 and was reported as a litigation-related special item in our consolidated statements of income. (ii) 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 \$0.01 in earnings per diluted share for 2003 and was reported as a litigation-related special item.

See Note 6, "Leases, Commitments and Contingencies" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding our litigation.

Other Income, Net

Other Income, Net	2004	2003	2002	Annual Percent Change	
				2004/2003	2003/2002
	(in millions)				
Gains on sales of biotechnology equity securities and other	\$ 11.9	\$ 21.1	\$ 47.9	(44) %	(56) %
Write-downs of biotechnology debt and equity securities	(12.4)	(3.8)	(40.8)	226	(91)
Interest income	90.5	78.4	101.4	15	(23)
Interest expense	(7.4)	(2.9)	(0.8)	155	263
Total other income, net	\$ 82.6	\$ 92.8	\$ 107.7	(11) %	(14) %

"Other income, net" decreased 11% to \$82.6 million in 2004 and 14% to \$92.8 million in 2003. The decrease in 2004 was primarily due to lower gains for the year associated with biotechnology equity securities, increased write-downs of our biotechnology equity security holdings, and higher interest expense related to our long-term variable interest entity debt, which we consolidated on July 1, 2003. These decreases were partially offset by higher interest income (driven by a higher average cash balance, partially offset by lower yields). The decrease in 2003 was due to lower gains on sales of biotechnology equity securities partially offset by fewer biotechnology security write-downs. Also contributing to the 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.

Our strategy is to use gains from the sale of biotechnology equity securities or, alternatively, increases in product sales and other revenues, to offset expenses related to in-licensing and new arrangements. Consistent with this strategy, in 2004, these expenses were offset by higher operating revenues. However, in the future, we may use a greater proportion of gains from biotechnology sales to offset these expenses.

#### Income Tax Provision (Benefit)

The income tax provision of \$434.6 million in 2004 differed from the income tax provision of \$287.3 million in 2003 primarily due to increased 2004 pretax income and reduced benefits from prior years' items. The income tax provision in 2003 differed from the income tax benefit of \$34.0 million in 2002 primarily due to substantially increased pretax income.

Our 2005 tax rate is expected to be comparable with the 2004 tax rate of 36%. Certain factors may have favorable or unfavorable effects on our effective tax rate in 2005 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, and changes in overall levels of pretax earnings.

#### Cumulative Effect of Accounting Change

FIN 46 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.

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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 \$325.9 million at December 31, 2004 and \$348.4 million at December 31, 2003 and was included in property, plant and equipment in the accompanying consolidated balance sheets. 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 litigation-related and other long-term liabilities, respectively, in the accompanying consolidated balance sheets at December 31, 2004 and 2003. We recorded a \$47.6 million charge, net of \$31.8 million in taxes, (or \$0.05 per share) as a cumulative effect of the accounting change in 2003. We had previously accounted for our involvement with this entity as an operating lease. See also Note 6, "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 all of our leases.

#### Net Income and Earnings Per Share

Net income increased in 2004 to \$784.8 million, or \$0.73 per diluted share, from a net income in 2003 of \$562.5 million, or \$0.53 per diluted share. The increase was primarily due to higher operating revenues, in particular, higher product sales partly offset by higher operating expenses. In addition, 2003 includes special litigation-related settlement receipts (net of charges) of \$113.1 million.

Net income increased in 2003 to \$562.5 million, or \$0.53 per diluted share, from a net income of \$63.8 million in 2002, or \$0.06 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.

#### In-Process Research and Development -- Redemption

At June 30, 1999, the Redemption date, we determined that the acquired in-process technology was not technologically feasible nor did it have any future alternative uses. As a result, \$500.5 million of in-process research and development (or IPR&D) related to Roche's 1990 through 1997 purchases of our common stock was charged to additional paid-in capital, and \$752.5 million of IPR&D related to the Redemption 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 in-process projects.

For the year ended December 31, 2004, a portion of our operating revenues and profits was derived from products that resulted from in-process projects at the Redemption date. As of December 31, 2004, the projects which were in-process at the Redemption date were either substantially complete or have been discontinued. We currently estimate that the research and development expenditures required to complete the remaining in-process R&D projects to be \$6.0 million at December 31, 2004, 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. As a result, no adjustments have been nor are expected to be made to the original IPR&D accounting.

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Our Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding our Horizon 2010 goals, the expected number of products in late-stage development through 2005, estimate of completion of phase for development projects, Avastin, Rituxan and Herceptin sales growth opportunities, the timeframe for manufacture of our products by Lonza and Wyeth, the impact of Medicare legislation on sales of our products, the impact of an updated Avastin product label on long-term prescribing habits, the impact of the Lonza and Wyeth arrangements on our cost of sales, the costs for completion of in-process projects and expected level of capital expenditures, R&D and MG&A expenses as a percentage of operating revenues,

increases in Rituxan, Xolair and Tarceva sales, total revenues, royalty income and contract revenues, and targeted growth in non-GAAP EPS. Actual results could differ materially. For a discussion of the risks and uncertainties associated with achieving our Horizon 2010 goal of adding programs into research and clinical development and bringing products/indications to market, estimate of completion of phase for development projects, timeframe for manufacturing by Lonza and Wyeth, impact of the Lonza and Wyeth arrangements on our cost of sales, the costs for completion of in-process projects, our capital expenditures, and R&D and MG&A expenses as a percentage operating revenue, 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 Products," "Difficulties or Delays in Product Manufacturing Could Harm Our Business," "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" sections of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below; for our Horizon 2010 goal of becoming number one in U.S. oncology sales and building a leading immunology business, Rituxan, Herceptin and Avastin sales growth opportunities, increases in product sales and the impact of an updated Avastin label on prescribing habits, see all of the foregoing and "We May Be Unable to Manufacture Certain of Our Products If There Is BSE Contamination of Our Bovine Source Raw Material," "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 royalty income and contract revenues, see "Our Royalty and Contract Revenues Could Decline"; for the impact of Medicare legislation on our product sales, see "Decreases in Third Party Reimbursement Rates May Affect Our Product Sales"; for total revenues and targeted non-GAAP EPS growth, see all of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" below. We disclaim any obligation and do not undertake to update or revise any forward-looking statements in this Form 10-K.

#### Relationship with Roche

We have certain affiliation arrangements with Roche, licensing and marketing agreements and a research collaboration with Hoffmann-La Roche, and a tax sharing agreement with Roche as follows:

#### Affiliation Arrangements

Our board of directors consists of three 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.

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 deferred compensation plans.

#### Licensing Agreements

We have a July 1999 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 incurred through completion of Phase III, and 75% of development costs subsequently incurred, and \$5.0 million 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 its option, and would not share the costs or benefits of the additional indication, but could "opt-back-in" before approval of the indication by paying twice what they would have owed for development of the indication if they had not opted out;
- 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;

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- 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
- 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.

We have further amended this licensing and marketing agreement with Hoffmann-La Roche to delete or add certain Genentech products under Hoffman-La Roche's commercialization and marketing rights for Canada.

We also have a July 1998 licensing and marketing agreement relating to anti-HER2 antibodies (Herceptin and Omnitarg) with Hoffmann-La Roche, providing them with exclusive marketing rights outside of the United States. Under the agreement, Hoffmann-La Roche contributes equally with us on global development costs. Either Genentech or Hoffmann-La Roche has the right to "opt-out" of developing an additional indication for a product and would not share the costs or benefits of the additional indication, but could "opt-back-in" before approval of the indication by paying twice what would have been owed for development of the indication if no opt-out had occurred. Hoffmann-La Roche has also agreed to make royalty payments of 20% on aggregate net product sales outside the United States up to \$500.0 million in each calendar year and 22.5% on such sales in excess of \$500.0 million in each calendar year.

Research Collaboration Agreement

We have an April 2004 research collaboration agreement with Hoffmann-La Roche that outlines the process by which Hoffmann-La Roche and Genentech will conduct and share in the costs of joint research on molecules in areas of mutual interest. The agreement further outlines how development and commercialization efforts will be coordinated with respect to select molecules, including the financial provisions for a number of different development and commercialization scenarios undertaken by either or both parties.

#### Tax Sharing Agreement

We have a tax sharing agreement with Roche that pertains to the state and local tax returns in which we are consolidated or combined with Roche. We 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 1,018,388,704 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999, October 2000 and May 2004. We repurchased shares of our common stock in 2004 and 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. Roche publicly offered zero-coupon notes in January 2000 which were exchangeable for Genentech common stock held by Roche. Roche called these notes in March 2004. Through April 5, 2004, the expiration date for investors to tender these notes, a total of 25,999,324 shares were issued in exchange for the notes, thereby reducing Roche's ownership of Genentech common stock to 587,189,380 shares. At December 31, 2004, Roche's ownership percentage was 56.1%. The Minimum Percentage at December 31, 2004 was 57.7% and, under the terms of the affiliation agreement, Roche's lowest ownership percentage is to be no lower than 55.7%.

#### Related Party Transactions



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

#### Roche

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 Avastin global development costs unless Hoffmann-La Roche specifically opts out of the development of certain other indications. We will receive royalties on net sales of Avastin in countries outside of the U.S. Hoffmann-La Roche received approval for Avastin in Israel in September 2004, in Switzerland in December 2004 and from the European Union in January 2005 for the treatment of patients with previously untreated metastatic cancer of the colon or rectum.

In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market 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 agreed to pay 50% of subsequent global development costs related to the humanized anti-CD20 antibody unless Roche opts out of the development of certain indications. We will receive royalties on the humanized anti-CD20 antibody in countries outside of the U.S.

We recognized royalty revenue at the 22.5% rate for net sales of Herceptin made by Hoffmann-La Roche outside of the U.S. exceeding \$500.0 million in 2004 and milestone-related royalty revenue of \$20.0 million in 2003 as a result of Hoffmann-La Roche reaching \$400.0 million 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 \$72.7 million in 2004, \$66.5 million in 2003, and \$7.6 million in 2002. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled \$449.9 million in 2004, \$353.5 million in 2003, and \$269.9 million in 2002. R&D expenses include amounts related to Hoffmann-La Roche of \$118.6 million in 2004, \$79.5 million in 2003, and \$8.6 million in 2002.

#### Novartis

We understand that 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.

We have an agreement with Novartis Ophthalmics (now merged into Novartis AG) under which Novartis Ophthalmics 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 Ophthalmics paid an upfront milestone and R&D reimbursement fee of \$46.6 million and the parties will equally share the cost 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 for the trials for which it is solely responsible 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 February 2004, Genentech, Inc., Novartis Pharma AG and Tanox, Inc. settled all litigation pending among them, and finalized the detailed terms of their three-party collaboration, begun in 1996, to govern the development and commercialization of certain anti-IgE antibodies including Xolair® (omalizumab) and TNX-901. This arrangement modifies the arrangement related to Xolair that we entered into with Novartis in 2000. All three parties are co-developing Xolair in the U.S., and Genentech and Novartis are co-promoting Xolair in the U.S. and both will make certain joint and individual payments to Tanox; Genentech's joint and individual payments will be in the form of royalties. Genentech records all sales and cost of sales in the U.S. and Novartis will market the product in and record all sales and cost of sales in Europe. Genentech and Novartis then share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. The existing royalty and profit-sharing percentages between the three parties remain unchanged. Genentech is currently supplying the product and receives cost plus a mark-up similar to other supply arrangements. Novartis is expected to undertake primary bulk manufacturing responsibility in late 2005. Future production costs of Xolair may initially be higher than those currently reflected in our cost of sales as a result of any production shift from Genentech to Novartis, or to any other party, until production economies of scale can be achieved by that manufacturing party.

Collaboration profit sharing expenses were \$75.1 million in 2004, \$9.9 million in 2003 and \$1.8 million in 2002. R&D expenses include amounts related to Novartis of \$44.0 million in 2004, \$22.7 million in 2003 and \$18.8 million in 2002. Revenue from Novartis related to product sales and the associated cost of sales was not material in 2004 or in prior years. Contract revenue from Novartis, including amounts recognized under new licensing arrangements entered into in 2003 and amounts earned related to manufacturing, commercial and ongoing development activities, was \$48.6 million in 2004, \$24.2 million in 2003 and \$5.7 million in 2002.

#### Liquidity and Capital Resources

	2004	2003	2002
December 31:		(in millions)	
Cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	\$ 2,780.4	\$ 2,934.7	\$ 1,601.9
Working capital	2,179.5	1,883.8	1,436.1
Current ratio	2.8:1	3.1:1	3.2:1
Year Ended December 31:			
Cash provided by (used in):			
Operating activities	1,195.8	1,236.9	587.7
Investing activities	(451.6)	(1,398.4)	(6.5)
Financing activities	(846.3)	325.5	(768.3)
Capital expenditures (included in investing activities above)	(649.9)	(322.0)	(322.8)

Cash, cash equivalents, short-term investments and long-term marketable securities, excluding restricted cash, were approximately: (i) \$2.8 billion at December 31, 2004, a decrease of \$154.3 million or 5% from December 31, 2003, and (ii) \$2.9 billion at December 31, 2003, an increase of \$1.3 billion, or 83% from December 31, 2002. These changes primarily reflect cash generated from operations, income from investments and proceeds from stock issuances, which in 2003 were more than offset by cash used for the repurchase of common stock, purchase of marketable securities and for capital investments.

#### Cash Provided by Operating Activities

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

Cash payments received from customers can differ greatly from the amount of revenue recognized in the statement of income. Opt-in and upfront payments from collaborators are deferred and recognized in earnings over various number of years depending on the stage of the product and the contractual arrangement. Deferred revenues declined \$14.9 million during 2004 compared to an increase of \$239.1 million during 2003. The decline in 2004 reflects the amortization of deferred revenues into earnings. The increase in 2003 was primarily due to a \$188.0 million opt-in payment from Hoffmann-La Roche on the development and commercialization of Avastin, and a \$46.6 million upfront payment and R&D reimbursement fee from Novartis on a new arrangement to develop and market Lucentis. Refer to our "Revenue Recognition" policy in Note 2, "Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

Our "accounts receivable -- product sales" was \$599.1 million at December 31, 2004, an increase of \$306.2 million from December 31, 2003. The average collection period of our "accounts receivable -- product sales" as measured in days sales outstanding (or DSO) was 58 days as of December 31, 2004 compared to 41 days as of December 31, 2003. The increase in our "accounts receivable -- product sales" and our DSO was primarily due to higher sales of new products, in particular Avastin, and the related longer payment cycles. For new product launches, we offer, for a limited period, extended payment terms to allow customers and doctors purchasing the drug sufficient time to process reimbursements. The average collection period of our accounts receivable as measured in 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.

Our inventories increased \$120.7 million in 2004 primarily due to the ongoing manufacture of various products, including Rituxan, Raptiva, Herceptin, ENBREL and Lucentis pre-approval inventory, partially offset by the charges related to our decision to discontinue commercializing Nutropin Depot and filling failures for other products. See Note 4, "Consolidated Financial Statements Detail," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on these charges. Our average days' inventory on hand (or DOH) for total inventories and DOH for finished goods were both down slightly in 2004 as compared with 2003. This decrease was primarily due to higher sales volume of our Avastin, Rituxan, Raptiva and Xolair products and, to a much lesser extent, higher filling failures for certain of our products.

#### Cash Used in Investing Activities

Cash used in investing activities primarily relate to purchases, sales and maturities of investments and capital expenditures. Capital expenditures were \$649.9 million during 2004, an increase of \$327.9 million from 2003. Capital expenditures in 2004 were made to purchase land and office buildings in South San Francisco, including the repayment of two of our synthetic leases, and for equipment and information systems purchases and ongoing construction costs in support of our manufacturing and corporate infrastructure needs. 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 2005, we expect to spend approximately \$1.2 billion in capital expenditures. This increase in spending over 2004 will primarily support our manufacturing expansion, projects related to existing facilities, equipment and information systems purchases, and increases in office space and land purchases.

Restricted cash decreased by \$4.6 million due to a release of \$56.6 million upon our buyout of a synthetic lease, partially offset by an increase of \$52.0 million related to the additional cash and investments we were required to pledge to secure the COH surety bond. Total cash and investments pledged to secure the COH surety bond was \$682.0 million at December 31, 2004, an increase from the \$630.0 million at December 31, 2003. These amounts were reflected in the consolidated balance sheets in "restricted cash and investments" at December 31, 2004 and 2003. See the Contingencies section of Note 6, "Leases, Commitments and Contingencies" 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 Provided by or Used in Financing Activities

Cash provided by or used in financing activities is primarily related to activity under our employee stock plans and our stock repurchase plan. We received \$505.4 million during 2004, \$526.9 million during 2003 and \$74.2 million during 2002 related to stock option exercises and stock issuances under our employee stock purchase plan. We also used cash for stock repurchases of \$1,351.7 million during 2004, \$201.3 million during 2003 and \$692.8 million during 2002 pursuant to our stock repurchase program approved by our Board of Directors. See below and refer to Note 8, "Capital Stock," in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for further information on our stock repurchase program approved by our Board of Directors.

Cash declined by \$149.7 million in 2002 due to the redemption of our debentures which matured in the first quarter of 2002.

Absent any additional financing, our total cash, unrestricted cash equivalents, short-term investments and marketable securities are expected to decline modestly over the next several years due to cash requirements for capital expenditures, share repurchases under our stock repurchase program, synthetic lease repayments and cash requirements under our Master Lease Agreement with Slough, SSF, LLC, and other uses of working capital. We believe our existing unrestricted 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 below for a discussion of our leasing arrangements. See "Our Affiliation Agreement With Roche Could Adversely Affect Our Cash Position" below in the "Forward-Looking Information and Cautionary Factors" section and Note 6, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for factors that could negatively affect our cash position.

Under a stock repurchase program approved by our Board of Directors in December 2003 and extended in September 2004, Genentech is authorized to repurchase up to 50,000,000 shares of our common stock for an aggregate price of

up to \$2.0 billion through December 31, 2005. In this program, as in previous stock repurchase programs, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. 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. See above in "Relationship with Roche" for more

information on Roche's minimum ownership percentage. Under a previous stock repurchase program approved by our Board of Directors, Genentech was authorized to repurchase up to \$1.0 billion of our common stock through the period ended June 30, 2003.

We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The trading plans cover approximately 3.5 million shares and the current plan will run through December 31, 2005.

Our stock repurchases under the above programs are summarized below (*in millions*).

	TOTAL		2004		2003		2002		2001	
	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts
Repurchase program expired June 30, 2003	47.6	\$ 893.7	-	\$ -	10.9	\$ 195.3	36.5	\$ 692.8	0.2	\$ 5.6
Repurchase program expiring December 31, 2005	25.7	1,357.7	25.6	1,351.7	0.1	6.0	-	-	-	-
Total repurchases	73.3	\$ 2,251.4	25.6	\$ 1,351.7	11.0	\$ 201.3	36.5	\$ 692.8	0.2	\$ 5.6

Under our current stock repurchase program, we had no repurchases during the first quarter of 2004. Our shares repurchased during 2004 were as follows (*shares in millions*):

Total Number of Shares Purchased	Average Price	Total Number of Shares Purchased as Part of Publicly	Maximum Number of Shares that May
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	in 2004	Paid per Share	Announced Plans or Programs	Yet Be Purchased Under the Plans or Programs
April 1 - 30, 2004	1.6	\$ 58.21		
May 1 - 31, 2004	4.8	59.25		
June 1 - 30, 2004	3.6	55.90		
July 1 - 31, 2004	3.2	51.85		
August 1 - 31, 2004	-	-		
September 1 - 30, 2004	1.6	50.12		
October 1 - 31, 2004	5.1	48.44		
November 1 - 30, 2004	2.1	48.48		
December 1 - 31, 2004	3.6	49.91		
Total	<u>25.6</u>	<u>\$ 52.85</u>	<u>25.7</u>	<u>24.3</u>

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

#### Off-Balance Sheet Arrangements

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

#### Leases

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. Two of our operating leases are commonly referred to as "synthetic leases." Under FIN 46R, each 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 or specified assets of the VIE.

One of our synthetic leases relates to our manufacturing facility located in Vacaville, California. Under FIN 46R, 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 46R on July 1, 2003, we consolidated the entity. 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 promissory notes are supported by a credit 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 an amount that does not constitute a purchase at less than fair market value.

Our other synthetic lease was entered into with BNP Paribas Leasing Corporation (or BNP), which leases directly to us a building that we occupy in South San Francisco, California. We have evaluated our accounting for this lease under the provisions of FIN 46R, and have determined the following:

- as of July 1, 2003 and for each quarterly reporting period through December 31, 2004, our remaining synthetic lease entered into with BNP represents a variable interest in BNP;
- we are not the primary beneficiary of BNP as we do not absorb the majority of BNP's expected losses or expected residual returns. As a partial basis for our determination, we have received quarterly confirmations from BNP representing to us and we have reviewed their portfolio statements to confirm that the fair value of the leased property does not represent greater than 50% of the fair value of all of BNP's assets; and
- we believe that the leased property is not a "specified asset" that represents essentially the only source of payment for our variable interest. As a partial basis for our determination, we have received quarterly confirmations from BNP representing to us and we have reviewed their portfolio statements to confirm that the leased property is not a "specified asset" held within a silo. That is, BNP has not financed an amount equal to or greater than 95% of the fair value of the leased assets with non-recourse debt, lessor participation, targeted equity or any other type of funding (silo funding) that would result in the leased property being the only source of payment. In addition, as part of BNP's representations and warranties, BNP has agreed not to incur additional indebtedness in the future or to change the character of other non-targeted equity or similar funding sources that in any way would result in the leased property being essentially the only source of repayment or to make any distributions from BNP that would result in silo funding equal to or exceeding 95% of the fair value of the leased property.

Accordingly, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP lease. See below in "Contractual Obligations" and Note 6, "Leases, Commitments and Contingencies" in the Notes to the Consolidated Financial Statements of Part II, Item 8 of this Form 10-K, for our future minimum lease payments under all leases at December 31, 2004.

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.

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*):

	Approximate Initial Fair Value of Leased Property	Lease Expiration	Maximum Residual Value Guarantee
Vacaville lease	\$ 425.0	11/2006	\$ 371.8
South San Francisco lease	160.0	06/2007	136.0
Total	<u>\$ 585.0</u>		<u>\$ 507.8</u>

Two of our synthetic leases expired in 2004. Upon the expiration of these leases, we purchased the related properties for \$81.6 million from our lessor, BNP.

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 indemnification 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.

#### Commitments

See Collaboration Arrangements section above in Part I, Item 1, "Business" and Note 11, "Subsequent Events" in the Notes to Consolidated Financial Statements in Part II, Item 8 for discussions of our significant collaborations and the related commitments.

We have entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to the Company's South San Francisco campus. The property will be developed into eight buildings and two parking structures (the Business Park). The lease of the property will take place in two phases pursuant to separate lease agreements for each building as contemplated by the Master Lease Agreement. Phase I building leases will begin throughout 2006 and Phase II building leases may begin as early as 2008. In the event the rent commencement date for one or more Phase II buildings is delayed, the initial lease payments for each such building will be increased pursuant to the terms of the Master Lease Agreement. The leases entered into under the Master Lease Agreement will be accounted for as capital leases in our consolidated financial statements beginning in 2005. As such, we will record the leased assets in property, plant and equipment and the associated minimum rental payments as long-term debt in



our consolidated balance sheet. Our aggregate lease payments as contemplated by the Master Lease Agreement through 2020 (if there is no acceleration or delay in the rent commencement date for the second phase of the building) will be approximately \$540.1 million. If there is a delay and the leases terminate one year later, we will pay approximately an additional \$28.0 million.

### Contractual Obligations

In the table below, we set forth our enforceable and legally binding obligations and future commitments and obligations related to all contracts that we are likely to continue regardless of the fact that they are cancelable as of December 31, 2004. Some of the figures we include in this table are based on management's estimate and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

Contractual Obligations	Total	Payments due by period			
		(in millions) Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligations <sup>(1)</sup>					
Vacaville synthetic lease <sup>(2)</sup>	\$ 13.4	\$ 6.5	\$ 6.9	\$ -	\$ -
South San Francisco synthetic leases	14.3	5.2	9.1	-	-
Other leases	99.5	10.3	21.2	21.3	46.7
Slough <sup>(3)</sup>	540.1	-	25.0	65.7	449.4
Purchase obligations <sup>(4)</sup>	776.3	207.1	450.4	100.2	18.6
Long-term debt <sup>(2)</sup>	412.3	-	412.3	-	-
Litigation-related and other long-term liabilities <sup>(2) (5)</sup>	697.9	-	677.4	20.5	-
<b>Total</b>	<b>\$ 2,553.8</b>	<b>\$ 229.1</b>	<b>\$ 1,602.3</b>	<b>\$ 207.7</b>	<b>\$ 514.7</b>

(1) See further discussion of our operating leases above in "Leases."

- (2) 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 litigation-related and other long-term liabilities, respectively, at December 31, 2004.
- (3) See further commitments related to the Slough lease above in "Commitments."
- (4) Purchase obligations include commitments related to capital expenditures, clinical development, collaborations, manufacturing and research operations and other significant purchase commitments.
- (5) Litigation-related and other long-term liabilities include our 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.

In addition to the above, we have committed to make potential future "milestone" payments to third-parties as part of in-licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on our consolidated balance sheet.

Excludes interest related payments on long-term debt and deferred tax liabilities.

#### 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. In addition, our stockholders approved in April 2004 our 2004 Equity Incentive Plan under which stock options, restricted stock, stock appreciation rights and performance shares and units may be granted to our employees, directors and consultants in the future.

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.

#### General Option Information

#### Summary of Option Activity

(Shares in thousands)

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
December 31, 2002	8,098	110,838	\$ 19.19
Grants	(21,780)	21,780	40.55
Exercises	-	(32,078)	34.14
Cancellations	4,414	(4,414)	23.80
Additional shares reserved	50,000	-	-
December 31, 2003	40,732	96,126	25.18
Grants	(20,967)	20,967	53.04
Exercises	-	(21,484)	20.81
Cancellations	1,843	(1,843)	29.92
Additional shares reserved <sup>(1)</sup>	80,000	-	-
December 31, 2004	101,608	93,766	\$ 32.32

(1) Additional shares have been reserved for issuance under the 2004 Equity Incentive Plan approved by stockholders on April 16, 2004. No awards have been made under this Plan.

#### In-the-Money and Out-of-the-Money Option Information

(Shares in thousands)

As of December 31, 2004	Exercisable		Unexercisable		Total	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
In-the-Money	46,339	\$ 24.93	46,633	\$ 39.24	92,972	\$ 32.11
Out-of-the-Money <sup>(1)</sup>	-	-	794	57.28	794	57.28
Total Options Outstanding	46,339		47,427		93,766	

(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, \$54.44, at the close of business on December 31, 2004.

#### Distribution and Dilutive Effect of Options

#### Employee and Executive Officer Option Grants

	2004	2003	2002
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Net grants during the year as % of outstanding shares	1.82 %	1.69 %	1.98 %
Grants to Named Executive Officers* during the period as % of outstanding shares	0.19 %	0.18 %	0.25 %
Grants to Named Executive Officers during the year as % of total options granted	9.63 %	8.54 %	10.27 %

\* "Named Executive Officers" refers to our Chief Executive Officer 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.

#### 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 forward-looking 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 research or early phases of development may fail to reach later stages of development or the market for several reasons including:

- Preclinical tests may show the product to be toxic or lack efficacy in animal models.
- Clinical trial results that may show the product to be less effective than desired (e.g., the trial failed to meet its primary or secondary 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 BLA preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety, efficacy or manufacturing issues.

- Difficulties formulating the product, scaling the manufacturing process or in getting approval for manufacturing.
- Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being developed or commercialized.

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 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 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.
- We participate in a number of collaborative research arrangements. On many of these collaborations, our share of expenses recorded in our financial statements are subject to volatility based on our collaborator's spending activities as well as the mix and timing of activities between the parties.
- We may incur charges associated with expanding our product manufacturing capabilities, as described in "Difficulties or Delays in Product Manufacturing Could Harm Our Business" below.
- 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 approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application or a BLA, are substantial and can require a number of years. In addition, 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 or 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.

We have had equipment malfunctions in our filling facility and, consequently, several product lots were not able to be released and a scheduled facility maintenance shut-down was extended. This situation resulted in decreased target inventory levels for certain of our products. If we experience another significant malfunction in our filling facility, we could experience a shortfall or stock-out of one or more products, which, if it were to continue for a significant period of time, could result in a material adverse effect on our product sales.

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 or stock-out of available product inventory, any of which could have a material adverse impact on our business. A number of factors could cause prolonged interruptions, including the inability of a supplier to provide raw materials used for manufacture of our products, equipment obsolescence, malfunctions or failures, product contamination problems, damage to a facility, including our warehouses and distribution 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 us that results in the halting or slowdown of production of one or more of our products due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Furthermore, certain of our raw materials and supplies required for the production of our principal products are available only through sole source suppliers (the only recognized supplier available to us) or single source suppliers (the only approved supplier for us among other sources), and such raw materials cannot be obtained from other sources without significant delay or at all. If such sole source or single source suppliers were to limit or terminate production or otherwise fail to supply these materials for any reason, such failures could also have a material adverse impact on our business. Because our manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our or our alliance companies' contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share, damage our reputation and could result in a material adverse effect on our product sales, financial condition and results of operations.

We currently plan to expand our Vacaville facility, to build new facilities or enter into contracts for additional manufacturing capacity in the future, and to pursue process improvements to increase yields for our commercial products. Any delay in the construction of the facilities, the ability to contract for additional manufacturing capacity or the receipt of FDA licensure for new facilities or process improvements may cause us to have insufficient available capacity for the manufacture of our products. Insufficient available capacity to manufacture or have manufactured for us existing or new products 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 unabsorbed or idle plant charges, resulting in an increase in our costs of sales. All of our efforts planning for additional manufacturing capacity are critical to providing for sufficient capacity to meet expected demand for our products, and we recognize that there are some inherent uncertainties associated with forecasting future demand, especially for newly introduced products, and that the manufacturing of biologics is a complex process.

#### We May Be Unable to Manufacture Certain of Our Products If There Is BSE Contamination of Our Bovine Source Raw Material

Most biotechnology companies, including Genentech, have historically used bovine source raw materials to support cell growth in 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 occur during the manufacture of any of our products that require the use of bovine source raw materials, 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.

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

The Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003 (or Medicare Act), 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 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 our oncology or other products.

#### Protecting Our Proprietary Rights Is Difficult and Costly

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the breadth of claims allowed in 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 litigation and other legal proceedings relating to our proprietary rights, such as the matters discussed in Note 6, "Leases, Commitments and Contingencies" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K. Such litigation and other legal proceedings are costly in their own right and could subject us to significant liabilities to third parties. An adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute. An adverse decision with respect to one or more of our patents or other intellectual property rights could cause us to incur a material loss of royalties and other revenue from licensing arrangements that we have with third parties, and could significantly interfere with our ability to negotiate future licensing arrangements.

The presence of patents or other proprietary rights belonging to other parties may lead to our termination of the R&D of a particular product.

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.



### 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 have policies and procedures governing our sales and marketing activities and 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 financial condition and results of operations. We have been in the past, are currently, and may in the future be investigated for the promotional practices related to our products.

### 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, on our ability to successfully integrate large number of new employees into our corporate culture, and on our ability to develop and maintain important relationships with leading research and medical 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 and changes in stock option accounting rules could have an adverse 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 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 follow-on biologics 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 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 payors.

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 certain of our therapeutic markets. In the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to competing thrombolytic therapies and to the use of mechanical reperfusion therapies to treat acute myocardial infarction. 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 the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. Competitors have also received approval to market their existing growth hormone products for additional indications beyond those that our products are currently approved. As a result of that competition, we have experienced and may continue to experience a loss in market share.

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 Amgen's ENBREL® (etanercept), co-marketed by Wyeth, which was approved for adult patients with moderate-to-severe psoriasis in April 2004.

Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil (or "5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with intravenous 5-FU/Leucovorin and CPT-11 (or "the Saltz Regimen"). In a Phase II trial, Avastin was found to provide benefit for first-line patients when used in combination with intravenous 5-FU/Leucovorin alone. The use of the intravenous 5-FU/Leucovorin and Saltz regimens in the first-line is likely to decline as more physicians adopt 5-FU/Leucovorin/Oxaliplatin (or "FOLFOX") regimen. In November 2004, we and Hoffmann-La Roche announced the preliminary results of a Phase III trial of Avastin in patients with advanced colorectal cancer who had previously received treatments. The trial achieved its primary endpoint of improving overall survival. With this positive data (assuming a sBLA is approved), Avastin may compete with ImClone/Bristol-Myers Squibb's ERBITUX®, an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer patients. In addition, an oral VEGF-inhibitor from Novartis, PTK-787, is currently in Phase III clinical trials in combination with FOLFOX in both the first-line and relapsed settings. Results from these studies are expected to be announced in 2005. If these results are successful, there is the potential for that product, if approved by the FDA, to compete with Avastin.

Tarceva faces competition from Iressa, the only other EGFR tyrosine kinase inhibitor indicated for NSCLC, although recent negative survival data about Iressa's efficacy in relapsed NSCLC (i.e. the ISEL trial) may substantially lessen that competition. Tarceva also faces competition from new and established chemotherapy regimens. Specifically, Tarceva competes with the chemotherapeutic products Taxotere® and Alimta®, both of which are indicated for the treatment of relapsed NSCLC.

#### 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 safety or efficacy data from new clinical studies could cause the utilization and sales of our products to decrease.

- Negative safety or efficacy data from post-approval marketing experience could cause sales of our products to decrease or for a product to be recalled.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products. For example, as described in Note 6, "Leases, Commitments and Contingencies" in the Notes to Consolidated Financial Statements of 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.
- 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.
- The termination of an existing arrangement with any of the wholesalers who supply our products.

#### 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.
- 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. For example, patent litigations, interferences, oppositions, and other proceedings involving our patents often include claims by third parties that such patents are invalid or unenforceable. If a court, patent office, or other authority were to determine that a patent under which we receive royalties and/or other revenues is invalid or

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

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

#### 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.

We also have acquired, and may continue to acquire in the future, land and buildings as we expand our operations. Some of these properties are "brownfields" for which redevelopment or use is complicated by the presence or potential presence of a hazardous substance, pollutant or contaminant. We have taken steps, when possible, to minimize potential environmental liability associated with the ownership and/or use of such properties by entering into agreements with responsible parties and relevant government agencies. However, certain events could occur which may require us to pay significant clean-up or other costs in order to maintain our operations on those properties. Such events include, but are not limited to, changes in environmental laws, discovery of new contamination, or unintended exacerbation of existing contamination. The occurrence of any such event could materially affect our ability to continue our business operations on those properties.

#### Fluctuations in Our Operating Results Could Affect the Price of Our Common Stock

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

- The overall competitive environment for our products as described in "We Face Competition" above.
- The amount and timing of sales to customers in the 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 by physicians and use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
- The potential introduction of new products and additional indications for existing products.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.
- The number and size of any product price increases we may issue.

Our Integration of New Information Systems Could Disrupt our Internal Operations, Which Could Harm Our Revenues and Increase Our Expenses

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors. We are in the process of implementing a new general ledger, financial reporting, order management, procurement and data warehouse systems to replace our current systems. We have functioning legacy systems in place, but we may not be successful in implementing the new systems, and transitioning data and other aspects of the process could be expensive, time consuming, disruptive and resource intensive. Any disruptions that may occur in the implementation of new systems or any future systems could adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows. Disruptions to these systems also could adversely impact our ability to fulfill orders and interrupt other operational processes. Delayed sales, lower margins or lost customers resulting from these disruptions could adversely affect our financial results.

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

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. In addition, the market price of our common stock has been and may continue to be highly 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.
- Economic and other external factors or a disaster or crisis.

- Period-to-period fluctuations in our financial results.

#### 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 Note 8, "Capital Stock" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K. See Note 7, "Relationship with Roche and Related Party Transactions -- Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock" 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, 2004, Roche owned 587,189,380 shares of our common stock or 56.1% 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 at least three directors designated by Roche, three independent directors nominated by the nominating committee and one Genentech executive officer 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 currently 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.

#### 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 Note 7, "Relationship with Roche and Related Party Transactions -- Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock" 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 Note 8, "Capital Stock" 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. Three of our directors, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles, currently serve as officers and employees of Roche Holding Ltd and its affiliates.

## 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, and changes in overall levels of pretax earnings.

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

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



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 December 2004, the FASB issued Statement No. 123 (revised 2004), "Share-Based Payment," effective beginning after June 15, 2005. FAS 123R supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock purchase plans. We will be required to implement FAS 123R no later than the quarter that begins July 1, 2005. Our adoption will be applied on a modified prospective basis and measured and recognized on July 1, 2005. We expect that the adoption of FAS 123R will have a material adverse impact on our consolidated results of operations and financial position.

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

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, 2004.

##### Interest Rate Risk

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 \$2,926.3 million or 31% of total assets at December 31, 2004. Interest income related to this portfolio was \$90.5 million in 2004. 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, 2004, 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 \$7.4 million.

#### Foreign Currency Exchange and Foreign Economic Conditions Risk

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 manufacturing facility as well as non-dollar expenses incurred in our collaborations are offsetting exchange rate exposures on these royalties. Currently, our foreign royalty revenues exceed our foreign expenses. In 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 or forward 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 or forward. Generally, the terms of these option or forward contracts are one to five years. To hedge the non-dollar expenses arising from our foreign manufacturing facility, we 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, 2004, 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 could result in a potential loss in the fair value of our foreign currency sensitive instruments of \$16.5 million.

#### Equity Securities Risks

As part of our strategic alliance efforts, we invest in equity instruments of biotechnology companies. Our biotechnology equity investment portfolio totaled \$536.2 million or 6% of total assets at December 31, 2004. These investments are subject to fluctuations from market value changes in stock prices. 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. 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 future periods 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, 2004, 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 \$20.6 million.

#### Counterparties Credit Risks

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.

## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Genentech, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting included in Item 9A, that Genentech, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Genentech, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of Genentech, Inc.'s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Genentech, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Genentech, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Genentech, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 and our report dated February 18, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 18, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Genentech, Inc.

We have audited the accompanying consolidated balance sheets of Genentech, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (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, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. 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 2 and 6 to the consolidated financial statements, in 2002 Genentech, Inc. changed its method of accounting for goodwill and other intangible assets and in 2003 changed its method of accounting for variable interest entities, respectively.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Genentech, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 18, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 18, 2005

CONSOLIDATED STATEMENTS OF INCOME

*(in thousands, except per share amounts)*

	Year Ended December 31,		
	2004	2003	2002
Revenues			

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Product sales (including amounts from related parties: 2004-\$112,065; 2003-\$108,078; 2002-\$117,257)	\$ 3,748,879	\$ 2,621,490	\$ 2,163,665
Royalties (including amounts from related party: 2004-\$338,733; 2003-\$245,623; 2002-\$152,642)	641,119	500,903	365,550
Contract revenue (including amounts from related parties: 2004-\$121,261; 2003-\$90,692; 2002-\$13,348)	231,159	177,934	54,443
<b>Total operating revenues</b>	<b>4,621,157</b>	<b>3,300,327</b>	<b>2,583,658</b>
Costs and expenses			
Cost of sales (including amounts for related parties: 2004-\$96,091; 2003-\$90,657; 2002-\$99,150)	672,526	480,123	441,630
Research and development (including amounts for related parties: 2004-\$162,642; 2003-\$102,234; 2002-\$27,417) (including contract related: 2004-\$131,636; 2003-\$95,473; 2002-\$24,060)	947,513	721,970	623,482
Marketing, general and administrative	1,088,111	794,845	546,276
Collaboration profit sharing (including amounts for related parties: 2004-\$75,090; 2003-\$9,898; 2002-\$1,781)	593,616	457,457	350,725
Recurring charges related to redemption	145,485	154,344	155,713
Special items: litigation-related	37,087	(113,127)	543,905
<b>Total costs and expenses</b>	<b>3,484,338</b>	<b>2,495,612</b>	<b>2,661,731</b>
Operating margin	1,136,819	804,715	(78,073)
Other income, net	82,597	92,791	107,822
Income before taxes and cumulative effect of accounting change	1,219,416	897,506	29,749
Income tax provision (benefit)	434,600	287,324	(34,038)
Income before cumulative effect of accounting change	784,816	610,182	63,787
Cumulative effect of accounting change (net of tax: 2003-\$31,770)	-	(47,655)	-
Net income	<b>\$ 784,816</b>	<b>\$ 562,527</b>	<b>\$ 63,787</b>
Earnings per share			

**Basic**

Earnings before cumulative effect of accounting change	\$ 0.74	\$ 0.59	\$ 0.06
Cumulative effect of accounting change (net of tax: 2003-\$0.03)	-	(0.05)	-
<b>Net earnings per share</b>	<b>\$ 0.74</b>	<b>\$ 0.54</b>	<b>\$ 0.06</b>

**Diluted**

Earnings before cumulative effect of accounting change	\$ 0.73	\$ 0.58	\$ 0.06
Cumulative effect of accounting change (net of tax: 2003-\$0.03)	-	(0.05)	-
<b>Net earnings per share</b>	<b>\$ 0.73</b>	<b>\$ 0.53</b>	<b>\$ 0.06</b>
Weighted-average shares used to compute basic earnings per share	1,055,165	1,034,480	1,038,384
Weighted-average shares used to compute diluted earnings per share	1,079,209	1,057,619	1,048,816

See Notes to Consolidated Financial Statements.

**CONSOLIDATED STATEMENTS OF CASH FLOWS***(in thousands)*

	Year Ended December 31,		
	2004	2003	2002
<b>Cash flows from operating activities</b>			
Net income	\$ 784,816	\$ 562,527	\$ 63,787
Adjustments to reconcile net income to net cash provided by operating activities:			
Cumulative effect of accounting change, net of tax	-	47,655	-
Depreciation and amortization	353,221	295,449	274,955

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Deferred income taxes	(73,585)	(149,001)	(196,644)
Deferred revenue	(14,927)	239,145	2,001
Litigation-related and other long-term liabilities	34,722	56,113	552,185
Tax benefit from employee stock options	329,470	264,981	16,946
Gain on sales of securities available-for-sale and other	(13,577)	(23,069)	(53,710)
Loss on sales of securities available-for-sale	1,839	3,137	5,868
Write-down of securities available-for-sale	12,340	3,795	40,759
Loss on fixed asset dispositions	5,115	10,760	15,883
Changes in assets and liabilities:			
Receivables and other current assets	(362,740)	(152,077)	(110,237)
Inventories	(120,703)	(93,264)	(36,596)
Investments in trading securities	(75,695)	(33,825)	(121,986)
Accounts payable and other current liabilities	335,542	204,610	134,489
<b>Net cash provided by operating activities</b>	<b>1,195,838</b>	<b>1,236,936</b>	<b>587,700</b>
Cash flows from investing activities			
Purchases of securities available-for-sale	(889,732)	(1,755,934)	(806,444)
Proceeds from sales and maturities of securities available-for-sale	1,149,113	739,867	1,746,198
Purchases of nonmarketable equity securities	(6,661)	(4,286)	(6,290)
Capital expenditures	(649,858)	(321,955)	(322,832)
Change in other assets	(59,020)	(56,122)	12,875
Transfer from (to) restricted cash, net	4,600	-	(630,000)
<b>Net cash used in investing activities</b>	<b>(451,558)</b>	<b>(1,398,430)</b>	<b>(6,493)</b>
Cash flows from financing activities			
Stock issuances	505,374	526,861	74,164
Stock repurchases	(1,351,683)	(201,345)	(692,752)
Repayment of short-term debt	-	-	(149,692)
<b>Net cash (used in) provided by financing activities</b>	<b>(846,309)</b>	<b>325,516</b>	<b>(768,280)</b>
Net (decrease) increase in cash and cash equivalents	(102,029)	164,022	(187,073)
Cash and cash equivalents at beginning of year	372,152	208,130	395,203
Cash and cash equivalents at end of year	\$ 270,123	\$ 372,152	\$ 208,130
Supplemental cash flow data			
Cash paid during the year for:			
Interest	\$ 6,626	\$ 2,223	\$ 7,482
Income taxes	131,611	167,761	128,108
Stock received as consideration for outstanding		29,600	-



loans

-

See Notes to Consolidated Financial Statements.

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## CONSOLIDATED BALANCE SHEETS

*(in thousands, except par value and shares)*

	December 31,	
	2004	2003
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 270,123	\$ 372,152
Short-term investments	1,394,982	1,139,620
Accounts receivable - product sales (net of allowances: 2004-\$59,366; 2003-\$45,099; including amounts from related parties: 2004-\$11,237; 2003-\$16,018)	599,052	292,861
Accounts receivable - royalties (including amounts from related party: 2004-\$119,080; 2003-\$113,739)	217,482	184,163
Accounts receivable - other (net of allowances: 2004-\$2,191; 2003-\$2,191; including amounts from related parties: 2004-\$68,594; 2003-\$71,863)	140,838	120,373
Inventories	590,343	469,640
Deferred tax assets	148,370	121,885
Prepaid expenses and other current assets	61,567	79,442
<b>Total current assets</b>	<b>3,422,757</b>	<b>2,780,136</b>
Long-term marketable debt and equity securities	1,115,327	1,422,886
Property, plant and equipment, net	2,091,404	1,617,912
Goodwill	1,315,019	1,315,019
Other intangible assets	668,391	810,810
Restricted cash and investments	682,000	686,600
Deferred tax assets	20,341	-
Other long-term assets	88,156	126,114
<b>Total assets</b>	<b>\$ 9,403,395</b>	<b>\$ 8,759,477</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		

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Accounts payable	\$ 104,832	\$ 59,700
Deferred revenue	45,989	47,478
Other accrued liabilities (including amounts to related parties: 2004-\$108,416; 2003-\$58,138)	1,092,445	789,159
<b>Total current liabilities</b>	<b>1,243,266</b>	<b>896,337</b>
Long-term debt	412,250	412,250
Deferred revenue	267,805	281,243
Litigation-related and other long-term liabilities	697,884	649,349
<b>Total liabilities</b>	<b>2,621,205</b>	<b>2,239,179</b>
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, \$0.02 par value; authorized: 100,000,000 shares; none issued	-	-
Common stock, \$0.02 par value; authorized: 3,000,000,000 shares; outstanding: 2004-1,047,126,660 shares; 2003-1,049,484,082 shares	20,943	20,990
Additional paid-in capital	8,002,754	7,359,416
Accumulated other comprehensive income	290,948	297,033
Accumulated deficit, since June 30, 1999	(1,532,455)	(1,157,141)
<b>Total stockholders' equity</b>	<b>6,782,190</b>	<b>6,520,298</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 9,403,395</b>	<b>\$ 8,759,477</b>

See Notes to Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income
Common Stock			