GENENTECH INC Form 10-K February 23, 2007

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

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**FORM 10-K** 

(Mark One)

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

For the fiscal year ended December 31, 2006

or

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

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

Commission file number: 1-9813

#### GENENTECH, INC.

(Exact name of registrant as specified in its charter)

## **A Delaware Corporation**

94-2347624

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

1 DNA Way, South San Francisco, California

94080

(Address of principal executive offices)

(Zip Code)

(650) 225-1000

(Registrant's telephone number, including area code)

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$0.02 par value

New York Stock Exchange

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

None

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes b No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the

## Act. Yes o No b

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 b No o

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. b

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

Large accelerated filer b

Accelerated filer o

Non-accelerated filer o

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

The aggregate market value of Common Stock held by non-affiliates as of June 30, 2006 was \$38,078,024,827. (A) All executive officers and directors of the registrant and Roche Holdings, Inc. have been deemed, solely for the purpose of the foregoing calculation, to be "affiliates" of the registrant.

Number of shares of Common Stock outstanding as of February 9, 2007: 1,053,185,944

## **Documents incorporated by reference:**

Portions of the Definitive Proxy Statement with respect to the 2006 Annual Meeting of Stockholders to be filed by Genentech, Inc. with the Securities and Exchange Commission (hereinafter referred to as "Proxy Statement")

Part III

(A) Excludes 587,254,604 shares of Common Stock held by directors and executive officers of	
Genentech and Roche Holdings, Inc.	

## GENENTECH, INC.

## 2006 Form 10-K Annual Report

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

We own or have rights to various copyrights, trademarks and trade names used in our business including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin® (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Herceptin® (trastuzumab) anti-HER2 antibody;

Lucentis® (ranibizumab, 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; 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 number of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products, 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.

## **Marketed Products**

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

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

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

- ·The treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, including retreatment and bulky disease;
- •The first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy;
- •The first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisone) chemotherapy regimens;
- •The treatment of patients with low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy; and
- ·Use in combination with methotrexate for reducing signs and symptoms in adult patients with moderately-to-severely active rheumatoid arthritis (or "RA") who have had an inadequate response to one or more tumor necrosis factor antagonist therapies.

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

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

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

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

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

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

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

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

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

*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.

See "Total Product Sales" under Results of Operations in Part II, Item 7 of this Form 10-K for a discussion of the sales of each of our products in the last three years, including those that accounted for 10% or more of our consolidated revenues.

## **Licensed Products**

## Royalty Revenue

We receive royalty revenue under license agreements with companies that sell and/or manufacture products based on technology developed by us or intellectual property to which we have rights. These licensed products are sometimes sold under different trademarks or trade names. Significant licensed products, including all related party licenses, representing approximately 92% of our royalty revenues in 2006, are presented in the following table:

Product Trastuzumab	Trade Name Herceptin	<u>Licensee</u> F. Hoffmann-La Roche	Licensed Territory Worldwide excluding U.S.	
Rituximab	Rituxan/MabThera®	F. Hoffmann-La Roche	Worldwide excluding U.S. and Japan	
Bevacizumab	Avastin	F. Hoffmann-La Roche	Worldwide excluding U.S.	
Dornase alfa, recombinant	Pulmozyme	F. Hoffmann-La Roche	Worldwide excluding U.S.	
Alteplase and Tenecteplase	Activase and TNKase	F. Hoffmann-La Roche	Canada	
Somatropin	Nutropin	F. Hoffmann-La Roche	Canada	
Etanercept	ENBREL®	Immunex Corporation (whose rights were acquired by Amgen Inc.)	n Worldwide	
D2E7/adalimumab	Humira®	Abbott Laboratories	Worldwide	
Infliximab	Remicade®	Celltech Pharmaceuticals plc (which transferred rights to Centocor, Inc. / Johnson & Johnson)	Worldwide	
Cetuximab	ERBITUX®	ImClone Systems, Inc.	Worldwide	
Antihemophilic factor, recombinant	Kogenate®/Helixate®	Bayer Corporation	Worldwide	

See Item 3, "Legal Proceedings" below for information regarding certain patent litigation matters.

## Other Revenues

We have granted a license to Zenyaku Kogyo Co., Ltd. (or "Zenyaku"), a Japanese pharmaceutical company, for the manufacture, use and sale of rituximab in Japan. Zenyaku co-promotes rituximab in Japan with Chugai Pharmaceutical Co., Ltd., a Japanese subsidiary of F. Hoffmann-La Roche, under the trademark Rituxan. The revenue earned from our sales of rituximab to Zenyaku is included in product sales.

#### **Products in Development**

Our product development efforts, including those of our collaborators, cover a wide range of medical conditions, including cancer and immune diseases. Below is a summary of products, current stages of development, and the estimated completion of the current phase of development. For additional information on our development pipeline, please visit our website at http://www.gene.com.

Estimated Completion of Current Phase<sup>(1)</sup>

2007

**Product** 

**Description** 

Awaiting U.S. Food and Drug Administration (or "FDA") Action

Herceptin

A supplemental Biologics Licensure Application 2007-2008 (or "sBLA") was submitted to the FDA on

December 21, 2006 for the use of Herceptin for the treatment of patients with early-stage HER2-positive breast cancer based on the HERA study to enable a broader label. This product is being developed in collaboration with F.

Hoffmann-La Roche.

## **Preparing for Filing**

Avastin

We are preparing to resubmit an sBLA to the FDA for the use of Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not previously received chemotherapy for their locally recurrent or metastatic breast cancer. This product is being developed in collaboration with F. Hoffmann-La Roche.

Avastin

We are in discussions with the FDA regarding the 2007-2008 submission requirements for a potential sBLA for

the use of Avastin in combination with interferon alpha-2a for the treatment of patients with previously untreated advanced renal cell carcinoma. This product is being developed in

collaboration with F. Hoffmann-La Roche.

Herceptin

We are preparing to submit an sBLA to the FDA for the use of Herceptin for the treatment of patients with early-stage HER2-positive breast cancer based on the BCIRG 006 study to enable a broader label. This product is being developed in

collaboration with F. Hoffmann-La Roche.

## Rituxan Immunology

We and our collaborator Biogen Idec are preparing to submit an sBLA to the FDA seeking expansion of the rheumatoid arthritis (anti-tumor necrosis factor inadequate responders) indication to include radiographic data demonstrating inhibition of joint damage in Rituxan treated patients. This product is being developed in collaboration with F. Hoffmann-La Roche and Biogen Idec.

2007

#### Phase III

2nd Generation anti-CD20 2nd Generation anti-CD20 is being evaluated in 2009-2010

rheumatoid arthritis. This product is being developed in collaboration with F. Hoffmann-La

Roche and Biogen Idec<sup>(2)</sup>.

Avastin Avastin is being evaluated in adjuvant colon 2007-2012

cancer, adjuvant rectal cancer, first- and second-line metastatic breast cancer in combination with several chemotherapy regimens, first-line non-squamous NSCLC, first-line ovarian cancer, and hormone refractory prostate cancer. This product is being developed in collaboration

with F. Hoffmann-La Roche.

Avastin +/- Tarceva Avastin and Tarceva are being evaluated as 2009

combination therapy in first-line NSCLC in combination with several chemotherapy regimens. This product is being developed in collaboration

with F. Hoffmann-La Roche and OSI.

Rituxan is being evaluated in first-line follicular 2010

Hematology/Oncology

non-Hodgkin's lymphoma with several chemotherapy regimens and in relapsed chronic lymphocytic leukemia. This product is being developed in collaboration with F. Hoffmann-La

Roche and Biogen Idec.

Rituxan Immunology Rituxan is being evaluated in rheumatoid arthritis 2007-2009

(DMARD inadequate responders) in collaboration with F. Hoffmann-La Roche and Biogen Idec. Rituxan is also being evaluated in primary progressive multiple sclerosis, systemic lupus erythematosus, lupus nephritis, and ANCA-associated vasculitis in collaboration with

Biogen Idec.

Tarceva is being evaluated in adjuvant NSCLC 2013

with several chemotherapy regimens and first-line NSCLC. This product is being developed in collaboration with F. Hoffmann-La Roche and

OSI.

Tarceva +/- Avastin Tarceva and Avastin are being evaluated as 2008

combination therapy in first-line metastatic pancreatic cancer and second-line NSCLC. This product is being developed in collaboration with F.

Hoffmann-La Roche and OSI.

TNKase is being evaluated in the treatment of 2008

dysfunctional hemodialysis and central venous

access catheters.

Xolair is being evaluated in pediatric asthma. This 2008

product is being developed in collaboration with

Novartis and Tanox, Inc. (or "Tanox").

## **Preparing for Phase III**

2nd Generation anti-CD20 We are preparing Phase III clinical trials in lupus 2007

nephritis and systemic lupus erythematosus. This product is being developed in collaboration with F.

Hoffmann-La Roche and Biogen Idec<sup>(2)</sup>.

ALTU-238 Altus is preparing a Phase III clinical trial in adult (3)

growth hormone deficiency. We have entered into an agreement to develop this product in collaboration with Altus, and this transaction is

subject to closing conditions.

Avastin We are preparing for Phase III clinical trials in 2007

adjuvant breast cancer, first-line metastatic breast cancer in combination with antihormonal therapy, adjuvant NSCLC, gastrointestinal stromal tumors, and second-line ovarian cancer. This product is being developed in collaboration with F.

Hoffmann-La Roche.

Herceptin +/- Avastin We are preparing for a Phase III clinical trial of 2007

Herceptin and Avastin as combination therapy in first-line HER2-positive metastatic breast cancer. This product is being developed in collaboration

with F. Hoffmann-La Roche.

Lucentis We are preparing for Phase III clinical trials in 2007

diabetic macular edema and retinal vein occlusion. This product is being developed in collaboration

with Novartis Ophthalmics.

Phase II

Anti-CD40 Anti-CD40 is being evaluated in non-Hodgkin's 2008-2009

lymphoma. We are developing this product in

collaboration with Seattle Genetics Inc.

Avastin Avastin is being evaluated in adjuvant 2007

HER2-negative breast cancer, relapsed glioblastoma multiforme, and non-squamous NSCLC with previously treated central nervous system metastases. This product is being developed in collaboration with F. Hoffmann-La

Roche.

HAE1 HAE1 is being evaluated in moderate-to-severe 2008-2009

allergic asthma.

Omnitarg	Our Phace	II clir	sical trial	evaluating	Omnitara	in 2007
Ommarg	Our Phase	II CIII	ncai utai	evaluating	Ommuare	m 2007

combination with chemotherapy in platinum-resistant ovarian cancer showed encouraging results. Roche is conducting a clinical trial evaluating Omnitarg in combination with chemotherapy in platinum-sensitive ovarian cancer. This product is being developed in collaboration with F. Hoffmann-La Roche.

Topical VEGF Topical VEGF is being evaluated for the treatment 2007

of diabetic foot ulcers.

## **Preparing for Phase II**

2<sup>nd</sup> Generation anti-CD20 We are preparing for a Phase II clinical trial in 2007-2008

relapsing remitting multiple sclerosis. This product is being developed in collaboration with F.

Hoffmann-La Roche and Biogen Idec<sup>(2)</sup>.

ALTU-238 Altus is preparing for a Phase II clinical trial in (3)

pediatric growth hormone deficiency. We have entered into an agreement to develop this product in collaboration with Altus, and this transaction is

subject to closing conditions.

Avastin We are preparing to initiate a Phase II clinical trial 2007

in extensive small cell lung cancer. This product is being developed in collaboration with F.

Hoffmann-La Roche.

**Phase I and Preparing for** We have multiple new molecular entities in Phase **Phase I** I or preparing for Phase I.

#### **Related Party 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, F. Hoffmann-La Roche and Novartis.

#### **Distribution and Commercialization**

We have a U.S.-based 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 U.S. 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.

The Genentech Access to Care Foundation provides free product to eligible uninsured patients and those deemed uninsured due to payer denial in the U.S. We have the Genentech Endowment for Cystic Fibrosis to assist cystic fibrosis patients in the U.S. with obtaining Pulmozyme. We also provide customer service programs relating to our products. We maintain a physician-related product waste replacement program for Rituxan, Avastin, Herceptin,

<sup>(1)</sup> For those projects preparing for a Phase, the estimated date of completion refers to the date the project is expected to enter the Phase for which it is preparing.

<sup>(2)</sup> Our collaborator Biogen Idec disagrees with certain of our development decisions under our 2003 collaboration agreement with them. We continue to pursue a resolution of our differences with Biogen Idec, and the disputed issues have been submitted to arbitration. See Part I, Item 3, "Legal Proceedings," of this Form 10-K for further information.

<sup>(3)</sup> Our collaborator is conducting the trial(s) and we are unable to provide the estimated date of completion for the current phase.

Activase, TNKase and Lucentis, that, subject to specific conditions, provides physicians 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 expired products to us for replacement or credit at a price based on a 12-month rolling average. To further support patient access to therapies for various diseases we donate to various independent, public charities that offer financial assistance, such as co-pay assistance, to eligible patients. We maintain the right to renew, modify or discontinue any of the patient programs described above.

In October 2006, we announced our plan to launch the Avastin Patient Assistance Program in the first quarter of 2007, which is a voluntary program that enables eligible patients who receive greater than 10,000 milligrams of Avastin over a 12-month period to receive free Avastin during the remainder of the 12-month period. Eligible patients include those who are being treated for an FDA-approved indication and who meet the household income criteria for this program. The program will be available for eligible patients who enroll regardless of whether they are insured.

As discussed in Note 12, "Segment, Significant Customer and Geographic Information," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K, our combined sales to three major wholesalers provided approximately 85% in 2006, 82% in 2005, and 79% in 2004, of our total net U.S. product sales. Also discussed in the note are material net foreign revenues by country in 2006, 2005 and 2004.

## **Manufacturing and Raw Materials**

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

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.

For risks associated with manufacturing and raw materials, see "Difficulties or delays in product manufacturing or in obtaining materials from our suppliers could harm our business and/or negatively affect our financial performance" under "Risk Factors."

## Proprietary Technology — Patents and Trade Secrets

We seek patents on inventions originating from our ongoing research and development (or "R&D") activities. 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. 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 as determined by the patent office or courts in the country, and the availability of legal remedies in the country. 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. Significant legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside of the U.S. 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 legal proceedings relating to the scope of protection and validity of our patents and those of others. These 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 that the patents we obtain or the unpatented proprietary technology we hold will afford us significant commercial protection.

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. In conjunction with these licenses, disputes sometimes arise regarding whether royalties are

owed on certain product sales or the amount of royalties that are owed. The resolution of such disputes may cause us to incur significant additional royalty expenses or other expenses.

Our trademarks, Activase, Avastin, Cathflo, Herceptin, Lucentis, Nutropin, 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 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 \$1,354 million in 2006, \$935 million in 2005, and \$641 million in 2004. Royalty expenses were \$568 million in 2006, \$462 million in 2005, and \$355 million in 2004.

## Competition

We face competition from pharmaceutical companies and biotechnology companies. The introduction of new competitive products or follow-on biologics or new information about existing products or pricing decisions by us or our competitors may result in lost market share for us, reduced utilization of our products, and/or lower prices, even for products protected by patents. For risks associated with competition, see "We face competition" under "Risk Factors" below in Part I, Item 1A of this Form 10-K.

## **Government Regulation**

Regulation by governmental authorities in the U.S. 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. 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.

The activities required before a pharmaceutical product may be marketed in the U.S. 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, 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 Biologics License Application (or "BLA"), for approval to commence commercial sales. In responding to an 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. Most R&D projects fail to produce data sufficiently compelling to enable progression through all the stages of development and to obtain FDA approval for commercial sale. See also "The successful development of biotherapeutics is highly uncertain and requires significant expenditures

and time" under "Risk Factors."

Among the conditions for an 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.

The requirements that we and our collaborators 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 levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third-party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the U.S. there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control.

In addition, in the U.S. 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"), revised the Medicare reimbursement rate for many drugs, including our oncology products, which resulted in a decrease in the revised reimbursement rate of several of our products and which was possibly offset to some extent by increased physician payment rates for drug administration services related to certain of our oncology products. To date, we have not seen any detectable effects of the new rules on our product sales, and we anticipate minimal effects on our revenues in 2007. See also "Decreases in third party reimbursement rates may affect our product sales, results of operations and financial condition" under "Risk Factors."

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. For risks associated with health care fraud and abuse, see "If there is an adverse outcome in our pending litigation or other legal actions our business may be harmed" under "Risk Factors."

#### **Research and Development**

A significant portion of our operating expenses is related to R&D. Generally, R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. R&D expenses were \$1,773 million in 2006, \$1,262 million in 2005, and \$948 million in 2004. 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 U.S. As discussed above, clinical development typically involves three phases of study: Phase I, II, and III. 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. Product completion dates and completion costs vary significantly by product and are difficult to predict.

#### **Human Resources**

As of December 31, 2006, we had 10,533 employees.

#### **Environment**

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 operations, or competitive position.

#### **Available Information**

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

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;
- our policies related to corporate governance, including Genentech's 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 charters of the Audit Committee and the Compensation Committee of our Board of Directors.

## Item RISK FACTORS

1A.

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 we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, royalties, contract revenues, expenses, net income and earnings per share.

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

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

- Preclinical tests may show the product to be toxic or lack efficacy in animal models.
- ·Clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects.
- ·Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, extended length of time to achieve study endpoints, additional time requirements for data analysis or Biologic Licensing Application (or "BLA") preparation, discussions with the U.S. Food and Drug Administration (or "FDA"), FDA requests for additional preclinical or clinical data, analyses or changes to study design, or unexpected safety, efficacy or manufacturing issues.
- · Difficulties formulating the product, scaling the manufacturing process or in getting approval for manufacturing.

- · Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- •The proprietary rights of others and their competing products and technologies that may prevent the product from being developed or commercialized.
- •The contractual rights of our collaborators or others that may prevent the product from being developed or commercialized.

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

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

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

Future levels of revenue.

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

We are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA's requirements covering R&D, testing, manufacturing, quality control, labeling and promotion of drugs for human use. A biotherapeutic cannot be marketed in the United States (or "U.S.") until it has been approved by the FDA, and then can only be marketed for the indications

approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a BLA or NDA, are substantial and can require a number of years. In addition, even if our products receive regulatory approval, they remain subject to ongoing FDA

regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and/or a product recall or withdrawal.

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

- ·Significant delays in obtaining or failing to obtain approvals as described in "The successful development of biotherapeutics is highly uncertain and requires significant expenditures and time" above.
- ·Loss of, or changes to, previously obtained approvals, including those resulting from post-approval safety or efficacy issues.
  - Failure to comply with existing or future regulatory requirements.
- ·Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices (or "GMP") following approval or changing interpretations of these factors.

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

#### We face competition

We face competition from pharmaceutical companies and biotechnology companies.

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

Avastin: Avastin competes with Erbitux® (Imclone/Bristol-Myers Squibb), which is an EGFR-inhibitor approved for the treatment of irinotecan refractory or intolerant metastatic colorectal cancer (or "CRC") patients, Nexavar® (sorafenib Bayer Corporation/Onyx Pharmaceuticals, Inc.) for the treatment of patients with advanced renal cell carcinoma (or "RCC") or kidney cancer (an unapproved use of Avastin), Sutent® (sunitinib malate, Pfizer, Inc.) for use in advanced RCC (an unapproved use of Avastin), Gleevec® (imatinib mesylate, Novartis) for use in refractory/intolerant gastrointestinal stromal tumor (an unapproved use of Avastin), and Vectibix™ (panitumumab, Amgen), for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. Avastin could face competition from products in development that currently do not have regulatory approval. Amgen has stated that it will initiate head-to-head clinical trials comparing AMG 706 and Avastin. There are also head-to-head clinical trials that have recently begun comparing both Sutent and AZD2171 (AstraZeneca) to Avastin. Additionally, there are more than 65 molecules that target VEGF inhibition, and over 130 companies that are developing molecules that, if approved, may compete with Avastin.

*Rituxan:* Rituxan's primary competitor is Bexxar® (GlaxoSmithKline (or "GSK")) which is radioimmunotherapy indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma (or "NHL"). Other potential competitors include Campath® in relapsed CLL (an unapproved use of Rituxan), Velcade® (Millennium Pharmaceuticals, Inc.) which is indicated for multiple myeloma and more recently, mantle cell lymphoma (both unapproved uses of Rituxan). Ofatumumab (Humax CD20<sup>TM</sup>), an anti-CD20

antibody being co-developed by Genmab and GSK is in late-stage development for refractory CLL and NHL. In addition to the products detailed above, we are aware of other anti-CD20 molecules in development that, if successful in clinical trials, may compete with Rituxan.

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

Herceptin: Herceptin could face competition in the future from experimental drugs and products in development that do not currently have regulatory approval for use outside of clinical trials, including lapatinib ditosylate (Tykerb®), a tyrosine kinase inhibitor being developed by GSK. On April 3, 2006, GSK announced that it stopped enrollment in its Phase III clinical trial to evaluate lapatinib ditosylate because of positive results in treating HER2-positive metastatic breast cancer in women whose disease had progressed following a Herceptin-containing regimen and other cancer therapies. Results from this trial showed that lapatinib ditosylate in combination with capecitabine increased time to disease progression compared to capecitabine alone. GSK filed for regulatory approval of lapatinib ditosylate in the third quarter of 2006 and was granted priority review with approval expected in the first quarter of 2007.

Lucentis: We are aware that retinal specialists are currently using Avastin to treat the wet form of age-related macular degeneration, an unapproved use for Avastin, which results in significantly less revenue to us per treatment as compared to Lucentis. We expect Avastin use to continue in this setting. Additionally, the National Eye Institute and National Institute of Health have announced a head-to-head trial of Avastin and Lucentis in this setting. Lucentis also competes with Macugen® (Pfizer/OSI Pharmaceuticals), and Visudyne® (Novartis) alone, or in combination with the off-label steroid triamcinolone in wet AMD.

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

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

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

Thrombolytics: We face competition in our acute myocardial infarction market, with sales of TNKase and Activase affected by the adoption by physicians of mechanical reperfusion strategies. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. TNKase, for acute myocardial infarction, also faces competition from Retavase® (PDL BioPharma Inc.), which engages in competitive price discounting.

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

Raptiva: Raptiva competes with established therapies for moderate-to-severe psoriasis including oral systemics such as methotrexate and cyclosporin, as well as ultraviolet light therapies. In addition, Raptiva competes with biologic agents Amevive® (Astellas), Enbrel® (Amgen), and Remicade® (Centocor, Inc.). Raptiva also competes with the biologic agent Humira® (Abbott Laboratories), which is currently used off-label in the psoriasis market.

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

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

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

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

Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated for this purpose. It can take longer than five years to design, construct, validate, and license a new biotechnology manufacturing facility. We currently produce our products at our manufacturing facilities located in South San Francisco, California and Vacaville, California and through various contract-manufacturing arrangements. Maintaining an adequate supply to meet demand for our products depends on our ability to execute on an aggressive production plan. Any significant problem 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, a shortfall or stock-out or recall of available product inventory, or unplanned increases in production costs, any of which could have a material adverse effect on our business. A number of factors could cause significant production problems or interruptions, including:

the inability of a supplier to provide raw materials used for manufacture of our products;

· equipment obsolescence, malfunctions or failures;

product quality or contamination problems;

- ·damage to a facility, including our warehouses and distribution facilities, due to natural disasters, including, but not limited to, earthquakes as our South San Francisco, Oceanside and Vacaville facilities are located in areas where earthquakes occur;
- · changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes;
- •action by the FDA or by us that results in the halting or slowdown of production of one or more of our products or products we make for others;

· a contract manufacturer going out of business or failing to produce product as contractually required;

failure to maintain an adequate state of GMP compliance; and

•successful implementation and integration of our new enterprise resource planning system, including the portions relating to manufacturing and distribution.

In addition, there are inherent uncertainties associated with forecasting future demand, especially for newly introduced products of ours or of those for whom we produce products, and as a consequence we may have inadequate capacity to meet our own actual demands and/or the actual demands of those for whom we produce product. Increasing our manufacturing capacity to keep pace with growing demand will depend, in part, on our ability to successfully implement key capacity enhancement projects, including the following: (i) licensure of 90,000 liters of capacity at our Oceanside, California manufacturing facility during the first half of 2007 to produce Avastin, and (ii) completion of construction, qualification and licensure of our new plant in Vacaville, California in 2009.

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

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

## 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 Cabilly reexaminations discussed in Note 8, "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, or to a loss of our entire investment in the product and subject us to infringement claims.

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

Litigation or other legal actions to which we are currently or have been subjected relates to, among other things, our patent and other intellectual property rights, licensing arrangements and other contracts with third parties, and product liability. We cannot predict with certainty the eventual outcome of pending proceedings, which may include an

injunction against the development, manufacture or sale of a product or potential product or a judgment with significant monetary award, including the possibility of punitive damages, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in these proceedings and such matters could divert management's attention from ongoing business concerns.

Our activities relating to the sale and marketing of our products are subject to regulation under the U.S. Federal Food, Drug and Cosmetic Act and other federal statutes. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). In 1999 we agreed to pay \$50 million to settle a federal investigation relating to our past clinical, sales and marketing activities associated with human growth hormone. We are currently being investigated by the Department of Justice with respect to our promotional practices, and may in the future be investigated for our promotional practices relating to any of our products. If the government were to bring charges against or convict us of violating these laws, or if we were subject to third party litigation relating to the same promotional practices, there could be a material adverse effect on our business, including our financial condition and results of operations.

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

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

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

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

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, (ii) successfully integrate large numbers of new employees into our corporate culture, and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships or that the costs of retaining such personnel or maintaining such relationships will not materially increase.

## Other factors could affect our product sales

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

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

- •Our pricing decisions, including a decision to increase or decrease the price of a product, the pricing decisions of our competitors, as well as our Avastin Patient Assistance Program, which is a voluntary program that enables eligible patients who receive greater than 10,000 milligrams of Avastin over a 12-month period to receive free Avastin during the remainder of the 12-month period. Eligible patients include those who are being treated for an FDA-approved indication.
- ·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 conducted either in the U.S. or internationally by any party could cause the sales of our products to decrease or a product to be recalled or withdrawn.
- ·Negative safety or efficacy data from post-approval marketing experience or production quality problems could cause sales of our products to decrease or a product to be recalled.
- •Efficacy data from clinical studies conducted by any party in the U.S. or internationally, showing or perceived to show, a similar or an improved treatment benefit at a lower dose or shorter duration of therapy could cause the sales of our products to decrease.
- •The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- •The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.
  - The increasing use and development of alternate therapies.
  - The rate of market penetration by competing products.
- ·Our distribution strategy, including the termination of, or change in, an existing arrangement with any major wholesalers who supply our products.

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

#### Our results of operations are affected by our royalty and contract revenues, and sales to collaborators

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

- ·Hoffmann-La Roche's decisions whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
  - Variations in Hoffmann-La Roche's sales and other licensees' sales of licensed products.
- •The expiration or termination of existing arrangements with other companies and Hoffmann-La Roche, which may include development and marketing arrangements for our products in the U.S., Europe and other countries outside the U.S.
- · The timing of non-U.S. approvals, if any, for products licensed to Hoffmann-La Roche and to other licensees.

- ·Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
  - · Fluctuations in foreign currency exchange rates.
  - The initiation of new contractual arrangements with other companies.
    - Whether and when contract milestones are achieved.
    - The failure of or refusal of a licensee to pay royalties.
- •The expiration or invalidation of our patents or licensed intellectual property. For example, patent litigations, interferences, oppositions, and other proceedings involving our patents often include claims by third-parties that such patents are invalid, unenforceable, or unpatentable. If a court, patent office, or other authority were to determine that a patent under which we receive royalties and/or other revenues is invalid, unenforceable, or unpatentable, that determination could cause us to suffer a loss of such royalties and/or revenues, and could cause us to incur other monetary damages.
- ·Decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect the sales of product.

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

Our affiliation agreement with Roche provides that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For more information on our stock repurchase program, see discussion in "Liquidity and Capital Resources—Cash Used in or Provided by Financing Activities." See Note 9, "Relationship with Roche and Related Party Transactions," in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for information regarding the Minimum Percentage.

Roche's ownership percentage is diluted by the exercise of stock options to purchase shares of our Common Stock by our employees and the purchase of shares of our Common Stock through our employee stock purchase plan. In order to maintain Roche's Minimum Percentage, we repurchase shares of our Common Stock under the stock repurchase program. See Note 3, "Employee Stock-Based Compensation," in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for information regarding employee stock plans. While the dollar amounts associated with future stock repurchase programs cannot currently be determined, future stock repurchases could have a material adverse effect on our liquidity, credit rating and ability to access additional capital in the financial markets.

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

The affiliation agreement between us and Roche contains provisions that:

- •Require the approval of the directors designated by Roche to make any acquisition or any sale or disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues.
  - Enable Roche to maintain its percentage ownership interest in our Common Stock.
- ·Require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our Common Stock based on an established Minimum Percentage. For information regarding Minimum Percentage,

see Note 9, "Relationship with Roche and Related Party Transactions," 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.

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

As of December 31, 2006, Roche owned 587,189,380 shares of our Common Stock, or 55.8% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our Common Stock. Sales of a substantial number of shares of our Common Stock by Roche in the public market could adversely affect the market price of our Common Stock.

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

Roche, as our majority stockholder, controls the outcome of most actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our board of directors shall consist of at least three directors designated by Roche, three independent directors nominated by the nomination committee and one Genentech executive officer nominated by the nominations committee. Our bylaws also provide that Roche will have the right to obtain proportional representation on our board until such time that Roche owns less than 5% of our stock. Currently, three of our directors, Mr. William Burns, Dr. Erich Hunziker and Dr. Jonathan K.C. Knowles, also serve as officers and employees of Roche Holding Ltd and its affiliates. As long as Roche owns in excess of 50% of our Common Stock, Roche directors will comprise two of the three members of the nominations committee. Our certificate of incorporation includes provisions relating to competition by Roche affiliates with us, offering of corporate opportunities, transactions with interested parties, intercompany agreements, and provisions limiting the liability of specified employees. We cannot assure that Roche will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, persons who are directors and/or officers of Genentech and who are also directors and/or officers of Roche may decline to take action in a manner that might be favorable to us but adverse to Roche.

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

#### We may incur material product liability costs

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

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

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

# We are subject to environmental and other risks

We use certain hazardous materials in connection with our research and manufacturing activities. In the event such hazardous materials are stored, handled or released into the environment in violation of law or any permit, we could

be subject to loss of our permits, government fines or penalties and/or other adverse governmental or private actions. The levy of a substantial fine or penalty, the payment of significant environmental remediation costs or the loss of a permit or other authorization to operate or engage in our ordinary course of business could materially adversely affect our business.

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

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

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

- The overall competitive environment for our products as described in "We face competition" above.
- •The amount and timing of sales to customers in the U.S. For example, sales of a product may increase or decrease due to pricing changes, fluctuations in distributor buying patterns or sales initiatives that we may undertake from time to time.
- •The amount and timing of our sales to Hoffmann-La Roche and our other collaborators of products for sale outside of the U.S. and the amount and timing of sales to their respective customers, which directly affects both our product sales and royalty revenues.
  - The timing and volume of bulk shipments to licensees.
  - The availability and extent of government and private third-party reimbursements for the cost of therapy.
    - The extent of product discounts extended to customers.
- ·The efficacy and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after the FDA approves it for sale.
- •The rate of adoption by physicians and use of our products for approved indications and additional indications. Among other things, the rate of adoption by physicians and use of our products may be affected by results of clinical studies reporting on the benefits or risks of a product.
  - The potential introduction of new products and additional indications for existing products.
  - The ability to successfully manufacture sufficient quantities of any particular marketed product.
- ·Pricing decisions that we or our competitors have adopted or may adopt, as well as our Avastin Patient Assistance Program.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors. As part of our Enterprise Resource Planning efforts, we are implementing new information systems, but we may not be successful in implementing all of the new systems, and transitioning data and other aspects of the

process could be expensive, time consuming, disruptive and resource intensive. Any disruptions that may occur in the implementation of new systems or any future systems could adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows. Disruptions to these systems also could adversely affect our ability to fulfill orders and interrupt other operational processes. Delayed sales, lower margins or lost customers resulting from these disruptions could adversely affect our financial results.

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

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

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

- · Announcements of technological innovations or new commercial products by us or our competitors.
- ·Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors.
- ·Concerns about the pricing of our products, or our pricing initiatives (including our Avastin Patient Assistance Program), and the potential effect of such on their utilization or our product sales.
  - Developments or outcome of litigation, including litigation regarding proprietary and patent rights.
  - Regulatory developments or delays concerning our products in the U.S. and foreign countries.
    - · Issues concerning the safety of our products or of biotechnology products generally.
      - Economic and other external factors or a disaster or crisis.
        - Period to period fluctuations in our financial results.

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

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

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

As of December 31, 2006, we had approximately \$2.0 billion of long-term debt. Our ability to make payments on and to refinance our indebtedness, including our long-term debt obligations, and to fund planned capital expenditures, R&D, as well as stock repurchases and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are and will remain beyond our control. Additionally, our indebtedness may increase our vulnerability to general adverse economic and industry conditions, require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, R&D, expansion efforts and other general corporate purposes, and limit our flexibility in

planning for, or reacting to, changes in our business and the industry in which we operate.

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

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

In June 2006, the FASB issued FASB Interpretation (or "FIN") No. 48, "Accounting for Uncertainty in Income Taxes." FIN 48 clarifies the application of FASB Statement 109, "Accounting for Income Taxes," by defining criteria that must be met for any part of a benefit related to an individual tax position to be recognized in the financial statements. FIN 48 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition and is effective for us beginning January 1, 2007. We are currently evaluating the effect that the adoption of FIN 48 will have on our consolidated results of operations and financial position, but we do not expect the effect to be material.

# Item UNRESOLVED STAFF COMMENTS 1B.

None.

#### **Item 2. PROPERTIES**

Our headquarters facilities are located in a research and industrial area in South San Francisco, California where we currently occupy 30 owned and 8 leased buildings which house our research and development, marketing and administrative activities, as well as bulk manufacturing facilities, a fill and finish facility and a warehouse. We have made and will continue to make improvements to these properties to accommodate our growth. We also have a commitment to lease an additional eight buildings in South San Francisco, California. We occupied one of these buildings in 2006, and we will occupy additional buildings beginning in 2007. In addition, we own other properties in South San Francisco for future expansion.

We own a manufacturing facility in Vacaville, California, which is licensed to produce commercial quantities of select 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. We expect completion of construction, qualification and licensure of our new Vacaville plant by the end of 2009.

In June 2005, we acquired a biologics manufacturing facility in Oceanside, California. In 2006 we began manufacturing Avastin bulk product at the plant and we anticipate FDA licensure in the first half of 2007.

In September 2006, we acquired land in Hillsboro, Oregon for the construction of a new fill, finish, warehousing and related office facility. Construction is expected to begin in 2007 with completion and FDA licensure in early 2010.

In December 2006, Lonza acquired the warehouse and cell culture manufacturing facility that we owned in Porriño, Spain and at which Lonza will continue to manufacture Avastin for us through December 31, 2009. We also have an

agreement under which we can elect to purchase Lonza's manufacturing facility currently under construction in Singapore. Such facility is expected to be licensed for the production of Avastin in 2010.

We also lease additional office facilities as regional offices for sales and marketing and other functions 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 U.S. Department of Justice, requesting documents related to the promotion of Rituxan, a prescription treatment now approved for five indications: (1) the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma, (2) the first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens (approved on February 10, 2006), (3) the first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with cyclophosphamide, vincristine, prednisone (or "CVP") chemotherapy (approved September 29, 2006), (4) the treatment of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy (approved on September 29, 2006), and (5) for use in combination with methotrexate to reduce signs and symptoms in adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies (approved on February 28, 2006). We are cooperating with the associated investigation, which we have been advised is both civil and criminal in nature. The government has called and will likely continue to call former and current Genentech employees to appear before a grand jury in connection with this investigation. The outcome of this matter cannot be determined at this time.

On July 29, 2005, a former Genentech employee, whose employment ended in April 2005, filed a qui tam complaint under seal in the United States District Court for the District of Maine against Genentech and Biogen Idec, alleging violations of the False Claims Act and retaliatory discharge of employment. On December 20, 2005, the United States filed notice of its election to decline intervention in the lawsuit. The complaint was subsequently unsealed and we were served on January 5, 2006. Genentech filed a motion to dismiss the complaint and on December 14, 2006, the Magistrate Judge assigned to the case issued a Recommended Decision on that motion, which is subject to review by the District Court Judge. The Magistrate Judge recommended that the False Claims Act portion of the complaint be dismissed, leaving as the only remaining claim against Genentech the plaintiff's retaliatory discharge claim. Plaintiff, Biogen Idec, and Genentech each subsequently filed objections with the District Court Judge concerning certain aspects of the Magistrate Judge's Recommended Decision. We are awaiting the District Court's decision on the Recommended Decision and the objections. The outcome of this matter cannot be determined at this time.

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

Appeal. On October 21, 2004, the California Court of Appeal affirmed the verdict and damages awards in all respects. On November 22, 2004, the California Court of Appeal modified its opinion without changing the verdict and denied Genentech's request for rehearing. On November 24, 2004, we filed a petition seeking review by the California Supreme Court. On February 2, 2005, the California Supreme Court granted that petition. The appeal to the California Supreme Court has been fully briefed and we are waiting to be

assigned an oral argument date. The amount of cash paid, if any, or the timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter, however, it may take longer than one year to resolve the matter.

We recorded accrued interest and bond costs of \$54 million in 2006 and 2005 related to the COH trial judgment. In conjunction with the COH judgment, we posted a surety bond and were required to pledge cash and investments of \$735 million at December 31, 2005 to secure the bond. During the third quarter of 2006, COH requested that we increase the surety bond value by \$50 million to secure the accruing interest, and we correspondingly increased the pledge amount to secure the bond by \$53 million to \$788 million. These amounts are reflected in "restricted cash and investments" in the accompanying Consolidated Balance Sheets. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results.

On April 11, 2003, MedImmune, Inc. (or "MedImmune") filed a lawsuit against Genentech, COH, and Celltech R & D Ltd. in the U.S. District Court for the Central District of California (Los Angeles). The lawsuit relates to U.S. Patent No. 6,331,415 (or "the '415 patent" or "Cabilly patent") that we co-own with COH and under which MedImmune and other companies have been licensed and are paying royalties to us. The lawsuit includes claims for violation of antitrust, patent, and unfair competition laws. MedImmune is seeking a ruling that the '415 patent is invalid and/or unenforceable, a determination that MedImmune does not owe royalties under the '415 patent on sales of its Synagis® antibody product, an injunction to prevent us from enforcing the '415 patent, an award of actual and exemplary damages, and other relief. On January 14, 2004 (amending a December 23, 2003 Order), the U.S. District Court granted summary judgment in our favor on all of MedImmune's antitrust and unfair competition claims. On April 23, 2004, the District Court granted our motion to dismiss all remaining claims in the case. On October 18, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the District Court in all respects. MedImmune filed a petition for certiorari with the United States Supreme Court on November 10, 2005, seeking review of the decision to dismiss certain of its claims. The Supreme Court granted MedImmune's petition and the oral argument of this case before the Supreme Court occurred on October 4, 2006. On January 9, 2007, the Supreme Court issued a decision reversing the Federal Circuit's decision and remanding the case to the lower courts for further proceedings in connection with the patent and contract claims. The outcome of this matter cannot be determined at this time.

On May 13, 2005, a request was filed by a third party for reexamination of the '415 or Cabilly patent. The request sought reexamination on the basis of non-statutory double patenting over U.S. Patent No. 4,816,567. On July 7, 2005, the U.S. Patent Office ordered reexamination of the '415 patent. On September 13, 2005, the Patent Office mailed an initial non-final Office action rejecting the claims of the '415 patent. We filed our response to the Office action on November 25, 2005. On December 23, 2005, a second request for reexamination of the '415 patent was filed by another third party, and on January 23, 2006, the Patent Office granted that request. On June 6, 2006, the two reexaminations were merged into one proceeding. On August 16, 2006, the Patent Office mailed a non-final Office action in the merged proceeding, rejecting the claims of the '415 patent based on issues raised in the two reexamination requests. We filed our response to the Office action on October 30, 2006. On February 16, 2007, the Patent Office mailed a final Office action rejecting all thirty-six claims of the '415 patent. We intend to respond to the final Office action, and, if necessary, appeal the decision. The '415 patent, which expires in 2018, relates to methods we and others use to make certain antibodies or antibody fragments, as well as cells and DNA used in these methods. We have licensed the '415 patent to other companies and derive significant royalties from those licenses. The claims of the '415 patent remain valid and enforceable throughout the reexamination and appeals process. Because the above-described proceeding is ongoing, the outcome of this matter cannot be determined at this time.

In 2006, we made development decisions involving our humanized anti-CD20 program. Our collaborator, Biogen Idec, disagrees with certain of our development decisions under our 2003 collaboration agreement with Biogen Idec relating to humanized anti-CD20 products. We believe that we are permitted under the agreement to proceed with

further trials of certain humanized anti-CD20 antibodies, and Biogen Idec disagrees with our position. We continue to pursue a resolution of our differences, and the disputed issues have been submitted to arbitration. In the arbitration, Biogen Idec has filed motions for a preliminary injunction and summary judgment seeking to stop us from proceeding with certain development activities, including planned clinical trials. A hearing on the motion for a

preliminary injunction was held on January 30, 2007 and we are waiting on a decision by the arbitrators on that motion. Briefing relating to the motion for summary judgment is ongoing. Resolution of the arbitration could require that both parties agree to certain development decisions before moving forward with humanized anti-CD20 antibody clinical trials, in which case we may have to alter or cancel planned trials in order to obtain Biogen Idec's approval. The outcome of this matter cannot be determined at this time.

On March 24, 2004, Dr. Kourosh Dastgheib filed a lawsuit against Genentech in the U.S. District Court for the Eastern District of Pennsylvania. The lawsuit stems from Dastgheib's claim that, based on a purported relationship with Genentech in the mid-1990's, he is entitled to profits or proceeds from Genentech's Lucentis product. Dastgheib has asserted multiple claims for monetary damages, including a claim under an unjust enrichment theory that he is entitled to the entire net present value of projected Lucentis sales, which he claims is between approximately \$1.4 billion and \$4.1 billion. On November 8, 2006, a unanimous jury ruled against Dastgheib and in favor of Genentech on all claims, and final judgment was entered in Genentech's favor. On January 30, 2007, Dastgheib's motion for a new trial was denied in its entirety. Because Dastgheib may still seek to appeal the judgment to the court of appeals, the final outcome of this matter cannot be determined at this time.

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

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

The executive officers of the Company and their respective ages (as of December 31, 2006) and positions with the Company are as follows:

Name Arthur D. Levinson, Ph.D.*	<b>Age</b> 56	<b>Position</b> Chairman and Chief Executive Officer
Susan D. Desmond-Hellmann, M.D., M.P.H.*	49	President, Product Development
Ian T. Clark*	46	Executive Vice President, Commercial Operations
David A. Ebersman*	37	Executive Vice President and Chief Financial Officer
Stephen G. Juelsgaard, D.V.M., J.D.*	58	Executive Vice President, Secretary and Chief Compliance Officer
Richard H. Scheller, Ph.D.*	53	Executive Vice President, Research
Patrick Y. Yang, Ph.D.*	58	Executive Vice President, Product Operations
Robert L. Garnick, Ph.D.	57	Senior Vice President, Regulatory, Quality and Compliance
John M. Whiting	51	Vice President, Finance and Chief Accounting Officer

<sup>\*</sup> Members of the Executive Committee of the Company.

The Board of Directors appoints all executive 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, Inc. in September 1999 and was elected its 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 the 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, Senior Vice President of Research and Development in March 1993 and President in July 1995. Dr. Levinson also serves as a member of the Board of Directors of Apple Computer, Inc. and Google, Inc.

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.

*Ian T. Clark* was appointed Executive Vice President, Commercial Operations of Genentech in December 2005. He previously served as Senior Vice President, Commercial Operations of Genentech from August 2005 to December 2005 and joined Genentech as Senior Vice President and General Manager, BioOncology and served in that role from January 2003 through August 2005. Prior to joining Genentech, he served as president for Novartis Canada from 2001 to 2003. Before assuming his post in Canada, he served as chief operating officer for Novartis United Kingdom from 1999 to 2001.

David A. Ebersman was appointed Executive Vice President of Genentech in December 2005 and Chief Financial Officer in March 2005. Previously, he served as Senior Vice President, Finance from January 2005 through March 2005 and 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.

Stephen G. Juelsgaard, D.V.M., J.D. was appointed Chief Compliance Officer of Genentech in June 2005, Executive Vice President in September 2002, 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, Senior Vice President from April 1998 to September 2002, and General Counsel from July 1994 to January 2007.

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.

Patrick Y. Yang, Ph.D. was appointed Executive Vice President, Product Operations of Genentech in December 2005. Previously, he served as Senior Vice President, Product Operations from January 2005 through December 2005 and Vice President, South San Francisco Manufacturing and Engineering from December 2003 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.

*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.

John M. Whiting was appointed Vice President, Finance of Genentech in June 2006, and Chief Accounting Officer in October 1997. He served as Controller from October 1997 to June 2006 and as Vice President from January 2001 to June 2006. He previously served in a variety of financial positions at Genentech from 1989 to 1997. Prior to joining Genentech, he served as Senior Audit Manager at Arthur Young.

#### **PART II**

# Item 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

See "Liquidity and Capital Resources — Cash Used in or Provided by Financing Activities" in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of Part II, Item 7 of this Form 10-K, Note 1, "Description of Business — Redemption of Our Special Common Stock," Note 9, "Relationship with Roche and Related Party Transactions," and Note 10, "Capital Stock," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

#### **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 near future.

#### **Common Stockholders**

As of December 31, 2006, there were approximately 2,612 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									
	20			2005						
	High		Low		High	Low				
4th Quarter	\$ 86.93	\$	79.65	\$	100.20	\$	79.87			
3rd Quarter	86.65		76.80		94.99		79.71			
2nd Quarter	84.72		75.58		84.10		54.68			
1st Quarter	95.16		81.15		59.00		43.90			

#### **Stock Repurchases**

See "Liquidity and Capital Resources — Cash Used in or Provided by Financing Activities" in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of Part II, Item 7 of this Form 10-K for information on our stock repurchases.

#### **Performance Graph**

We show below the cumulative total return to our stockholders during the period from December 31, 2001 through December 31, 2006 in comparison to the cumulative return on the Standard & Poor's 500 Index, the Standard & Poor's 500 Pharmaceuticals Index and the Standard & Poor's 500 Biotechnology Index during that same period. The results assume that \$100 was invested on December 31, 2001.

	Base									
	Period				Yea	ers Ending				
	<b>December December</b>		December		December		December		December	
Company / Index	2001	2002		2003		2004		2005		2006
GENENTECH, INC	100 \$	61.12	\$	172.48	\$	200.70	\$	341.01	\$	299.10
S&P 500 INDEX	100	77.90		100.25		111.15		116.61		135.03
S&P 500										
PHARMACEUTICALS	100	79.96		86.98		80.51		77.81		90.14
S&P BIOTECHNOLOGY	100	79.59		102.55		110.35		130.52		126.94

(1)

The total return on investment (change in year end stock price plus reinvested dividends) assumes \$100 invested on December 31, 2001 in our common stock, the Standard & Poor's 500 Index, the Standard & Poor's 500 Pharmaceuticals Index and the Standard & Poor's 500 Biotechnology Index. The Standard & Poor's 500 Pharmaceuticals Index was comprised at December 31, 2006 of Abbott Laboratories, Allergan, Inc., Barr Pharmaceuticals Inc., Bristol-Myers Squibb Company, Forest Laboratories, Inc., Johnson & Johnson, King Pharmaceuticals, Inc., Merck & Co., Inc., Mylan Laboratories Inc., Lilly (Eli) and Company, Pfizer Inc., Schering-Plough Corporation, Watson Pharmaceuticals, Inc. and Wyeth. The Standard & Poor's 500 Biotechnology Index was comprised at December 31, 2006 of Amgen Inc., Biogen Idec Inc., Genzyme Corporation, Gilead Sciences, Inc. and MedImmune, Inc.

The information under "Performance Graph" is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of Genentech under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this 10-K and irrespective of any general incorporation language in those filings.

#### Item 6. SELECTED FINANCIAL DATA

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" and Item 1A, "Risk Factors" of this Form 10-K and the consolidated financial statements and related notes thereto included in Item 8 of this Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

#### SELECTED CONSOLIDATED FINANCIAL DATA

(in millions, except per share amounts)

	2006		2005		2004		2003		2002
Total operating revenues	\$ 9,284	\$	6,633	\$	4,621	\$	3,300	\$	2,584
Product sales	7,640		5,488		3,749		2,621		2,164
Royalties	1,354		935		641		501		366
Contract revenue	290		210		231		178		54
Income before cumulative effect of									
accounting changes	\$ 2,113	\$	1,279	\$	785	\$	610	\$	64
Cumulative effect of accounting							$(47)^{(3)}$	)	
changes, net of tax	-		-		-				-
Net income	\$ 2,113 (1)	\$	1,279	\$	785	\$	563 (3	\$	64 (4)
Basic earnings per share	\$ 2.01	\$	1.21	\$	0.74	\$	0.54	\$	0.06
Diluted earnings per share	1.97		1.18		0.73		0.53		0.06
Total assets	\$ 14,842	\$	12,147	\$	9,403 (2	2) \$	8,759 (2	\$	6,776
Long-term debt	2,204 (2)	)	2,083 (2	2)	412 (2	2)	412 (2	)	_
Stockholders' equity	9,478		7,470		6,782		6,520		5,339

We have paid no dividends.

- (1) Net income in 2006 includes employee stock-based compensation costs of \$182 million, net of tax, due to our adoption of FAS 123R on a modified prospective basis on January 1, 2006. No employee stock-based compensation expense was recognized in reported amounts in any period prior to January 1, 2006.
- (2) Long-term debt in 2006 and 2005 includes \$1.99 billion related to our debt issuance in July 2005, and includes \$216 million in 2006 and \$94 million in 2005 in construction financing obligations related to our agreements with Slough and Lonza. Long-term debt in 2005 also reflects the repayment of \$425 million to extinguish the consolidated debt and noncontrolling interest of a synthetic lease obligation related to our manufacturing facility located in Vacaville, California. Upon adoption of the Financial Accounting Standards Board Interpretation No. 46 (or "FIN 46"), "Consolidation of Variable Interest Entities," in 2003, we consolidated the entity from which we lease our manufacturing facility located in Vacaville, California. Accordingly, we included in property, plant and equipment assets with net book values of \$326 million at December 31, 2004 and

All per share amounts reflect the two-for-one stock split that was effected in 2004. Certain prior year amounts have been reclassified to conform to the current year presentation.

- \$348 million at December 31, 2003. We also consolidated the entity's debt of \$412 million and noncontrolling interest of \$13 million, which amounts are included in long-term debt and litigation-related and other long-term liabilities, respectively, at December 31, 2004 and 2003.
- (3) Net income in 2003 includes the receipt of \$113 million in pre-tax litigation settlements with Amgen Inc. and Bayer Inc. Net income in 2003 also reflects our adoption of FIN 46 on July 1, 2003, which resulted in a \$47 million charge, net of \$32 million in taxes, (or \$0.05 per share) as a cumulative effect of an accounting change in 2003.
- (4) Net income in 2002 includes \$544 million of pre-tax litigation-related special charges, which are comprised of the COH litigation judgment in 2002, and accrued interest and bond costs, and certain other litigation-related matters.

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

#### Overview

#### The Company

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

#### Major Developments in 2006

We primarily earn revenues and income and generate cash from product sales and royalty revenues. Our total operating revenues in 2006 were \$9.28 billion, an increase of 40% from \$6.63 billion in 2005. Product sales in 2006 were \$7.64 billion, an increase of 39% from \$5.49 billion in 2005. Product sales represented 82% of our operating revenues in 2006 and 83% in 2005. Royalty revenues were \$1.35 billion in 2006, an increase of 45% from \$935 million in 2005. Royalty revenues represented 15% of our operating revenues in 2006 and 14% in 2005. Our net income in 2006 was \$2.11 billion, an increase of 65% from \$1.28 billion in 2005. Net income in 2006 includes the effect of employee stock-based compensation expense related to employee stock options and employee stock purchases under Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" (or "FAS 123R"), which decreased our net income by \$182 million after taxes in 2006.

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

- Lucentis for the treatment of neovascular (wet) age-related macular degeneration (or "AMD");
- · Avastin in combination with intravenous 5-fluorouracil (or "5-FU")-based chemotherapy for second-line metastatic colorectal cancer;
- · Avastin for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer (or "NSCLC");
- ·Rituxan for the treatment of patients with active rheumatoid arthritis (or "RA") who have had an inadequate response to tumor necrosis factor antagonist therapy;
- ·Rituxan for use in first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma (or "DLBCL");
- ·Rituxan for the first-line treatment of previously untreated patients with follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine, prednisone) chemotherapy;
- ·Rituxan for the treatment of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy; and
- ·Herceptin for the adjuvant treatment of HER2-positive node-positive breast cancer patients in combination with doxorubicin, cyclophosphamide, and paclitaxel.

In October 2006, we announced our plan to launch the Avastin Patient Assistance Program in the first quarter of 2007, which is a voluntary program that enables eligible patients who receive greater than 10,000 milligrams of Avastin over a 12-month period to receive free Avastin during the remainder of the 12-month period. Based on the current wholesale acquisition cost, the 10,000 milligrams is valued at \$55,000 in gross revenue. Eligible patients include those who are being treated for an FDA-approved indication and who meet the household income criteria for this program. The program will be available for eligible patients who enroll regardless of whether they are insured. Because the program will apply retrospectively to patients currently on Avastin for all approved indications, we deferred approximately \$9 million of our fourth quarter 2006 Avastin product sales to address our estimated free drug commitment to current patients. See "Critical Accounting Policies and the Use of Estimates - Revenue Recognition" below for further discussion.

On November 9, 2006 we and Tanox Inc. announced that we entered into an agreement to acquire Tanox, a biotechnology company specializing in the discovery and development of biotherapeutics based on monoclonal antibody technology, for \$20 per share for a total cash value of approximately \$0.9 billion. We and Tanox have been working together in collaboration with Novartis since 1996 to develop and commercialize Xolair. The terms of the acquisition have been unanimously approved by the Boards of Directors of both companies and approved by the stockholders of Tanox. We received a request for additional information from the U.S. Federal Trade Commission (or "second request") in connection with the proposed acquisition. The second request extends the waiting period imposed by the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (or "Hart-Scott-Rodino Act"). The transaction is expected to be completed within the first half of 2007, subject to satisfaction of certain closing conditions, including the absence of a material adverse effect with respect to Tanox and the expiration or termination of the waiting period under the Hart-Scott-Rodino Act. Funds will be provided from Genentech's cash on hand at the time of closing. We are currently evaluating the effects of the acquisition on our results of operations and financial condition and expect that if the transaction closes a substantial portion of the purchase price will be expensed as in-process research and development (or "R&D").

On December 8, 2006, Lonza Group Ltd. (or "Lonza") purchased all the outstanding shares of Genentech España, our wholly-owned subsidiary, for \$150 million. Under the terms of the agreement, Lonza acquired from us the FDA-licensed Porriño facility, which has 40,000 liters of biologic manufacturing capacity and is currently dedicated to the production of Avastin. Lonza will continue to produce Avastin for us at the Porriño facility for the short-term. At the same time, we entered into a supply agreement with Lonza for the manufacture of certain of our products at Lonza's facility under construction in Singapore, which is currently expected to receive FDA licensure in 2010. We are committed to fund the pre-commissioning production qualification costs at that facility, and, upon FDA licensure, we are committed to purchase 100 percent of products successfully manufactured at that facility for a period of three years after commissioning of the facility. The total estimated cost of these pre- and post-commissioning commitments is approximately \$440 million. We also received an exclusive option to purchase the Lonza Singapore facility during the period from 2007 up to one year after FDA licensure for a purchase price of \$290 million. Regardless of whether the purchase option is exercised, we will be obligated to make a milestone payment of approximately \$70 million if certain performance milestones are met in connection with the construction of the facility.

In the fourth quarter of 2006, we received FDA approvals for yield improvement projects at our manufacturing plants in Vacaville, California related to the production of Rituxan and in South San Francisco, California related to the production of Avastin. In the fourth quarter of 2006, prior to the sale of our Porriño facility to Lonza, we received licensure of an additional 20,000 liters of capacity to manufacture bulk Avastin at that facility. In addition, in the first quarter of 2006, the FDA approved the production of bulk Xolair at Novartis' production facility in Huningue, France and in the third quarter of 2006, the FDA approved the manufacture of bulk Herceptin at Wyeth's Andover, Massachusetts facility. Our manufacturing plant in Oceanside, California, which currently has a total capacity of 90,000 liters, is expected to receive FDA licensure in the first half of 2007.

# Our Strategy and Goals

Our business objectives for the years 2006 through 2010 include bringing at least 20 new molecules into clinical development, bringing at least 15 major new products or indications onto the market, becoming the number one U.S.

oncology company in sales, and achieving certain financial growth measures. These objectives are reflected in our revised Horizon 2010 strategy and goals summarized on our website at http://www.gene.com. At the end of 2006, we had 16 new molecules in the early development pipeline and approximately 30 projects in late stage research.

Our near-term growth will depend on our ability to execute on recent product approvals, including Lucentis for AMD and Avastin for lung cancer, and to successfully obtain FDA approvals for potential new indications for our existing products such as Avastin for breast cancer and Rituxan for immunological disorders. Continued long-term growth will depend on our ability to bring new molecules to the market that make a meaningful difference for patients and provide significant commercial opportunities. With the current highly competitive marketplace for licensing and mergers and acquisitions, particularly for late stage product opportunities, we expect the development of our internal products to provide the majority of our long-term growth.

#### Economic and Industry-wide Factors

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

- ·We face significant competition in the diseases of interest to us from pharmaceutical companies and biotechnology companies. The introduction of new competitive products or follow-on biologics, new information about existing products or pricing decisions by us or our competitors may result in lost market share for us, reduced utilization of our products, reduced product sales, and/or lower prices, even for products protected by patents.
- Our long-term business growth, commercial performance and clinical success depend upon our ability to continue to develop and commercialize important novel therapeutics to treat unmet medical needs, such as cancer. We recognize that the successful development of biotherapeutics is highly difficult and uncertain and that it will be challenging for us to continue to discover and develop innovative treatments. Our business requires significant investment in R&D over many years, often for products that fail during the R&D process. Once a product receives FDA approval, it remains subject to ongoing FDA regulation, including changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisement to physicians, and/or product recalls or withdrawals.
- ·We believe our business model is only sustainable with appropriate pricing and reimbursement for our products to offset the costs and risks of drug development. The pricing of our products has received negative press coverage and public scrutiny. We will continue to meet with patient groups, payers and other stakeholders in the healthcare system to understand their issues and concerns. However, the future reimbursement environment for our products is uncertain.
- ·As the Medicare and Medicaid programs are the largest payers for our products, rules relating to coverage and reimbursement continue to represent an important area of focus. New regulations relating to hospital and physician payment continue to be implemented annually. To date, we have not seen any detectable effects of the new rules on our product sales, and we anticipate minimal effects on our revenues in 2007.
- ·Manufacturing biotherapeutics is difficult and complex, and requires facilities specifically designed and validated to run biotechnology production processes. The manufacture of a biotherapeutic requires developing and maintaining a process to reliably manufacture and formulate the product at an appropriate scale, obtaining regulatory approval to manufacture the product, and is subject to changes in regulatory requirements or standards that may require modifications to the manufacturing process.

- •Our ability to attract and retain highly qualified and talented people in all areas of the company, and our ability to maintain our unique culture, will be critical to our success over the long-term. We are working diligently across the company to make sure that we successfully hire, train and integrate new employees into the Genentech culture and environment. In keeping with our desire to maintain and protect our culture, we continued our broad-based stock option program in 2006.
- ·Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection on one or more products could result in lost sales to competing products and may negatively affect our sales, royalty revenues and operating results. We are often involved in disputes over contracts and intellectual property and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position.

#### **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 generally accepted accounting principles in the United States (or "GAAP"). The preparation of these Consolidated Financial Statements requires management 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, and we have established internal controls related to the preparation of these estimates. Actual results and the timing of the results could differ materially from these estimates.

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

#### **Contingencies**

We are currently, and have been, involved in certain legal proceedings, including patent infringement litigation. We are also involved in licensing and contract disputes, and other matters. Refer to Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on these matters. We assess the likelihood of any adverse judgments or outcomes for these legal matters as well as potential ranges of probable losses. We record an estimated loss as a charge to income if we determine that, based on information available at the time, the loss is probable and the amount of loss can be reasonably estimated. Included in "litigation-related and other long-term liabilities" in the accompanying Consolidated Balance Sheet at December 31, 2006 is \$726 million, which represents our estimate of the costs for the current resolution of these matters. The nature of these matters is highly uncertain and subject to change; as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the final outcome of these matters. An outcome of such matters different than previously estimated could have a material effect on our financial position or our results of operations in any one quarter.

#### Revenue Recognition

In October 2006, we announced our plan to launch the Avastin Patient Assistance Program in the first quarter of 2007, which is a voluntary program that enables eligible patients who receive greater than 10,000 milligrams of Avastin over a 12-month period to receive free Avastin during the remainder of the 12-month period. Based on the current wholesale acquisition cost, the 10,000 milligrams is valued at \$55,000 in gross revenue. Eligible patients include those

who are being treated for an FDA-approved indication and who meet the household income criteria for this program. The program will be available for eligible patients who enroll regardless of whether they are insured. We defer a portion of the Avastin product sales revenue to reflect our estimate of the free Avastin commitment to those patients who elect to enroll in the program. A maximum amount of \$55,000 of gross revenue earned from an

enrolled patient will be recognized ratably over the total number of product vials used for infusions from their physicians which were obtained through normal commercial channels as well as those vials we will deliver directly to their physician in conjunction with the Avastin Patient Assistance Program. As a result of our announced commitment to the program and because retroactive credit provisions are applicable for patients currently on Avastin for all FDA-approved indications, we deferred \$9 million of our fourth quarter 2006 Avastin product sales to reflect our estimate of the free Avastin commitments we incurred for patients treated in the fourth quarter of 2006 who will receive free Avastin later in the course of their therapy.

In order to make our estimate of the amount of free Avastin to be provided to patients under the program, we need to estimate several factors, most notably: the number of patients who are currently being treated for FDA-approved indications and the start date for their treatment regimen, the extent to which doctors and patients may elect to enroll in the program, the number of patients who will meet the financial eligibility requirements of the program, and the duration and extent of treatment for the FDA-approved indications, among other factors. We have based our enrollment assumptions on physician surveys and other information that we consider relevant. We have analyzed a range of reasonably possible outcomes, and as of December 31, 2006, the range of reasonably possible outcomes was estimated to be between \$3 million and \$20 million, with \$9 million as the most likely outcome in that range. We will continue to update our estimates in each reporting period as new information becomes available. If the actual results underlying this deferred revenue accounting vary significantly from our estimates, we will need to make adjustments to these estimates, which could have a material effect on revenue and earnings in the period of adjustment.

#### **Product Sales Allowances**

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

Definitions for the product sales allowance types are as follows:

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

 $\cdot$  Healthcare provider contractual chargebacks are the result of contractual commitments by us to provide products to healthcare providers at specified prices or discounts.

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

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

All of the aforementioned categories of allowances and accruals are evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could materially affect our results of operations or financial position; however, to date they have not been material. However, it is possible that we may need to adjust our estimates in future periods. As of December 31, 2006, our Consolidated Balance Sheet reflected estimated product sales allowance reserves and accruals totaling approximately \$139 million and for the year ended December 31, 2006, our net product sales were approximately \$7,640 million.

#### Royalties

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

#### **Income Taxes**

Income tax expense is based on income before taxes and is computed using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. Various internal and external factors may have favorable or

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

#### **Inventories**

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

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

On January 1, 2006, we began accounting for employee stock-based compensation in accordance with FAS 123R. Under the provisions of FAS 123R, employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Due to the redemption of our Special Common Stock in June 1999 (or "Redemption") by Roche Holdings, Inc. (or "Roche"), there is limited historical information available to support our estimate of certain assumptions required to value our stock options. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. As of December 31, 2006, total compensation cost related to unvested stock options not yet recognized was \$839 million, which is expected to be allocated to expense and production costs over a weighted-average period of 28 months. For the year ended December 31, 2006, employee stock-based compensation expense, net of tax, was approximately \$182 million, or \$0.17 per diluted share. For 2007, employee stock-based compensation is expected to be in the range of \$0.23 to \$0.25 per diluted share, of which \$0.04 represents employee stock-based compensation expense as a component of cost of sales, which had previously been capitalized in inventory.

# **Results of Operations**

(In millions, except per share amounts)

						Annual Per	rcentage
						Chan	ige
	2006		2005		2004	2006/2005	2005/2004
Product sales	\$ 7,640	\$	5,488	\$	3,749	39%	46%
Royalties	1,354		935		641	45	46
Contract revenue	290		210		231	38	(9)
Total operating revenues	9,284		6,633		4,621	40	44
Cost of sales	1,181		1,011		673	17	50
Research and development	1,773		1,262		948	40	33
Marketing, general and administrative	2,014		1,435		1,088	40	32
Collaboration profit sharing	1,005		823		594	22	39
Recurring charges related to redemption	105		123		145	(15)	(15)
Special items: litigation-related	54		58		37	(7)	57
Total costs and expenses	6,132		4,712		3,485	30	35
Operating income	3,152		1,921		1,136	64	69
Other income (expense):							
Interest and other income (expense), net	325		142		91	129	56
Interest expense	(74)		(50)		(7)	48	614
Total other income, net	251		92		84	173	10
Income before taxes	3,403		2,013		1,220	69	65
Income tax provision	1,290		734		435	76	69
Net income	\$ 2,113	\$	1,279	\$	785	65	63
Earnings per share:							
Basic	\$ 2.01	\$	1.21	\$	0.74	66	64
Diluted	\$ 1.97	\$	1.18	\$	0.73	67	62
Pretax operating margin	34%	6	29%	6	25%	)	
COS as a % of product sales	15		18		18		
R&D as a % of operating revenues	19		19		21		
MG&A as a % of operating revenues	22		22		24		
NI as a % of operating revenues	23		19		17		
Tax rate	38		36		36		

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

# **Total Operating Revenues**

Total operating revenues increased 40% to \$9,284 million in 2006 and increased 44% to \$6,633 million in 2005. These increases were primarily due to higher product sales and royalty revenue, and are further discussed below.

**Total Product Sales** 

(In millions)

				<b>Annual Percen</b>	tage Change
Product Sales	2006	2005	2004	2006/2005	2005/2004
Net U.S. Product Sales					
Avastin	\$ 1,746 \$	1,133 \$	545	54%	108%
Rituxan	2,071	1,832	1,574	13	16
Herceptin	1,234	747	479	65	56
Lucentis	380	-	-	-	-
Xolair	425	320	188	33	70
Tarceva	402	275	13	46	*
Nutropin products	378	370	349	2	6
Thrombolytics	243	218	194	11	12
Pulmozyme	199	186	157	7	18
Raptiva	90	79	52	14	52
Total U.S. product sales	7,169	5,162	3,551	39	45
Net product sales to collaborators	471	326	198	44	65
Total product sales	\$ 7,640 \$	5,488 \$	3,749	39	46

<sup>\*</sup> Calculation not meaningful.

Total net product sales increased 39% to \$7,640 million in 2006 and increased 46% to \$5,488 million in 2005. Net U.S. sales increased 39% to \$7,169 million in 2006 and increased 45% to \$5,162 million in 2005. These increases in U.S. sales were due to higher sales across all products, in particular higher sales of our oncology products and sales of Lucentis in 2006. U.S. oncology sales accounted for 76% of U.S. product sales in 2006 compared to 77% in 2005. Increased U.S. sales volume accounted for 89%, or \$1,785 million, of the increase in U.S. net product sales in 2006, and 88%, or \$1,411 million in 2005. The increased U.S. sales volume in 2006 also included new product shipments of Lucentis. Changes in net U.S. sales prices across the portfolio accounted for most of the remainder of the increases in U.S. net product sales in 2006 and 2005.

Effective July 1, 2006, we made changes to our distribution model for Avastin, Herceptin and Rituxan and renegotiated our distribution agreements with a number of our major wholesalers. As part of these changes, the time at which we recognize products sales revenue for domestic product shipments changed from the time at which we ship our products to the time at which our products arrive at the designated receiving location. These distribution changes did not have a material effect on our 2006 results of operations.

Our references to market research and market adoption and penetration by treatment regimen are derived from our analyses of market tracking studies and surveys we undertake with physicians. We use statistical analyses to extrapolate the data we obtain.

#### Avastin

Net U.S. sales of Avastin increased 54% to \$1,746 million in 2006 and 108% to \$1,133 million in 2005. Net U.S. sales in 2006 reflect \$9 million of deferred revenue resulting from the announcement of our Avastin Patient Assistance Program and our estimated free drug commitment for patients currently on Avastin for an FDA-approved indication. The increase in sales in 2006 was primarily a result of increased use of Avastin in metastatic NSCLC, approved on October 11, 2006, and metastatic breast cancer, an unapproved use of Avastin. In addition, the increase

The values shown above are exact; therefore, the totals may not appear to sum due to rounding.

reflects modest gains in the treatment of first-line metastatic colorectal cancer (or "CRC"), for which Avastin is approved. Growth in the use of Avastin for the treatment of metastatic NSCLC was due to greater pre-launch adoption and post-launch penetration rates during 2006 as compared to 2005. In first-line metastatic NSCLC we estimate that Avastin penetration was 26% among all first-line NSCLC patients in the fourth quarter of 2006. In first-line metastatic CRC, we estimate that Avastin penetration was up slightly to 72% during 2006 as compared to

2005; however, over the course of 2006 we observed a flattening in penetration, duration and dose. These increases were partially offset by declining revenues in metastatic renal cell carcinoma (or "RCC") and metastatic pancreatic cancer, both unapproved uses. As a result of competing products that have entered the market since the first quarter of 2006, we have seen a decline in the adoption of Avastin in metastatic RCC (an unapproved use). Revenues from metastatic pancreatic cancer have also declined following our June 2006 announcement that we halted a Phase III trial of Avastin in combination with chemotherapy for the first-line treatment of advanced pancreatic cancer because of failure to meet the primary endpoint of overall survival. Growth in 2005 relative to 2004 was primarily a result of increased use of Avastin in CRC. There were no price increases in 2006 or 2005.

We anticipate that the major driver of Avastin growth for 2007 will come from use in the first-line treatment of metastatic NSCLC.

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

On February 21, 2007, we announced that a Roche-sponsored Phase III study evaluating two different doses of Avastin in combination with gemcitabine and cisplatin chemotherapy met the primary endpoint of prolonging progression-free survival (or "PFS") in patients with previously untreated, advanced NSCLC. This study evaluated a 15 mg/kg/every 3 weeks dose of Avastin (the dose approved in the U.S. for use in combination with carboplatin and paclitaxel) and a lower dose of 7.5 mg/kg/every 3 weeks (a dose not approved for use in the U.S.). Both doses of Avastin significantly improved PFS compared to chemotherapy alone as assessed by trial investigators. Although the study was not designed to compare the Avastin doses, a similar treatment effect in PFS was observed between the two arms.

#### Rituxan

Net U.S. sales of Rituxan increased 13% to \$2,071 million in 2006 and 16% to \$1,832 million in 2005. Rituxan's channel inventory finished the year at the upper level of our target range, adding approximately \$10 million to \$12 million to 2006 sales. Sales growth in 2006 resulted from increased use of Rituxan in rheumatoid arthritis, approved on February 28, 2006, as well as Rituxan following chemotherapy in combined NHL, including areas of unapproved use, and chronic lymphocytic leukemia (or "CLL"), an unapproved use. We estimate that Rituxan's overall adoption rate in combined markets of NHL and CLL remained flat at 82% at the end of 2006 and at the end of 2005. Also contributing to the increases in product sales were price increases effective on July 6, 2005, October 5, 2005, March 29, 2006, and October 5, 2006.

The sales growth in 2005 resulted from increased physician adoption for treatment of indolent NHL with ongoing use of Rituxan following induction therapy, treatment of aggressive NHL, and treatment of CLL (unapproved uses of Rituxan in 2005). Net U.S. sales in 2005 included \$10 million for a reorder to replace a shipment that was destroyed while in transit to a wholesaler. Also contributing to the increases in product sales were price increases in 2005 noted above.

Rituxan was approved for the treatment of adult patients with moderately-to-severely active RA in the first quarter of 2006. It remains difficult to precisely determine the sales split between Rituxan use in oncology and immunology settings since many treatment centers treat both types of patients.

# Herceptin

Net U.S. sales of Herceptin increased 65% to \$1,234 million in 2006 and 56% to \$747 million in 2005. The sales growth in 2006 and 2005 was primarily the result of increased use of Herceptin in the treatment of early stage HER2-positive breast cancer (approved on November 16, 2006), increased use in the treatment of first-line HER2-positive

metastatic breast cancer, and increased cumulative duration of therapy relative to the comparable periods in 2005 and 2004. In first-line HER2-positive metastatic breast cancer patients, we estimate Herceptin's penetration remained flat at 70% at the end of 2006 as adoption was also 70% at the end of 2005. While use in early stage breast cancer patients increased in 2006 relative to 2005, we believe usage in this setting flattened in the second half of 2006. We estimate Herceptin's penetration in the adjuvant setting was 62% at the end of 2006 as compared to 43% adoption at the end of 2005. Also contributing, to a lesser extent, to the increases in product sales were price increases effective on February 24, 2005, March 29, 2006, and October 3, 2006.

#### Lucentis

We received FDA approval to market Lucentis for the treatment of AMD on June 30, 2006. Net U.S. sales of \$380 million in 2006 were driven by high demand among existing AMD patients previously on other therapies and by newly diagnosed patients. We estimate that as of December 31, 2006 approximately 75 percent of Lucentis patients were AMD patients previously on other therapies that were switched to Lucentis and the remaining 25 percent were newly diagnosed patients. Our market research indicates that at six months post launch approximately 55 percent of newly diagnosed patients were treated with Lucentis. Sales growth in 2007 may be negatively impacted by (i) a decrease in existing AMD patients switching to Lucentis from other therapies, as we believe most of the existing AMD patients were switched to Lucentis or have chosen not to change therapies; (ii) less frequent dosing of existing patients who have completed their first four months of treatment; and (iii) continued use of Avastin in this setting.

#### **Xolair**

Net U.S. sales of Xolair increased 33% to \$425 million in 2006 and 70% to \$320 million in 2005. Sales growth in 2006 and 2005 were driven by increased penetration in the asthma market and, to a lesser extent, price increases effective on July 21, 2005, April 4, 2006, and October 17, 2006.

On February 21, 2007, the FDA announced it requested that Genentech strengthen the existing warning on the potential risk for anaphylaxis in patients receiving Xolair by adding a boxed warning to the product label and implementing a Risk Mitigation Action Plan, including providing a medication guide for patients. Genentech and Novartis will be working with FDA on its request.

### **Tarceva**

Net U.S. sales of Tarceva increased 46% to \$402 million in 2006. Net U.S. sales in 2005 were \$275 million after the product launch in November 2004. The increase in product sales in 2006 was primarily due to price increases effective on April 5, 2005, November 9, 2005, and November 14, 2006. Also affecting our product sales was growth in penetration and duration of treatment in both second-line NSCLC and first-line pancreatic cancer; however, penetration in second-line NSCLC decreased in the second half of 2006. We estimate Tarceva's penetration in second-line NSCLC averaged 30% in 2006 compared to 24% in 2005. We estimate Tarceva's penetration in the first-line pancreatic cancer setting was 40% at the end of 2006 as compared to 24% at the end of 2005. Future sales growth in NSCLC will depend on gains in penetration against chemotherapy within select second-line NSCLC patient subsets, increased patient compliance with prescribed therapy, continuing recent gains in duration of therapy, and reducing obstacles for patient access to therapy.

# Nutropin Products

Combined net U.S. sales of our Nutropin products increased 2% to \$378 million in 2006 and 6% to \$370 million in 2005. The increases in 2006 and 2005 were primarily due to price increases effective on March 3, 2005 and January 10, 2006. The 2006 increase in price was partially offset by a decrease in sales volume in 2006 compared to 2005,

resulting from declining new patient market share and the loss of managed care product placement due to price discounting by competitors.

## **Thrombolytics**

Combined net U.S. sales of our three thrombolytics products, Activase, Cathflo Activase, and TNKase, increased 11% to \$243 million in 2006 and 12% to \$218 million in 2005. Sales growth in 2006 and 2005 was due to growth in Cathflo Activase sales in the catheter clearance market and increased Activase sales in the acute ischemic stroke market. Also contributing to the increases in product sales were price increases effective on January 11, 2005, February 14, 2006, and July 6, 2006.

### Pulmozyme

Net U.S. sales of Pulmozyme increased 7% to \$199 million in 2006 and 18% to \$186 million in 2005. The sales growth in both 2006 and 2005 represents price increases effective on April 26, 2005 and June 29, 2006, as well as a focus on aggressive treatment of cystic fibrosis early in the course of the disease.

### Raptiva

Net U.S. sales of Raptiva increased 14% to \$90 million in 2006 and 52% to \$79 million in 2005. The growth in 2006 was primarily due to price increases effective on April 21, 2005, November 17, 2005, and August 10, 2006.

### Sales to Collaborators

Product sales to collaborators, the majority of which were for non-U.S. markets, increased 44% to \$471 million in 2006 and 65% to \$326 million in 2005. The increase in 2006 was primarily due to higher sales of Herceptin, Avastin and Rituxan to F. Hoffmann-La Roche. The increase in 2005 was primarily due to sales of Avastin and Rituxan to F. Hoffmann-La Roche and sales of product manufactured under a contract with a third party. In January 2007, Novartis received European Union approval for Lucentis for the treatment of patients with wet AMD. For 2007, we expect sales to collaborators to approximately double relative to 2006 levels.

## Royalties

Royalty revenues increased 45% to \$1,354 million in 2006 and 46% to \$935 million in 2005. The increases were due to higher sales by F. Hoffmann-La Roche of Herceptin, Avastin and Rituxan in 2006, and Herceptin and Rituxan in 2005; and higher sales by various other licensees on other products. Of the overall royalties recognized, royalty revenue from F. Hoffmann-La Roche represented approximately 62% in 2006, 53% in 2005, and 52% in 2004. Also contributing to the increase in 2005 was a new license arrangement with ImClone Systems, Inc. under which we receive royalties on sales of ERBITUX®. We received a one-time payment in the first quarter of 2005 relating to royalties on ERBITUX® sales from the period between launch of the product in 2004 and the signing of the agreement in January 2005. Royalties from other licensees include royalty revenue on our patents, including our Cabilly patents noted below.

We have confidential licensing agreements with a number of companies on U.S. Patent No. 6,331,415 and No. 4,816,567 (or the "Cabilly patents"), under which we receive royalty revenue on sales of products that are covered by one or more of the Cabilly patents. The '567 patent expired in March 2006, while the '415 patent expires in December 2018. The licensed products for which we receive the most significant Cabilly royalties are Humira®, Remicade®, Synagis®, and ERBITUX®. Cabilly royalties affect three lines on our Consolidated Statement of Income: (i) We record gross royalties we receive from Cabilly patent licensees as royalty revenue; (ii) On royalties we receive from Cabilly licensees, we in turn pay City of Hope National Medical Center (or "COH") a percentage of our royalty revenue and these payments to COH are recorded with our marketing, general and administrative (or "MG&A") expenses as royalty expense; (iii) We pay royalty expenses directly to COH on sales of our products that are covered by the

Cabilly patents and these payments to COH are recorded in cost of sales. The overall net pre-tax contribution from revenues and expenses related to the Cabilly patents was approximately \$105 million in 2006, or approximately \$0.06 per diluted share, and \$70 million in 2005, or approximately \$0.04 per diluted share, excluding the effects of the one-time licensee payment we recorded in the first quarter of 2005 as discussed above. See also

Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on our Cabilly patent reexaminations.

Cash flows from royalty revenues include amounts denominated in foreign currencies. We currently enter into foreign currency option and forward contracts to hedge these foreign currency cash flows. These options and forwards are due to expire in 2007 through 2008. See also Note 2, "Summary of Significant Accounting Policies," and Note 4, "Investments Securities and Financial Instruments — Derivative Financial Instruments," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

For 2007, we expect royalty revenue to increase approximately 25% over 2006 levels of \$1,354 million; however, royalties are difficult to forecast because of the number of products involved.

#### **Contract Revenues**

Contract revenues increased 38% to \$290 million in 2006, and decreased 9% to \$210 million in 2005. The increase in 2006 was primarily due to higher contract revenues from Hoffmann-La Roche driven by higher reimbursements related to R&D development efforts on Avastin and manufacturing plant start-up costs, and a Herceptin milestone payment. Also contributing to the increase in 2006 were higher reimbursements from Biogen Idec related to R&D development efforts on Rituxan (RA and other immunology indications). The decrease in 2005 was mainly due to lower contract revenues from our collaborators, including OSI and XOMA, Ltd. (or "XOMA"). Due to the commercialization of Tarceva in November 2004, subsequent development efforts on this product were included in net operating profit sharing with OSI, which was reflected in the collaboration profit sharing line. In January 2005, we restructured our Raptiva collaboration arrangement with XOMA, whereby XOMA is no longer obligated to co-develop Raptiva, and we no longer earn contract revenue on the development of Raptiva. These decreases were partially offset by higher reimbursements in 2005 on R&D development efforts related to our Rituxan collaboration with Biogen Idec. See "Related Party Transactions" below for more information on contract revenue from F. Hoffmann-La Roche.

Contract revenues vary each quarter and are dependent on a number of factors, including the timing and level of reimbursements from ongoing development efforts, milestones and opt-in payments received, and new contract arrangements. For 2007, we expect contract revenues to decrease by approximately 15% as compared to \$290 million in 2006.

# Cost of Sales

Cost of sales (or "COS") as a percentage of net product sales was 15% in 2006 as compared to 18% in both 2005 and 2004. COS in 2006 and 2005 was favorably affected by increased sales of our higher margin products, primarily Lucentis, Avastin, Herceptin and Rituxan in 2006 and Avastin, Herceptin and Rituxan in 2005. COS in 2005 was also favorably affected by a reversal of a royalty accrual of \$7 million, partially offset by charges of \$41 million in payments to Amgen Inc. (or "Amgen") and another collaborator to cancel and amend certain future manufacturing obligations, higher production costs, and a \$20 million one-time royalty cost associated with a sales milestone that we owed a collaborator.

In 2007, we will begin recording employee stock-based compensation expense in the cost of sales line related to products sold for which employee stock-based compensation expense was previously capitalized as part of inventory costs upon implementation of FAS 123R on January 1, 2006.

### Research and Development

Research and development (or "R&D") expenses increased 40% to \$1,773 million in 2006, and increased 33% to \$1,262 million in 2005. R&D as a percentage of total operating revenues was 19% in 2006 and 2005, and 21% in 2004. The year-over-year decline in this ratio reflects the increase in operating revenues.

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

				<b>Annual Percen</b>	tage Change
Research and Development	2006	2005	2004	2006/2005	2005/2004
Product development (including					
post-marketing)	\$ 1,269 \$	935 \$	668	36%	40%
Research	326	235	218	39	8
In-licensing	178	92	62	93	48
Total	\$ 1,773 \$	1,262 \$	948	40	33

*Product development:* Product development expenses include costs of conducting clinical trials, activities to support regulatory filings, and post-marketing expenses, which include Phase IV and investigator-sponsored trials and product registries. Such costs include costs of personnel, drug supply costs, research fees charged by outside contractors, co-development costs, and facility expenses, including depreciation. Total development expenses increased 36% to \$1,269 million in 2006 and 40% to \$935 million in 2005. See "Products in Development" in the Business section of Part I, Item 1 of this Form 10-K for further information regarding our development pipeline.

The increase in 2006 expense was primarily driven by: (i) \$184 million higher development expenses due to increased activity across our entire product portfolio, including increased spending on clinical programs, including late-stage clinical trials for Avastin, Rituxan Immunology, humanized anti-CD20, and other programs, early stage projects and higher clinical manufacturing expenses in support of our clinical trials; and (ii) a \$37 million increase in post-marketing expense related to studies of Avastin, Lucentis, Rituxan Immunology and Xolair. In addition, development expenses in 2006 included \$113 million of employee stock-based compensation expense related to FAS 123R.

The increase in 2005 expense was primarily driven by: (i) \$222 million higher development expenses due to an increase in clinical programs including our broad Avastin development program, Rituxan Immunology, Lucentis, anti-HER2 and BR3-Fc for rheumatoid arthritis; higher clinical manufacturing start-up costs associated with new contract sites, including costs related to testing the Herceptin manufacturing process at Wyeth, increased clinical manufacturing of our anti-CD20 molecule, and various new molecular entities including Apo2L/TRAIL; and increased headcount and related expenses and higher depreciation and facility expenses; and (ii) a \$45 million increase in post-marketing expense related to studies of Avastin, Rituxan Immunology, Lucentis and Nutropin.

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, benefits, recruiting and relocation costs. Research expenses increased 39% to \$326 million in 2006 and 8% to \$235 million in 2005. 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. In addition, research expenses in 2006 included \$27 million of employee stock-based compensation expense related to FAS 123R.

*In-licensing:* In-licensing includes costs incurred to acquire licenses to develop and commercialize various technologies and molecules. In-licensing expenses increased 93% to \$178 million in 2006 and 48% to \$92 million in 2005. The increase in 2006 primarily related to new in-licensing collaborations with (i) Exelixis to co-develop a small-molecule inhibitor of methyl ethyl keyton (or "MEK"), (ii) AC Immune to research and develop anti-beta-amyloid antibodies for the potential treatment of Alzheimer's and other diseases, (iii) Inotek Pharmaceuticals Corporation to discover, develop, manufacture and commercialize inhibitors of poly (ADP-ribose) polymerase (or "PARP") for the potential treatment of cancer, and (iv) CGI Pharmaceuticals to research, develop, manufacture, and commercialize therapeutics for the potential treatment of cancer and immunological disorders. The increase in 2005 was primarily

due to the expansion of research collaborations.

For 2007, we expect R&D absolute dollar spending to increase over 2006 levels due to continued investment in our late stage pipeline, and the addition of new molecules and indications to the early stage pipeline.

### Marketing, General and Administrative

Overall marketing, general and administrative (or "MG&A") expenses increased 40% to \$2,014hillion in 2006 and 32% to \$1,435 million in 2005. MG&A as a percentage of total operating revenues was 22% in 2006 and 2005, and 24% in 2004. The decline in this ratio since 2004 primarily reflects the increase in operating revenues.

The increase in 2006 expense was primarily due to: (i) an increase of \$149 million in marketing and sales spending primarily in support of launch activities related to Lucentis for AMD and Rituxan for RA; (ii) an increase of \$84 million in marketing and sales spending on Avastin primarily in support of launch activities for NSCLC, a recently approved indication, and pre-launch activities for a potential breast cancer indication; (iii) a \$47 million increase resulting from ongoing marketing efforts with established products, primarily Herceptin, partially offset by a \$40 million decrease in Raptiva marketing costs; (iv) an increase of \$131 million in support of our continued corporate growth including headcount growth and headcount related expenses, charitable donations, of which \$26 million related to increased donations to independent public charities that provide co-pay assistance to eligible patients, and legal costs; and (v) an increase of \$39 million in royalty expense, primarily to Biogen Idec resulting from higher Hoffmann-La Roche sales of Rituxan. In addition, MG&A expenses in 2006 included \$169 million of employee stock-based compensation expense related to FAS 123R.

The increase in 2005 expense was primarily due to: (i) an increase of \$121 million primarily in support of the launch of Tarceva and higher marketing costs for Avastin, Xolair and Raptiva; (ii) an increase of \$89 million primarily due to pre-launch costs associated with pipeline products, including Rituxan RA and Lucentis and other pipeline product investments; (iii) an increase of \$19 million resulting from ongoing marketing efforts with established products, primarily Herceptin; (iv) an increase of \$79 million in general corporate expenses to support our continued growth and higher legal costs; and (v) \$39 million in increased charitable donations, of which \$21 million was donated to various independent, third party, public charities that provide co-pay assistance to eligible patients, and \$13 million was donated to the Genentech Foundation, which primarily funds health science education.

For 2007, we expect MG&A expense to increase primarily driven by higher costs in support of recently launched products and anticipated launches of potential new product indications, including those for Avastin, and continued support of our corporate growth and infrastructure needs.

### Collaboration Profit Sharing

Collaboration profit sharing expenses increased 22% to \$1,005 million in 2006 and 39% to \$823 million in 2005 due to higher sales of Rituxan, Tarceva and Xolair and the related profit sharing expenses. Our collaboration profit sharing expenses are expected to grow in 2007, consistent with our expectations of higher sales for the respective products.

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

				<b>Annual Percent</b>	tage Change
	2006	2005	2004	2006/2005	2005/2004
U.S. Rituxan profit sharing expense	\$ 672 \$	603 \$	518	11%	16%
U.S. Tarceva profit sharing expense	146	83	-	76	-
U.S. and ex-U.S. Xolair profit sharing					
expense	187	137	76	36	80
Total collaboration profit sharing					
expense	\$ 1,005 \$	823 \$	594	22	39

Currently, our most significant collaboration profit sharing agreement is with Biogen Idec, with whom we co-promote Rituxan in the U.S. Under the collaboration agreement, Biogen Idec granted us a worldwide license to develop, commercialize and market Rituxan in multiple indications. In exchange for these worldwide rights, Biogen Idec has co-promotion rights in the U.S. and a contractual arrangement under which we share a portion of the pretax U.S. co-promotion profits of Rituxan and royalty revenue on sales of Rituxan by collaborators. In June 2003, we

amended and restated the collaboration agreement with Biogen Idec to include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to Rituxan, for a broad range of indications.

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

Collaboration profit sharing expense, exclusive of research and development expenses, related to Biogen Idec for the years ended December 31, 2006, 2005 and 2004, consisted of the following commercial activity (*in millions*):

				<b>Annual Percent</b>	age Change
	2006	2005	2004	2006/2005	2005/2004
Product sales, net	\$ 2,071 \$	1,832 \$	1,574	13%	16%
Combined commercial costs and					
expenses	489	390	316	25	23
Combined co-promotion profits	\$ 1,582 \$	1,442 \$	1,258	10	15
Amount due to Biogen Idec for their					
share of co-promotion profits - included					
in collaboration profit sharing expense	\$ 672 \$	603 \$	518	11	16

Biogen Idec's relative share of combined commercial costs determines the amount shown as collaboration profit sharing expense, exclusive of research and development expenses.

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

	2006	2005	2004	Annual Percent 2006/2005	age Change 2005/2004
Contract revenue	\$ 79 \$	59 \$	41	34%	44%
Co-promotion profit sharing expense	\$ 672 \$	603 \$	518	11	16
Royalty expense on ex-U.S. sales of					
Rituxan and other patent costs -					
included in MG&A expense	\$ 175 \$	139 \$	119	26	17

## Recurring Charges Related to Redemption

We record recurring charges related to the June 1999 redemption of our Special Common Stock and push-down accounting (see discussion below in "Relationship with Roche — Redemption of Our Special Common Stock"). These charges were comprised of the amortization of Redemption-related other intangible assets in the periods presented.

# Special Items: Litigation-Related

We recorded accrued interest and bond costs related to the COH trial judgment of \$54 million each year in 2006, 2005 and 2004. 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. The amount of cash paid, if any, or the

timing of such payment in connection with the COH matter will depend on the outcome of the California Supreme Court's review of the matter; however, it may take longer than one year to resolve this matter. See Note 8, "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. Also included in this line in 2005 is a charge related

to a litigation settlement, net of amounts received on a separate litigation settlement. Also, included in this line in 2004 is a released accrual as a result of the resolution of a separate litigation matter.

## **Operating Income**

Operating income increased 64% to \$3,152 million in 2006 and increased 69% to \$1,921 million in 2005. Our operating income as a percentage of operating revenues (or "pretax operating margin") was 34% in 2006, 29% in 2005 and 25% in 2004.

### Other Income (Expense)

The components of "other income (expense)" are as follows (in millions):

				<b>Annual Percen</b>	tage Change
	2006	2005	2004	2006/2005	2005/2004
Gains on sales of biotechnology equity					
securities, net	\$ 93 \$	9 \$	13	933%	(31)%
Write-down of biotechnology debt and					
equity securities	(4)	(10)	(12)	(60)	(17)
Interest income	230	143	90	61	59
Interest expense	(74)	(50)	(7)	48	614
Other miscellaneous income	6	-	-	-	-
Total other income, net	\$ 251 \$	92 \$	84	173	10

Other income, net, increased 173% to \$251 million in 2006, and increased 10% to \$92 million in 2005. The components of other income (expense) have changed primarily due to gains on sales of biotechnology equity securities resulting from Amgen's acquisition of Abgenix, Pfizer's acquisition of Rinat, Stiefel Laboratories acquisition of Connetics Corporation, and Astra Zeneca's acquisition of Cambridge Antibody and the effects of our debt issuance in July 2005. Interest expense increased in 2006 and 2005 due to the new debt service costs, and in 2006 investment income increased as a result of the higher average cash balances maintained and higher yields. In 2007, we expect other income, net, to be approximately 60% lower than 2006 levels, although this may vary with fluctuations in interest rates and unexpected acquisition-related gains from our biotechnology equity portfolio.

### **Income Tax Provision**

The effective income tax rate was 38% in 2006 and 36% in 2005 and 2004. The effective tax rate in 2006 was higher than 2005 and 2004 primarily due to new Final Regulations issued by the U.S. Department of Treasury, which required a \$34 million reduction in research credits claimed in prior years. The increase in the 2006 effective income tax rate also resulted from higher income before taxes in 2006. The effective income tax rate in 2005 was comparable to 2004 but included a \$39 million benefit for increased research credits resulting from new Temporary Regulations issued by the U.S. Department of Treasury in 2005. The additional benefit in 2005 was partially offset by changes in estimates of prior years' research credits and by higher income before taxes in 2005.

We anticipate that our annual 2007 effective income tax rate will be approximately 36%, excluding the effect of the potential Tanox acquisition. Various factors may have favorable or unfavorable effects on our effective income tax rate during 2007 and in subsequent years. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, changes in estimates to prior years' items, past and future levels of R&D spending, and changes in overall levels of income before taxes, all of which may result in periodic revisions to our effective income tax rate.

## Relationship with Roche

As a result of the June 1999 redemption of our Special Common Stock ("the Redemption") and subsequent public offerings, we amended our certificate of incorporation and bylaws, amended our licensing and marketing agreement 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 below:

### **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.

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 amended and restated 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 Investigational New Drug Application (or "IND") for a product, (2) completion of the first Phase II trial for a product or (3) if Hoffmann-La Roche previously paid us a fee of \$10 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 of our decision to file 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 the first 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 indications, 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 III, 75% of development costs incurred through completion of Phase III, and 75% of development costs subsequently incurred, and \$5 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" within 30 days of decision to file for 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;
- ·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 or completion of the first Phase II trial, a royalty of 12.5% on the first \$100 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 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 a Phase III trial, a royalty of 15% on its sales of that product 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; however, \$5 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 million.

We have further amended this licensing and marketing agreement with Hoffmann-La Roche to delete or add certain Genentech products under Hoffmann-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 U.S. Under the agreement, Hoffmann-La Roche funds one-half the global development costs incurred in connection with developing

anti-HER2 antibody products under the agreement. 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" with 30 days of decision to file for 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 U.S. up to \$500 million in each calendar year and 22.5% on such sales in excess of \$500 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 may agree to conduct and share in the costs of joint research on certain molecules. 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. If we and Roche elect to file a combined state and local tax return in certain states where we may be eligible, our tax liability or refund with Roche for such jurisdictions will be calculated on a stand alone basis.

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

We issue additional shares of Common Stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that with respect to any issuance of Common Stock by us in the future, we will repurchase a sufficient number of shares so that immediately after such issuance the percentage of our Common Stock owned by Roche will be no lower than 2% below the "Minimum Percentage" (as defined below), provided however, as long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, we will repurchase a sufficient number of shares of our Common Stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The Minimum Percentage equals the lowest number of shares of 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 stock splits. We have repurchased shares of our Common Stock since 2001 (see discussion below in Liquidity and Capital Resources). The affiliation agreement also provides that, upon Roche's request, we will repurchase shares of our Common Stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. The Minimum Percentage at December 31, 2006 was 57.7% and, under the terms of the affiliation agreement, Roche's ownership percentage is to be no lower than 55.7%. At December 31, 2006, Roche's ownership percentage was 55.8%.

### **Related Party Transactions**

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

In our royalty and supply arrangements with related parties, we are the principal, as defined under Emerging Issues Task Force (or "EITF") Issue No. 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent" (or "EITF 99-19"), because we bear the manufacturing risk, general inventory risk, and the risk to defend our intellectual

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

# Hoffmann-La Roche

We recognized royalty revenue of 20% of net sales of Herceptin made by Hoffmann-La Roche outside of the U.S. of up to \$500 million, and 22.5% of net sales outside of the U.S. in excess of \$500 million, a sales plateau which was exceeded in 2006, 2005 and 2004. For all other products distributed by Hoffmann-La Roche outside of the U.S., we recognize royalty revenue at rates ranging from 8% to 20%.

In July 2006, we signed two new product supply agreements with Hoffmann-La Roche. The Umbrella Manufacturing Supply Agreement (or "Umbrella Agreement") supersedes our existing product supply agreements with Hoffmann-La Roche. The Short-Term Supply Agreement (or "Short-Term Agreement") supplements the terms of the Umbrella Agreement. Under the Short-Term Agreement, Hoffmann-La Roche has agreed to purchase specified amounts of Herceptin, Avastin and Rituxan through 2008. Under the Umbrella Agreement, Hoffmann-La Roche has agreed to purchase specified amounts of Herceptin and Avastin through 2012 and, on a perpetual basis, either party may order other collaboration products from the other party, including Herceptin and Avastin after 2012, pursuant to certain forecast terms. The Umbrella Agreement also provides that either party may terminate its obligation to purchase and/or supply Avastin and/or Herceptin with six years notice on or after December 31, 2007.

We currently have no active profit sharing arrangements with Hoffmann-La Roche.

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

	2006	2005	2004
Ex-U.S. product sales to Hoffmann-La Roche	\$ 359	\$ 177	\$ 111
Royalties received from Hoffmann-La Roche	\$ 846	\$ 500	\$ 334
Cost of sales on ex-U.S. product sales to Hoffmann-La			
Roche	\$ 268	\$ 154	\$ 95
Contract revenue from Hoffmann-La Roche	\$ 125	\$ 65	\$ 73

R&D expenses include amounts related to Hoffmann-La Roche of \$213 million in 2006, \$144 million in 2005, and \$125 million in 2004. These amounts represent R&D development expenses we incurred on joint development projects, but are reimbursable to us by Hoffmann-La Roche. In addition, these amounts include R&D expenses resulting from the net settlement of amounts owed to Hoffmann-La Roche on R&D development expenses it incurred on joint development products/projects, less amounts reimbursable to us on these respective projects.

### Novartis

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

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

We, along with Novartis Pharma AG and Tanox, Inc., are co-developing Xolair in the U.S., and we and Novartis are co-promoting Xolair in the U.S. and both make certain joint and individual payments to Tanox; our joint and

individual payments are in the form of royalties. We record all sales and cost of sales in the U.S. and Novartis markets the product in and records all sales and cost of sales in Europe. We and Novartis share the resulting U.S. and European operating profits, respectively, according to prescribed profit-sharing percentages. On January 20, 2006, Novartis received FDA approval to manufacture bulk supply of Xolair at their Huningue production facility in France. We now acquire bulk supply of Xolair from Novartis and compensate them on a cost plus mark up basis.

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

	2006	2005	2004
Ex-U.S. product sales to Novartis	\$ 5	\$ 7	\$ 1
_			
Royalties received from Novartis	\$ 3	\$ 1	\$ 1
Cost of sales on ex-U.S. product sales to Novartis	\$ 4	\$ 17	\$ 1
Contract revenue from Novartis	\$ 40	\$ 50	\$ 48
Novartis' share of co-promotion profits - included in			
collaboration profit sharing expense	\$ 187	\$ 136	\$ 75

Under the Xolair collaboration agreement, we contractually share a portion of the pretax U.S. and European co-promotion profits earned on the commercial sales of Xolair. Our U.S. and European profit sharing expenses are recorded as collaboration profit sharing expense.

R&D expenses include amounts related to Novartis of \$38 million in 2006, \$39 million in 2005, and \$44 million in 2004.

### **Liquidity and Capital Resources**

Liquidity and Capital Resources	2006		2005	2004
December 31:		(ii	n millions)	
Unrestricted cash, cash equivalents, short-term investments and long-term marketable debt and equity				
securities	\$ 4,325	\$	3,814	\$ 2,781
Net receivable — equity hedge instruments	50		73	21
Total unrestricted cash, cash equivalents, short-term investments, long-term marketable debt and equity				
securities, and equity hedge instruments	\$ 4,375	\$	3,887	\$ 2,802
Working capital	\$ 3,547	\$	2,726	\$ 2,187
Current ratio	2.6:1		2.6:1	2.8:1
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	\$ 2,138	\$	2,363	\$ 1,195
Investing activities	(1,681)		(1,776)	(450)
Financing activities	(432)		368	(847)
Capital expenditures (included in investing activities				
above)	(1,214)		(1,400)	(650)

Total unrestricted cash, cash equivalents, short-term investments and long-term marketable securities, including the estimated fair value of the related equity hedge instruments, were approximately \$4.4 billion at December 31, 2006, an increase of approximately \$488 million, or 13%, from December 31, 2005. This increase primarily reflects cash generated from operations; partially offset by cash used for capital expenditures, payments of taxes, purchases of marketable securities, and repurchases of our Common Stock. To mitigate the risk of market value fluctuations, certain of our biotechnology equity securities are hedged with zero-cost collars and forward contracts, which are carried at estimated fair value. See Note 2, "Summary of Significant Accounting Policies — Comprehensive

Income," in the Notes to the Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding activity in our marketable investment portfolio and derivative instruments.

See "Leases" below for a discussion of our leasing arrangements. See "Our affiliation agreement with Roche could limit our ability to make acquisitions" and "To pay our indebtedness will require a significant amount of cash and may adversely affect our operations and financial result," above in Part I, Item 1A "Risk Factors" and below in Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for factors that could negatively affect our cash position.

## Cash Provided by Operating Activities

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

Receivables and other assets increased \$628 million in 2006. This increase is primarily due to an increase in "accounts receivable - product sales" of \$411 million in 2006 from 2005, which is primarily due to sales of our new product, Lucentis, on which we offer extended payment terms. The average collection period of our "accounts receivable — product sales" as measured in days sales outstanding (or "DSO") was 46 days as of December 31, 2006, 37 days as of December 31, 2005, and 58 days as of December 31, 2004. The increase in DSO in 2006 over 2005 is primarily due to the extended payment terms we offered to certain wholesalers in conjunction with the launch of Lucentis on June 30, 2006. This program will be in effect for 12 months following the launch date; therefore, we expect our DSO to continue to increase in the first half of 2007 due to these extended payment terms. The decline in DSO in 2005 over 2004 reflects the termination in the first quarter of 2005 of our extended payment term incentive program that was put into place during the first quarter of 2004 for sales of new products at that time, in particular Avastin. The level of accounts receivable with extended dating declined steadily in 2005 as customer payments were received. The DSO as of December 31, 2005 also decreased by an additional four days, primarily due to favorable collections.

Our inventory balance increased \$408 million in 2006. The increase is primarily due to bulk production of our Avastin and Herceptin products. We expect that our inventory levels will continue to rise in 2007 in support of sales growth, in particular, sales growth related to our recently approved indications.

Accounts payable, other accrued liabilities and other long-term liabilities increased \$683 million in 2006. This increase is mainly due to an increase in taxes payable, accrued compensation, accrued royalties and accrued collaboration expenses, which are mainly due to the growth in the business.

# Cash Used in Investing Activities

Cash used in investing activities primarily relates to purchases, sales and maturities of investments and capital expenditures. Capital expenditures were \$1.21 billion during 2006, compared to \$1.40 billion during 2005, and \$650 million during 2004. Capital expenditures in 2006 included ongoing construction of our second manufacturing facility in Vacaville, California, validation costs at our manufacturing facility in Oceanside, California, the purchase of a second facility in Oceanside, purchase of equipment and information systems, and ongoing expenditures to support our corporate infrastructure needs. Capital expenditures in 2005 included the purchase of the Oceanside plant for \$408 million in cash plus \$9 million in closing costs, ongoing construction of our second manufacturing facility in Vacaville, California, \$160 million repayment of our synthetic lease obligation on a research facility in South San Francisco, California, the purchase of land, equipment and information systems, and ongoing construction costs in support of our manufacturing and corporate infrastructure needs. 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.

Restricted cash increased by \$53 million in 2006 and in 2005 due to the additional cash and investments we were required to pledge to secure the COH surety bond. Total cash and investments pledged to secure the COH surety bond were \$788 million at December 31, 2006 and \$735 million at December 31, 2005 and were reflected in the Consolidated Balance Sheets in "restricted cash and investments". See the Contingencies section of Note 8, "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.

We anticipate that our capital expenditures for 2007 will stay relatively flat at approximately \$1.2 billion, primarily driven by manufacturing expansion, in particular ongoing construction of our second manufacturing facility in Vacaville, and for projects related to existing facilities, increases in office space, and land purchases.

### Cash Used in or Provided by Financing Activities

Cash used in or provided by financing activities includes activity under our stock repurchase program and our employee stock plans. We used cash for stock repurchases of approximately \$1.0 billion in 2006, \$2.02 billion during 2005, and \$1.35 billion during 2004 pursuant to our stock repurchase program approved by our Board of Directors. We also received \$385 million during 2006, \$821 million during 2005, and \$505 million during 2004, related to stock option exercises and stock issuances under our employee stock purchase plan.

Prior to our adoption of FAS 123R, the tax benefit from stock option exercises was reported as operating cash flows. FAS 123R requires excess tax benefits be reported as a financing cash inflow rather than as a reduction of cash used in operating activities. At December 31, 2006, the excess tax benefit from stock-based compensation arrangements was \$179 million.

In July 2005, we received proceeds of \$1.99 billion from our debt issuance, and we used a portion of those proceeds in the third quarter of 2005 to extinguish our remaining \$425 million total lease obligation with respect to our Vacaville, California manufacturing facility.

Under a stock repurchase program approved by our Board of Directors in December 2003 and most recently extended in April 2006, we are authorized to repurchase up to 100,000,000 shares of our Common Stock for an aggregate price of up to \$6.0 billion through June 30, 2007. In this program, as in previous stock repurchase programs, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. We also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. As of December 31, 2006, we have not engaged in any such transactions. We intend to use the repurchased stock to offset dilution caused by the issuance of shares in connection with our employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage; (ii) to make prudent investments of our cash resources; and (iii) to allow for an effective mechanism to provide stock for our employee stock plans. See above in "Relationship with Roche" for more information on Roche's minimum ownership percentage.

We have entered into Rule 10b5-1 trading plans to repurchase shares in the open market during those periods each quarter when trading in our stock is restricted under our insider trading policy. The trading plan covers approximately four million shares and the current plan is effective through June 30, 2007.

Under our current stock repurchase program, we repurchased 12 million shares for \$1.0 billion in 2006, 24 million shares for \$2.02 billion in 2005 and 26 million shares for \$1.35 billion in 2004.

Our shares repurchased during 2006 were as follows (shares in millions):

	Total Number of Shares Purchased	Average Price Paid per Share
January 1-31	0.9	\$ 88.37
February 1-28	0.7	85.31
March 1-31	1.0	84.24
April 1-30	0.7	80.31
May 1-31	2.1	78.83
June 1-30	1.2	79.30
July 1-31	0.9	79.39
August 1-31	0.9	80.89
September 1-30	0.9	79.84
October 1-31	0.3	83.97
November 1-30	1.4	80.81
December 1-31	1.2	82.11
Total	12.2	\$ 81.45

As of December 31, 2006, 62 million shares have been purchased under our stock repurchase program for \$4.37 billion, and a maximum of 38 million additional shares may be purchased under the program through June 30, 2007.

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

## **Off-Balance Sheet Arrangements**

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

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.

In December 2004, we entered into a Master Lease Agreement with Slough SSF, LLC for the lease of property adjacent to our South San Francisco campus. The property is being developed into eight buildings and two parking structures. The lease of the property is taking place in two phases pursuant to separate lease agreements for each building as contemplated by the Master Lease Agreement. Phase I building leases began in 2006 and Phase II building leases begin in 2007 and 2008. For accounting purposes, due to the nature of our involvement with the construction of the buildings subject to the Master Lease Agreement, we are considered to be the owner of the assets during the construction period through the lease commencement date, even though the funds to construct the building shell and some infrastructure costs are paid by the lessor. As such, as of December 31, 2006, we have capitalized \$205 million of construction costs, including capitalized interest, in property, plant and equipment, excluding approximately \$150 million in leasehold improvements that we have installed at the property to date. We have recognized \$198 million as a construction financing obligation, which is primarily included in "long-term debt" in the accompanying Consolidated Balance Sheets. As of December 31, 2005, we had capitalized \$94 million of construction costs in property, plant and equipment and recognized the same amount as a construction financing obligation in "long-term debt" in the

accompanying Consolidated Balance Sheets. Concurrent with the commencement of the rental period, during the third quarter of 2006, we began repayment of the construction financing obligation. We expect at the time of completion of the project, if all the buildings and infrastructure were completed by the lessor, our construction asset and related obligation may be as much as \$365 million, excluding costs related to leasehold improvements.

In November 2006, we entered into a series of agreements with Lonza Group Ltd (or "Lonza"), including a supply agreement to purchase product produced by Lonza at their Singapore manufacturing facility, which is currently under construction. For accounting purposes, due to the nature of the supply agreement and our involvement with the construction of the buildings, we are considered to be the owner of the assets during the construction period, even though the funds to construct the building shell and some infrastructure costs are paid by Lonza. As such, during 2006, we capitalized \$20 million in construction-in-progress and have also recognized a corresponding amount as a construction financing obligation in "long-term debt" in the accompanying Consolidated Balance Sheets. We also entered into a loan agreement with Lonza to advance \$290 million to Lonza for the construction of this facility and approximately \$9 million for a related land lease option, the majority of which is not expected to be advanced until 2008. See Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further discussion of the agreements.

During the third quarter of 2005, we paid \$160 million to exercise our right to purchase a research facility in South San Francisco, California, which was subject to a synthetic lease with BNP Paribas Leasing Corporation (or "BNP"). As a result, the value of the property in South San Francisco was included in the accompanying Consolidated Balance Sheets at December 31, 2005. Prior to the purchase of this facility, we evaluated our accounting for this lease under the provisions of FASB Interpretation No. 46R (or "FIN 46R"), a revision to Interpretation 46, "Consolidation of Variable Interest Entities," and determined we were not required to consolidate either the leasing entity or the specific assets leased under the BNP lease.

During the third quarter of 2005, we paid \$425 million to extinguish the debt and acquire the noncontrolling interest related to a synthetic lease obligation on our manufacturing plant in Vacaville, California. Prior to the extinguishment of the debt, we were required to consolidate the entity from which we leased the Vacaville facility as it qualified as a variable interest entity (or "VIE") under the provisions of FIN 46R and because we were determined to be the primary beneficiary of the VIE as we absorb the majority of the entity's expected losses.

# **Commitments**

See Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

#### **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 were cancelable as of December 31, 2006. 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.

	Payments due by period (in millions)									
	_	_			2	2008 and	2	010 and		012 and
Contractual Obligations	Total		2007		2009		2011		beyond	
Operating lease obligations and										
other <sup>(1)</sup>	\$	218	\$	24	\$	50	\$	45	\$	99
Slough <sup>(2)</sup> (Financing lease)		541		19		67		75		380
Lonza <sup>(3)</sup> (Singapore facility										
agreement)		510		-		75		293		142
Purchase obligations <sup>(4)</sup>		1,567		958		532		64		13
Long-term debt <sup>(5)</sup>		2,000		-		-		500		1,500
Litigation-related and other long-term										
liabilities <sup>(6)</sup>		768		-		748		-		20
Interest expense on long-term debt <sup>(7)</sup>		1,254		101		198		161		794
Total	\$	6,858	\$	1,102	\$	1,670	\$	1,138	\$	2,948

(1)

Operating lease obligations include Owner Association Fees on buildings we own. See further discussion of our operating leases above in "Off-Balance Sheet Arrangements."

(2)

See further discussion related to the Slough lease above in "Off-Balance Sheet Arrangements."

(3)

Included in 2010 is a manufacturing milestone payment. See further discussion of the agreements with Lonza above in "Off-Balance Sheet Arrangements" and in Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

(4)

Purchase obligations include commitments related to capital expenditures, clinical development, collaborations, manufacturing and research operations and other significant purchase commitments. Purchase obligations exclude capitalized labor and capitalized interest on construction projects. Included in this line are our purchase obligations under our contract manufacturing arrangements with Lonza Biologics, a subsidiary of Lonza Group Ltd, for commercial quantities of Rituxan and with Wyeth Pharmaceuticals, a division of Wyeth, for bulk supply of Herceptin, and Novartis for the manufacture of Xolair and Lucentis. See also Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

(5)

See also Note 7, "Long-Term Debt," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

(6)

Litigation-related and other long-term liabilities include our litigation liabilities and other similar items which are reflected on our balance sheet.

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; this item is captured in the "2008 and 2009" category in the table above.

Interest expense includes the effects of an interest rate swap agreement. See also, Note 4 "Investment Securities and Financial Instruments," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

Excludes payment obligations associated with deferred tax liabilities.

In addition to the above, we have committed to make potential future "milestone" payments to third-parties as part of in-licensing and product 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 Sheets. We also entered into a loan agreement, subject to certain mutually acceptable conditions of securitization, with Lonza to advance up to \$290 million to Lonza for the construction of their Singapore facility and approximately \$9 million for a related land lease option, the majority of which is not expected to be advanced until 2008. See Note 8, "Leases, Commitments and Contingencies," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on these matters.

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(7)

#### **Stock Options**

### **Option Program Description**

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

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors or an authorized delegate. See "Compensation Discussion and Analysis" appearing in our 2007 Proxy Statement for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

#### General Option Information

# Summary of Option Activity (Shares in millions)

	Options O	utstandi	nding	
Shares		W	eighted	
Available	Number of	A	verage	
for Grant	Shares	Exer	cise Price	
102	94	\$	32.32	
(20)	20		84.01	
-	(29)		25.88	
2	(2)		42.16	
84	83	\$	46.64	
(17)	17		79.85	
-	(9)		30.42	
3	(3)		62.09	
70	88	\$	54.53	
	Available for Grant  102 (20)  - 2 84 (17) - 3	Shares         Number of Shares           102         94           (20)         20           -         (29)           2         (2)           84         83           (17)         17           -         (9)           3         (3)	Available for Grant         Number of Shares         Available Exer           102         94         \$           (20)         20         \$           -         (29)         \$           2         (2)         \$           84         83         \$           (17)         17         \$           -         (9)         \$           3         (3)         \$	

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

	Exercisable		Unexe	able	Total				
		Wtd. Avg. Exercise		Wtd. Avg. Exercise					td. Avg. Exercise
As of December 31, 2006	<b>Shares</b>		Price	Shares		Price	Shares		Price
In-the-Money	42	\$	32.16	27	\$	66.70	69	\$	45.81
Out-of-the-Money <sup>(1)</sup>	5		86.02	14		85.97	19		85.99
Total Options Outstanding	47			41			88		

(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, which was \$81.13 at the close of business on December 29, 2006.

#### Distribution and Dilutive Effect of Options

#### Employee and Executive Officer Option Grants

	2006*	2005*	2004*
Net grants during the year as % of outstanding shares	1.43%	1.70%	1.83%
Grants to Executive Officers during the period as % of			
outstanding shares	0.14%	0.18%	0.25%
Grants to Executive Officers during the year as % of			
total options granted	8.60%	9.44%	12.29%

<sup>\*</sup> Executive officers as of December 31 for the years presented.

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

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

\*\*\*\*\*

This report contains forward-looking statements regarding completion of phases for, and regulatory approval of, development projects; our Horizon 2010 strategy of brining 20 new molecules into clinical development, bringing at least 15 major new products or indications onto the market, becoming the number one U.S. oncology company in sales, and achieving certain financial growth measures; the development of our internal products providing the majority of our long-term growth; an Avastin sBLA submission; construction, qualification and licensure of our new Vacaville, Hillsboro facilities and Oceanside facility, and Lonza's Singapore facility; manufacturing of Avastin and Rituxan by Lonza; the adequacy of our capital resources to meet long-term growth; Wyeth's manufacture of Herceptin; the Avastin Patient Assistance program; new product indication launches for Avastin; Avastin sales growth and sales growth in recently approved indications; sales to collaborators; royalty and contract revenue; collaboration profit sharing and sales for collaborative products; the effects of the Medicare Prescription Drug Improvement and Modernization Act on our revenues; expenditures to comply with environmental laws; stock-based compensation, R&D and MG&A expenses; other income, net; effective income tax rate; inventory levels; capital expenditures; extending a loan to Lonza; the effect of FIN 48 on our results of operations and financial position; and the acquisition of Tanox and closing certain licensing transactions.

These forward-looking statements involve risks and uncertainties, and the cautionary statements set forth below and those contained in "Risk Factors" in this Form 10-K identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. Such factors include, but are not limited to, additional time requirements for data analysis; BLA preparation and decision making; FDA actions or delays; failure to obtain FDA approval; difficulty in obtaining materials from suppliers; unexpected safety, efficacy or manufacturing issues for us or our contract/collaborator manufacturers; the ability to supply product and meet demand for our products; increased capital expenditures including greater than expected construction and validation costs; product withdrawals; competition; pricing decisions by us or our competitors; our ability to protect our proprietary rights; the outcome of, and expenses associated with, litigation or legal settlements; the level of patient participation in the Avastin Patient Assistance Program; increased R&D, MG&A and environmental expenses, and increased cost of sales; variations in collaborator sales and expenses; our indebtedness and ability to pay our indebtedness; actions by Roche that are adverse to our interests; decreases in third party reimbursement rates; greater than expected income tax rate; the ability of management and others to integrate new employees into our culture; the number of options granted to employees, Genentech's stock price and certain valuation assumptions concerning Genentech stock; and the extent to which all closing conditions are met for our proposed acquisition of Tanox and certain licensing transactions,

including the absence of a material adverse effect with respect to Tanox, the extent to which such transactions are permitted under the antitrust laws, and the extent to which we have cash on hand to consummate such transactions. We disclaim and do not undertake any obligation to update or revise any forward-looking statement in this Form 10-K.

# 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. 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 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 (or "VAR") estimation as fair market value loss. Our VAR model utilizes historical simulation of daily market data over the past three years and calculates market data changes using a 21-trading day holding period to estimate expected loss in fair value at a 95% confidence level. The VAR model is not intended to represent actual losses but is used as a risk estimation and management tool.

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

#### Interest Rate Risk

Our 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 \$4,747 million or 32% of total assets at December 31, 2006 and \$4,169 million or 34% of total assets at December 31, 2005. Interest income related to this portfolio was \$230 million in 2006 and \$143 million in 2005. 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.

Our long-term debt is comprised of the following debt instruments: \$500 million principal amount of 4.40% Senior Notes due 2010, \$1.0 billion principal amount of 4.75% Senior Notes due 2015 and \$500 million principal amount of 5.25% Senior Notes due 2035. To protect the fair value of our 2010 Notes against fluctuations in the benchmark U.S. interest rates, we entered into a series of interest rate swap agreements with respect to the 2010 Notes. See Note 7, "Long-Term Debt," and Note 4, "Investment Securities and Financial Instruments — Derivative Financial Instruments," section in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.

Based on our overall interest rate exposure, which includes the net effect of our interest rate exposures on our interest-bearing assets and our Senior Note debt instruments, using a 21-trading day holding period with a 95% confidence level, the potential loss in estimated fair value of our interest rate sensitive instruments was \$24 million at December 31, 2006 and \$34 million at December 31, 2005. A significant portion of the potential loss in estimated fair value at both December 31, 2006 and 2005 was attributed to the longer duration of our Senior Notes.

## 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. Our exposure to foreign

exchange rates is most significant relative to the Swiss Franc, though we are also exposed to changes in exchange rates elsewhere in Europe, Asia (primarily Japan) and Canada. 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. Currently, our foreign currency royalty revenues exceed our foreign currency expenses. In addition, as part of our overall investment strategy, a portion of our portfolio is in non-dollar denominated investments. As a result, we are exposed to changes in the exchange rates of the currencies in which these non-dollar investments are denominated.

To mitigate our net foreign exchange exposure, our policy allows us to hedge certain of our anticipated royalty revenues by entering into option or forward contracts with one to five year expiration dates and amounts of currency that are based on up to 90% of forecasted future revenues so that the potential adverse effect 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. As of December 31, 2006, these options and forwards are due to expire in 2007 through 2008.

Based on our overall currency rate exposure, using a 21-trading day holding period with a 95% confidence level, the potential loss in the estimated fair value of our foreign currency sensitive instruments was \$17 million at December 31, 2006 and \$18 million at December 31, 2005. Because we use foreign currency instruments to hedge anticipated future cash flows, losses incurred on those instruments are generally offset by increases in the fair value of the underlying future cash flows they were intended to hedge.

#### **Equity Security Risks**

As part of our strategic alliance efforts, we invest in publicly traded equity instruments of biotechnology companies. Our biotechnology equity investment portfolio totaled \$360 million or 2% of total assets at December 31, 2006 and \$375 million or 3% of total assets at December 31, 2005. Impairment charges on our biotechnology equity investments were \$4 million in 2006 and \$5 million in 2005. 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 forward contract, we receive interest income based on the notional amount and a floating-rate index. 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, using a 21-trading day holding period with a 95% confidence level, the potential loss in estimated fair value of our equity securities portfolio was \$24 million at December 31, 2006 and \$19 million at December 31, 2005.

Also, as part of our strategic alliance efforts, we invest in privately held biotechnology companies, some of which are in the startup stage. These investments are primarily carried at cost, which were \$33 million at December 31, 2006 and \$29 million at December 31, 2005, and are recorded in "other long-term assets" in the Consolidated Balance Sheets.

Our impairment charges on investments in privately held companies was \$5 million in 2005. Our evaluation of investments in private companies is based on the fundamentals of the businesses, including, among other factors, the nature and success of their R&D efforts.

## Counterparty 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 the accompanying consolidated balance sheets of Genentech, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, 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 Note 2 to the consolidated financial statements, in 2006 Genentech, Inc. changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment".

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, 2006, 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 5, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California February 5, 2007

## CONSOLIDATED STATEMENTS OF INCOME

(in millions, except per share amounts)

	Year Ended December 31,				
	2006		2005		2004
Revenues					
Product sales (including amounts from related parties:					
2006-\$364; 2005-\$184; 2004-\$112)	\$ 7,640	\$	5,488	\$	3,749
Royalties (including amounts from related parties:					
2006-\$849; 2005-\$501; 2004-\$335)	1,354		935		641
Contract revenue (including amounts from related					
parties: 2006-\$165; 2005-\$115; 2004-\$121)	290		210		231
Total operating revenues	9,284		6,633		4,621
Costs and expenses					
Cost of sales (including amounts for related parties:					
2006-\$272; 2005-\$171; 2004-\$96)	1,181		1,011		673
Research and development (including amounts for					
related parties: 2006-\$251; 2005-\$183; 2004-\$169)					
(including contract related: 2006-\$185; 2005-\$144;					
2004-\$132)	1,773		1,262		948
Marketing, general and administrative	2,014		1,435		1,088
Collaboration profit sharing (including amounts for a					
related party: 2006-\$187; 2005-\$136; 2004-\$75)	1,005		823		594
Recurring charges related to redemption	105		123		145
Special items: litigation-related	54		58		37
Total costs and expenses	6,132		4,712		3,485
Operating income	3,152		1,921		1,136
Other income (expense):					
Interest and other income (expense), net	325		142		91
Interest expense	(74)		(50)		(7)
Total other income, net	251		92		84
Income before taxes	3,403		2,013		1,220
Income tax provision	1,290		734		435
Net income	\$ 2,113	\$	1,279	\$	785
Earnings per share					
Basic	\$ 2.01	\$	1.21	\$	0.74
Diluted	\$ 1.97	\$	1.18	\$	0.73
	1.070		4.077		4.075
Shares used to compute basic earnings per share	1,053		1,055		1,055
Shares used to compute diluted earnings per share	1,073		1,081		1,079

See Notes to Consolidated Financial Statements.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)

	Year Ended December 31,							
		2006		2005		2004		
Cash flows from operating activities								
Net income	\$	2,113	\$	1,279	\$	785		
Adjustments to reconcile net income to net cash								
provided by operating activities:								
Depreciation and amortization		407		370		353		