

Edgar Filing: GENENTECH INC - Form 10-K

GENENTECH INC
Form 10-K
March 12, 2001

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

(Mark One)

X ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2000

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.

A Delaware Corporation
(State or other jurisdiction of
incorporation or organization)

94-2347624
(I.R.S. employer
identification number)

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

(650) 225-1000
(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

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

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

The approximate aggregate market value of voting stock held by nonaffiliates of the registrant is \$12,980,808,884 as of January 31, 2001. (A)

Number of shares of Common Stock outstanding as of January 31, 2001:
525,712,793

Documents incorporated by reference:

DOCUMENT PARTS INCORPORATED BY REFERENCE

Edgar Filing: GENENTECH INC - Form 10-K

- | | |
|---|-----|
| (1) Annual Report to stockholders for the year ended
December 31, 2000 (specified portions) | II |
| (2) Definitive Proxy Statement with respect to the 2001
Annual Meeting of Stockholders to be filed by Genentech,
Inc. with the Securities and Exchange Commission
(hereinafter referred to as "Proxy Statement") | III |
-
- (A) Excludes 306,627,411 shares of Common Stock held by Directors and Officers of Genentech and Roche Holdings, Inc.

In this Form 10-K, "Genentech," "we," "us" and "our" refer to Genentech, Inc., "Common Stock" refers to Genentech's common stock, par value \$0.02 per share, "Special Common Stock" refers to Genentech's callable puttable Common Stock, par value \$0.02 per share and "Redeemable Common Stock" refers to Genentech's redeemable common stock, par value \$0.02 per share. In addition, all numbers relating to the number of shares, price per share and per share amounts of Common Stock, Special Common Stock and Redeemable Common Stock give effect to the two-for-one splits of our Common Stock that were effected in October 2000 and November 1999.

BASIS OF PRESENTATION AND RESTATEMENT

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche Holdings, Inc., commonly known as Roche, with funds deposited by Roche for that purpose. This event, referred to as the "Redemption" in this report, caused Roche to own 100% of the outstanding common stock of Genentech on that date. The Redemption of our Special Common Stock on June 30, 1999 was reflected as a purchase of a business which, under U.S. generally accepted accounting principles, required push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value. The Redemption created our New Basis of accounting as discussed further below. The Redemption was effective as of June 30, 1999, however, the transaction was reflected as of the end of the day on June 30, 1999 in the financial statements. We previously issued consolidated financial statements that presented limited information related to the results of operations for the period January 1, 1999 through June 30, 1999 immediately prior to the Redemption ("Old Basis"), and the period June 30, 1999 (including and subsequent to the Redemption) to December 31, 1999 ("New Basis"). We did not present separate statements of operations, stockholders' equity or cash flows reflecting the new basis of accounting. Upon further review and based on discussions with the Securities and Exchange Commission, our statements of operations, cash flows and stockholders' equity have been revised and presented on the New Basis of accounting that resulted from the Redemption transaction. As such, a vertical black line is inserted to separate the "Old Basis" and "New Basis" presentation in the financial statements. For more information about Old Basis and New Basis, you should read the "Consolidated Financial Statements" and the "Basis of Presentation and Restatement" note in the Notes to Consolidated Financial Statements (Part II, Item 8 of this Form 10-K). Accordingly, the Old Basis reflects the period January 1 through June 30, 1999, and all periods prior to the Redemption, and the New Basis reflects the period from June 30 through December 31, 1999, and all subsequent periods. As a result of the accounting change, we reclassified \$941.5 million from accumulated deficit to additional paid-in capital.

We also restated our financial statements to correct the accounting related to the write up of the valuation allowance pertaining to unrealized gains on certain marketable equity securities, resulting from

Edgar Filing: GENENTECH INC - Form 10-K

the Redemption. As a result of this accounting change, the aggregate amount of contract and other income in 1999 decreased by \$20.3 million, and net income decreased by \$13.6 million (\$0.03 per share) for the quarter and six month period ended June 30, 1999. In addition, amortization expense decreased by \$0.6 million (less than \$0.01 per share) during the six month period ended December 31, 1999, and goodwill, net of accumulated amortization, decreased by \$19.7 million, other accrued liabilities decreased by \$6.8 million and accumulated deficit increased by \$12.9 million at December 31, 1999.

PART I

ITEM 1. Business

Genentech is a leading biotechnology company using human genetic information to discover, develop, manufacture and market human pharmaceuticals that address significant unmet medical needs. Fourteen of the approved products of biotechnology stem from our science. We manufacture and market nine protein-based pharmaceuticals listed below, and license several additional products to other companies. See the "Products" section below for further information.

Redemption of Our Special Common Stock

On June 30, 1999, we redeemed all of our outstanding Special Common Stock held by stockholders other than Roche Holdings, Inc., commonly known as Roche, at a price of \$20.63 per share in cash with funds deposited by Roche for that purpose. We refer to this event as the "Redemption." As a result, on that date, Roche's percentage ownership of our outstanding Common Stock increased from 65% to 100%. Consequently, under U.S. generally accepted accounting principles, we were required to use push-down accounting to reflect in our financial statements the amounts paid for our stock in excess of our net book value. Push-down accounting required us to record \$1,685.7 million of goodwill and \$1,499.0 million of other intangible assets onto our balance sheet on June 30, 1999. Also, as a result of push-down accounting, we recorded special charges related to the Redemption of \$1,207.7 million on June 30, 1999. For more information about special charges and push-down accounting, you should read "Special Charges" in the Financial Review section (Part II, Item 7 of this Form 10-K) and the "Redemption of Our Special Common Stock" note in the Notes to Consolidated Financial Statements (Part II, Item 8 of this Form 10-K). Roche subsequently made public offerings of our Common Stock as described below.

Stock Splits

On October 24, 2000, we effected a two-for-one stock split of our Common Stock in the form of a dividend of one share of Genentech Common Stock for each share held at the close of business on October 17, 2000. Our stock began trading on a split-adjusted basis on October 25, 2000. On November 2, 1999, we effected a two-for-one stock split of our Common Stock in the form of a dividend of one share of Genentech Common Stock for each share held at the close of business on October 29, 1999. Our stock began trading on a split-adjusted basis on November 3, 1999. All information in this report relating to the number of shares, price per share and per share amounts of Common Stock, Special Common Stock and Redeemable Common Stock give effect to these splits. We currently intend to retain all future income for use in the operation of our business and to fund future growth and, therefore we do not intend to declare or pay any cash dividends on our Common Stock in the foreseeable future.

Edgar Filing: GENENTECH INC - Form 10-K

Public Offerings

On July 23, 1999, October 26, 1999, and March 29, 2000, Roche completed public offerings of our Common Stock. We did not receive any of the net proceeds from these offerings. On January 19, 2000, Roche completed an offering of zero-coupon notes that are exchangeable for an aggregate of 13,034,618 shares of our Common Stock held by Roche. Roche's percentage ownership of our outstanding Common Stock is approximately 58.4% at December 31, 2000.

As a result of the Redemption and the subsequent public offerings, changes occurred with respect to our stock options as discussed below in "Stock Options Changes." In addition, we amended our certificate of incorporation and bylaws, amended our licensing and marketing agreement with F. Hoffmann-La Roche Ltd, and entered into or amended certain agreements with Roche, which are discussed below in "Relationship With Roche."

Products

We manufacture and market nine protein-based pharmaceuticals listed below and license several others to other companies.

- Herceptin, registered trademark, (trastuzumab) antibody for the treatment of certain patients with metastatic breast cancer whose tumors overexpress the human epidermal growth factor receptor2, or HER2, protein;
- Rituxan, registered trademark, (rituximab) antibody which we market together with IDEC Pharmaceuticals Corporation, commonly known as IDEC, for the treatment of patients with relapsed or refractory low-grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma;
- TNKase, registered trademark, (tenecteplase) single-bolus thrombolytic agent for the treatment of acute myocardial infarction;
- Activase, registered trademark, (alteplase, recombinant) tissue plasminogen activator, or t-PA, for the treatment of acute myocardial infarction, acute ischemic stroke within three hours of the onset of symptoms and acute massive pulmonary embolism;
- Nutropin Depot, registered trademark, [somatropin (rDNA origin) for injectable suspension] long-acting growth hormone for the treatment of growth failure associated with pediatric growth hormone deficiency;
- Nutropin AQ, registered trademark, [somatropin (rDNA origin) injection] liquid formulation growth hormone for the same indications as Nutropin;
- Nutropin, registered trademark, [somatropin (rDNA origin) for injection] growth hormone for the treatment of growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency prior to kidney transplantation and short stature associated with Turner syndrome;
- Protropin, registered trademark, (somatrem for injection) growth hormone for the treatment of inadequate endogenous growth hormone secretion, or growth hormone deficiency, in children; and
- Pulmozyme, registered trademark, (dornase alfa, recombinant) inhalation solution for the treatment of cystic fibrosis.

We receive royalties on sales of rituximab outside of the United States (excluding Japan), on sales of Pulmozyme and Herceptin outside of the United

Edgar Filing: GENENTECH INC - Form 10-K

States and on sales of certain products in Canada from F. Hoffmann-La Roche Ltd, an affiliate of Roche Holdings, Inc., that is commonly known as Hoffmann-La Roche. We receive royalties on sales of growth hormone products and t-PA outside of the United States and Canada, and we will receive royalties on sales of rituximab in Japan through other licensees. We also receive worldwide royalties on seven additional licensed products that are marketed by other companies. Six of these products originated from our technology.

Herceptin

In September 1998, we received U.S. Food and Drug Administration, or FDA, approval to market Herceptin in the United States for use as a first line therapy in combination with Taxol, registered trademark, (paclitaxel), a product made by Bristol-Myers Squibb Company, or Bristol-Myers, and as a single agent in second and third line therapy in patients with metastatic breast cancer who have tumors that overexpress the HER2 protein.

Herceptin is the first humanized monoclonal antibody for the treatment of HER2 overexpressing metastatic breast cancer and the second U.S. approval in this new class of monoclonal antibody biotherapeutic cancer drugs. We have granted Hoffmann-La Roche exclusive marketing rights to Herceptin outside of the United States.

In September 1999, Hoffmann-La Roche announced it had obtained authorization to sell Herceptin in Switzerland as a treatment for breast cancer. This was the product's first European approval and came shortly after authorization of the product in Canada for treatment of metastatic or advanced breast cancer, alone, and in combination with Taxol. During the third quarter of 2000, Hoffmann-La Roche received approval from the European Commission to market Herceptin for the treatment of HER2-positive metastatic breast cancer in Europe. We receive royalties from Hoffmann-La Roche for these Herceptin product sales.

On May 3, 2000, we sent a letter to physicians advising them of some serious adverse events that have been reported related to the use of Herceptin in certain patients and that have occurred subsequent to its approval. In 15 patients who experienced such serious adverse events following Herceptin therapy, death ensued. Nine of these patients died within 24 hours after Herceptin administration. Most of these patients had significant pre-existing pulmonary compromise as a consequence of lung disease or malignancies that had spread to the lung. On October 6, 2000, we issued a follow-up letter to physicians which included an amended package insert for Herceptin including this information.

Rituxan

Rituxan is marketed in the United States for the treatment of relapsed or refractory low-grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma, a cancer of the immune system. We co-developed Rituxan with IDEC from whom we license Rituxan. In November 1997, Rituxan was cleared for marketing in the United States by the FDA. Rituxan was the first monoclonal antibody approved in the United States to treat cancer. We jointly promote Rituxan with IDEC in the United States. We shared responsibility with IDEC for manufacturing the product, until the end of the third quarter of 1999, when IDEC finished transferring all bulk manufacturing responsibilities for Rituxan to us. Hoffmann-La Roche is responsible for marketing MabThera, registered trademark, (rituximab) in the rest of the world, excluding Japan, and has agreed to pay us royalties and a mark-up on the supply of MabThera. In 1999, Genentech and IDEC, in consultation with the FDA, updated the warning section of the package insert for Rituxan to include information on infusion-related reactions and cardiovascular events. IDEC filed a

Edgar Filing: GENENTECH INC - Form 10-K

supplemental Biologics License Application, or BLA, in October 1999 related to the use of Rituxan in expanded dosing, including retreatment, times 8 and bulky disease for the treatment of B-cell non-Hodgkin's lymphoma.

In December 1998, a letter was sent to physicians advising them of some deaths associated with administration of Rituxan. As a result, Genentech and IDEC updated the warning section of the package insert to include information on infusion-related reactions and cardiovascular events.

Activase and TNKase

Tissue plasminogen activator, or t-PA, is an enzyme that is produced naturally by the body to dissolve blood clots. However, when a blood clot obstructs blood flow in the coronary artery and causes a heart attack, the body is unable to produce enough t-PA to dissolve the clot rapidly enough to prevent damage to the heart. We produce Activase, a recombinant form of t-PA, in sufficient quantity for therapeutic use. The FDA approved Activase for marketing in the United States in 1987 for the treatment of acute myocardial infarction (heart attack); in 1990 for use in the treatment of acute pulmonary embolism (blood clots in the lungs); and in June 1996 for the treatment of acute ischemic stroke or brain attack (blood clots in the brain) within three hours of symptom onset. TNKase received FDA approval in early June 2000 and was launched in late June 2000.

In exchange for royalty payments, we have licensed marketing rights to a recombinant t-PA in Japan to Kyowa Hakko Kogyo, Ltd., or Kyowa, and Mitsubishi Chemical Corporation, formerly Mitsubishi Kasei Corporation, or Mitsubishi. Kyowa and Mitsubishi are marketing forms of a recombinant t-PA under the trademarks Activacin, registered trademark, and GRTPA, registered trademark, respectively. In a number of countries outside of the United States, Canada and Japan, we have licensed t-PA marketing and manufacturing rights to Boehringer Ingelheim, GmbH. We have also licensed certain rights to Boehringer Ingelheim regarding future sales of TNKase. Boehringer Ingelheim, which markets a recombinant t-PA under the trademark Actilyse, registered trademark, filed a marketing application for Metalyse, registered trademark, (tenecteplase), with European regulatory authorities in September 1999. Boehringer Ingelheim has received marketing approval for Metalyse in Switzerland and Australia.

Nutropin Depot

In December 1999, we received regulatory approval to market Nutropin Depot. We launched this product in late June 2000. Nutropin Depot is a long-acting form of our recombinant human growth hormone using ProLease, registered trademark, an injectable extended-release drug delivery system, which was developed by our partner Alkermes, Inc. This new formulation was designed to reduce the frequency of injections by encapsulating the drug in biodegradable microspheres.

During the first quarter of 1999, we entered into an agreement with Schwarz Pharma AG, for the development and distribution of Nutropin AQ and the sustained-release Nutropin Depot for the treatment of certain pediatric and adult growth disorders in Europe and certain other countries outside of the United States, Canada and Japan. With our partner, Alkermes, we will manufacture these products for sale by Schwarz Pharma. The agreement also entitles us to receive additional benchmark payments upon achievement of certain product development milestones. As part of a strategic alliance with Sumitomo Pharmaceuticals Co., Ltd., or Sumitomo, we have agreed to provide Sumitomo exclusive rights to develop, import and distribute in Japan, Nutropin Depot.

Nutropin AQ

Edgar Filing: GENENTECH INC - Form 10-K

In December 1995, we received regulatory approval to market Nutropin AQ, a liquid formulation of Nutropin, aimed at providing improved convenience in administration. Nutropin AQ is the first and only liquid (aqueous) recombinant human growth hormone product available in the United States. Nutropin AQ was approved for the treatment of growth hormone inadequacy in children, growth hormone failure in children associated with chronic renal insufficiency up to the time of renal transplantation and short stature associated with Turner syndrome. In December 1997, we received FDA approval to market Nutropin AQ for the treatment of growth hormone deficiency in adults.

Nutropin

Nutropin is a human growth hormone similar to Protropin, see below,; however, it does not have the additional N-terminal amino acid, methionine, found in the Protropin chemical structure. Nutropin was approved in November 1993 and launched in January 1994 for marketing in the United States for the treatment of growth failure in children associated with chronic renal insufficiency up to the time of renal transplantation. Nutropin had been designated as a U.S. Orphan Drug for treatment of growth failure in children with chronic renal insufficiency. This status terminated in November 2000. Nutropin was approved by the FDA in March 1994 for the treatment of growth hormone inadequacy in children. In December 1996, the FDA approved Nutropin for the treatment of short stature associated with Turner syndrome. In December 1997, we received FDA approval to market Nutropin for the treatment of growth hormone deficiency in adults.

Protropin

Human growth hormone is a naturally occurring human protein produced in the pituitary gland that regulates metabolism and is responsible for growth in children. We developed a recombinant growth hormone product, Protropin, that was approved by the FDA in 1985 for marketing in the United States for the treatment of growth hormone inadequacy in children.

In exchange for royalty payments, we licensed rights to manufacture and market recombinant growth hormone to Pharmacia Corporation, which manufactures and markets recombinant growth hormone under the trademarks Genotropin, registered trademark, (somatotropin (rDNA) for injection) and Genotropin MiniQuick, registered trademark.

Pulmozyme

Pulmozyme is marketed in the United States for the treatment of cystic fibrosis, for which it had U.S. Orphan Drug designation. This status terminated in December 2000. It was first approved for use in 1993. In November 1996, Pulmozyme was cleared for marketing by the FDA for the treatment of cystic fibrosis patients with advanced disease. In February 1998, we received approval from the FDA for a label extension that includes the safety and alternative administration of Pulmozyme in children with cystic fibrosis under the age of five, adding to the product's previous approvals for patients five years of age and older.

Actimmune

Actimmune interferon gamma-1b is approved in the United States for the treatment of chronic granulomatous disease. In 1998, we licensed certain U.S. marketing and development rights to interferon gamma, including Actimmune to Connetics Corporation in return for a royalty on net sales. Thereafter, Connetics sublicensed all of its rights to InterMune Pharmaceuticals, Inc., or InterMune. As of January 1999, we no longer sell

Edgar Filing: GENENTECH INC - Form 10-K

Actimmune directly in the United States. We have agreed to sell packaged drug product to InterMune at cost plus a mark-up. We receive royalty payments from Boehringer Ingelheim from the sale of interferon gamma in certain countries outside of the United States, Canada and Japan and The People's Republic of China.

Licensed Products

In addition to the royalties mentioned above, we also receive royalties on the following products:

Product	Trademark	Company
Human growth hormone	Humatrope	Eli Lilly and Company
Recombinant interferon alpha	Roferon-A	Hoffmann-La Roche
Hepatitis B vaccine	Recombivax	Merck and Company, Inc.
Hepatitis B vaccine	Engerix-B	GlaxoSmithKline plc (formerly SmithKline Beecham Biologicals S.A.)
Factor VIII	Kogenate	Bayer Corporation
Bovine growth hormone	Posilac	Monsanto Company
Interferon gamma-1b	Actimmune	InterMune
Soluble TNF receptor	Enbrel	Immunex Corporation

In May 1999, we entered into a license agreement with Immunex Corporation. We granted to Immunex a worldwide, co-exclusive license under our immunoadhesin patents to make, use and sell Enbrel, registered trademark, Immunex's product to treat moderately to severely active rheumatoid arthritis. Immunex paid us an initial license fee and has agreed to pay royalties on sales of Enbrel from November 6, 1998, the date of product launch, through the life of our patents.

Products in Development

A number of other products are in various stages of research and development, or R&D. Our product development efforts cover a wide range of medical conditions, including cancer, respiratory disorders, cardiovascular diseases, endocrine disorders and inflammatory and immune problems.

Below is a summary of products in clinical development:

Product	Description
Awaiting Regulatory Approval	
Activase t-PA	A protein that is an approved treatment for heart attack, acute ischemic stroke within three hours of symptom onset, and acute massive pulmonary embolism. We have completed a Phase III trial of this product for intravenous catheter clearance and have submitted U.S. regulatory filings seeking marketing approval.
Xolair, trademark, (Anti-IgE Antibody)	An anti-IgE monoclonal antibody designed to interfere early in the process

Edgar Filing: GENENTECH INC - Form 10-K

leading to symptoms of allergic asthma and seasonal allergic rhinitis. In collaboration with Novartis Pharmaceuticals Corporation, or Novartis, and Tanox, Inc., Phase III clinical trials have been completed in patients with allergic asthma and in patients with seasonal allergic rhinitis and we have submitted U.S. and European regulatory filings seeking marketing approval.

Phase III

Xanelim, trademark

An antibody designed to block certain immune cells as a potential treatment for psoriasis. In collaboration with XOMA Corporation, we are currently conducting Phase III trials in patients with psoriasis.

TNKase

A second generation tissue-plasminogen activator (t-PA) that is a selectively mutated version of wild-type t-PA. TNKase is being studied in combination with various anti-thrombotic agents in the potential treatment of acute myocardial infarction. This product is being developed in collaboration with Boehringer Ingelheim.

Rituxan antibody

A monoclonal antibody approved for the treatment of relapsed or refractory low-grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma, a cancer of the immune system. We are in Phase III clinical trials for the treatment of intermediate- and high-grade non-Hodgkin's lymphoma. This product is being developed in collaboration with IDEC.

Thrombopoietin (TPO)

A protein that is being studied for treatment of thrombocytopenia, a reduction in platelets, in cancer patients treated with chemotherapy. This molecule has been exclusively licensed to Pharmacia.

Tezosentan

Tezosentan, a small molecule, is an endothelin receptor antagonist being developed as a potential treatment for patients with acute heart failure. Tezosentan, which is currently in Phase III clinical trials, is being developed in collaboration with Actelion, Ltd.

Anti-VEGF antibody

An antibody developed to inhibit angiogenesis (the formation of new blood vessels) as a potential treatment for solid-tumor cancers. Phase III trials are ongoing to treat several types of solid

Edgar Filing: GENENTECH INC - Form 10-K

tumors.

Herceptin antibody

An antibody that is an approved treatment for metastatic breast cancer. In collaboration with Hoffmann-La Roche and U.S. national cooperative groups, we are conducting Phase III trials for adjuvant treatment of early-stage breast cancer in patients who overexpress the HER2 protein.

Tracleer (Bosentan)

An orally administered endothelin receptor antagonist that is being developed for the potential treatment of pulmonary hypertension (New Drug Application, or NDA, filed) and congestive heart failure (Phase III). The development effort is being led by our partner Actelion.

Preparing for Phase III trials

Nutropin Depot for adult
growth hormone deficiency

Nutropin Depot is a long-acting formulation of growth hormone developed in collaboration with Alkermes. The product is approved for the treatment of growth failure associated with pediatric growth hormone deficiency. Phase III trials are being planned for the treatment of adults with growth hormone deficiency.

Phase II

Herceptin antibody

An antibody that is an approved treatment for metastatic breast cancer. Herceptin is being evaluated for application in other tumor types in which the HER2 protein is overexpressed, including lung cancer. We are conducting Phase II studies alone or in collaboration with Hoffmann-La Roche, the National Cancer Institute or other clinical research groups.

LDP-02

A monoclonal antibody for the treatment of inflammatory bowel diseases. This product is licensed from and being developed in collaboration with Millennium Pharmaceuticals, Inc., formerly Leukosite, Inc., or Millennium. Millennium is conducting Phase II clinical trials in Canada.

INS365

A second generation P2Y2 agonist, for the potential treatment of patients with chronic bronchitis. Our partner, Inspire Pharmaceuticals, Inc., or Inspire, is currently planning to initiate a Phase II trial.

Dornase alfa inhalation

A recombinant human protein used for the

Edgar Filing: GENENTECH INC - Form 10-K

solution with Aradigm's
delivery system

treatment of cystic fibrosis. Aradigm Corporation completed a Phase IIa clinical trial of dornase alfa delivery via Aradigm's AERx, trademark, delivery system. We canceled the program in late January 2001.

Phase I

AMD Fab

A customized fragment of an anti-VEGF antibody for the potential treatment of age-related macular degeneration, or AMD. In this condition, excessive blood vessel growth in the retina of the eye can lead to blindness. Phase I trials are being conducted.

E-26

A second generation anti-IgE monoclonal antibody for the potential treatment of allergic asthma and allergic rhinitis. E26 is being developed in collaboration with Novartis and Tanox. The product has completed Phase I trials.

Anti-CD11a Antibody

An antibody designed to block certain immune cells as a potential treatment to prevent solid organ transplant rejection. Our collaborator, Xoma, is conducting Phase I trials.

INS37217

A second generation P2Y2 agonist, for the potential treatment of patients with cystic fibrosis, being developed in collaboration with Inspire.

Preparing for Phase I trials

Apo2 Ligand/TRAIL

A protein, also known as tumor necrosis factor-related apoptosis-inducing ligand, for the potential treatment of cancer. In collaboration with Immunex, we are currently conducting preclinical studies in order to enable an Investigational New Drug exemption application, or IND, filing.

2C4

2C4 is a monoclonal antibody directed against the human epidermal growth factor receptor, type 2 (HER2) as a potential treatment for cancer. 2C4 is designed to block the association of HER2 with other HER family members, thereby inhibiting intra-cellular signaling through the HER pathway. We are currently conducting preclinical studies in order to enable an IND filing.

In conjunction with our amended licensing and marketing agreement with Hoffmann-La Roche in July, 1999, Hoffmann-La Roche was granted an option until at least 2015 for licenses to use and sell certain of our products in non-U.S. markets (the Licensing Agreement). See "Relationship With Roche"

Edgar Filing: GENENTECH INC - Form 10-K

below for further information.

In general, with respect to our products, Hoffmann-La Roche pays us a royalty on aggregate sales outside of the United States. Hoffmann-La Roche has rights to, and pays us royalties for, Canadian sales of Activase, Nutropin Depot, Nutropin AQ, Nutropin, Protropin, Pulmozyme, Actimmune and Rituxan, and outside of the United States, excluding Japan, sales of Pulmozyme, Herceptin and MabThera. We supply the products to Hoffmann-La Roche, and have agreed to supply the products for which Hoffmann-La Roche has exercised its option, for sales outside of the United States.

In addition to the products described above, we are working on additional products and new indications for currently marketed products. In May 1999, we entered into a license and collaboration agreement with Aradigm Corporation to develop an advanced pulmonary delivery system for our Pulmozyme product in the United States. As part of the agreement, we agreed to provide Aradigm a loan of up to \$10.4 million for development costs. In late January 2001, we canceled the program and we forgave the loan. We expect to record a charge of approximately \$7.0 million to development costs in the first quarter of 2001 related to this cancellation.

In November 1997, we entered into a research collaboration agreement with CuraGen Corporation, whereby we made a \$5.0 million equity investment in CuraGen and agreed to provide a convertible equity loan to CuraGen of up to \$26.0 million. In October 1999, CuraGen exercised its right to borrow \$16.0 million. Simultaneously, with this draw down, CuraGen repaid the loan by issuing 977,636 shares of CuraGen stock valued at \$16.37 per share at such issuance, or an aggregate of \$16.0 million. At December 31, 2000, there were no outstanding loans to CuraGen.

In December 1997, we entered into a collaboration agreement with Millennium to develop and commercialize Millennium's LDP-02, a humanized monoclonal antibody for the potential treatment of inflammatory bowel diseases. Under the terms of the agreement, we made a \$4.0 million equity investment in Millennium and have agreed to provide a convertible equity loan for approximately \$15.0 million to fund Phase II development costs. Upon successful completion of Phase II, if Millennium agrees to fund 25% of Phase III development costs, we have agreed to provide a second loan to Millennium for such funding. As of December 31, 2000, there were no outstanding loans to Millennium.

Distribution

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

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

During the year, we provided certain marketing programs relating to Activase, including comprehensive wastage replacement and expired product programs for Activase that, subject to specific conditions, provides customers the right to return Activase to us for replacement related to both patient-related product wastage and product expiration. We maintain the right to renew, modify or discontinue the above programs.

Edgar Filing: GENENTECH INC - Form 10-K

As discussed in the "Segment, Significant Customer And Geographic Information" note in the Notes to Consolidated Financial Statements (Part II, Item 8 of this Form 10-K), we had four major customers, including Hoffmann-La Roche, who individually provided over 10% of our total revenues in at least one of the last three years. Also discussed in the note are material foreign revenues by country in 2000, 1999 and 1998.

Raw Materials

Raw materials and supplies required for the production of our principal products are generally available in quantities adequate to meet our needs.

Proprietary Technology - Patents and Trade Secrets

We seek patents on inventions originating from our ongoing R&D activities. Patents issued or applied for cover inventions ranging from basic recombinant DNA techniques to processes relating to specific products and to the products themselves. We have either been granted patents or have patent applications pending that relate to a number of current and potential products including products licensed to others. We consider that in the aggregate our patent applications, patents and licenses under patents owned by third-parties are of material importance to our operations. Important legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the United States and other important markets outside of the United States. We expect that litigation will likely be necessary to determine the validity and scope of certain of our proprietary rights. We are currently involved in a number of patent lawsuits, as either a plaintiff or defendant, and administrative proceedings relating to the scope of protection of our patents and those of others. These lawsuits and proceedings may result in a significant commitment of our resources in the future. We cannot assure you that the patents we obtain or the unpatented proprietary technology we hold will afford us significant commercial protection.

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

Our trademarks, Actimmune, Activase, Herceptin, Nutropin Depot, Nutropin AQ, Nutropin, Protropin, Pulmozyme, Rituxan (licensed from IDEC), TNKase (licensed from Boehringer Ingelheim), Xolair (licensed from Novartis) and Xanelim 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.

Our royalty income for patent licenses, know-how and other related rights amounted to \$207.2 million in 2000, \$189.3 million in 1999, and \$229.6 million in 1998. Royalty expenses were \$100.3 million in 2000, \$88.8 million in 1999, and \$66.3 million in 1998.

Competition

We face competition, and believe significant long-term competition can be expected, from large pharmaceutical companies and pharmaceutical divisions of chemical companies as well as biotechnology companies. This competition can be expected to become more intense as commercial applications for biotechnology products increase. Some competitors, primarily large pharmaceutical companies, have greater clinical, regulatory and marketing resources and experience than us. Many of these companies have commercial arrangements with other companies in the biotechnology industry to supplement

Edgar Filing: GENENTECH INC - Form 10-K

their own research capabilities.

The introduction of new products or the development of new processes by competitors or new information about existing products may result in price reductions or product replacements, even for products protected by patents. However, we believe our competitive position is enhanced by our commitment to research leading to the discovery and development of new products and manufacturing methods. Other factors that should help us meet competition include ancillary services provided to support our products, customer service, and dissemination of technical information to prescribers of our products and to the health care community, including payers.

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

Herceptin

Herceptin is the first humanized monoclonal antibody for the treatment of HER2 overexpressing metastatic breast cancer and the second United States approval in this new class of monoclonal antibody biotherapeutic cancer drugs. The first was Rituxan. We are aware of other potentially competitive biologic therapies in development.

Rituxan

Rituxan received designation as a U.S. Orphan Drug by the FDA in 1994 for the treatment of relapsed or refractory low-grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma. We are aware of other potentially competitive biologic therapies in development. Corixa Corporation, formerly Coulter Pharmaceuticals, Inc., has filed and received an expedited review of a revised BLA in 2000 for Bexxar, trademark, (tositumomab and iodine I 131 tositumomab), which may compete with our product Rituxan and IDEC has filed a BLA for Zevalin, trademark, (ibritumomab tiuxetan), a product which could also potentially compete with Rituxan. Both Bexxar and Zevalin are radiolabeled molecules while Rituxan is not. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

Activase and TNKase

We continue to face competition in the thrombolytic market. Activase has lost market share and could lose additional market share to Centocor Inc.'s Retavase, registered trademark, either alone or in combination with the use of another Centocor product, ReoPro, registered trademark; the resulting adverse effect on sales could be material. Retavase received approval from the FDA in October 1996 for the treatment of acute myocardial infarction. In addition, the market for thrombolytic therapy has declined as there is an increasing use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction. In June 2000, TNKase was approved by the FDA for the treatment of acute myocardial infarction.

Nutropin Depot, Nutropin AQ, Nutropin and Protropin

Eli Lilly and Company received FDA approval in 1987 to market its growth hormone product for treatment of growth hormone inadequacy in children. Three other companies-Bio-Technology General Corporation, or BTG, Novo Nordisk A/S, or Novo, and Pharmacia-received FDA approval in 1995 to market

Edgar Filing: GENENTECH INC - Form 10-K

their growth hormone products in the United States. BTG was preliminarily enjoined from selling its product, but it is now free to enter the market. A fifth competitor, Serono, Inc., received FDA approval in October 1996 to market its growth hormone product. In the first quarter of 1997, Serono, Novo and Pharmacia began selling their growth hormone products in the United States. On June 21, 2000, Novo announced that the FDA approved Norditropin, registered trademark, SimpleXx, trademark, a liquid form of its recombinant somatotropin product, for the long-term treatment of children who have growth hormone failure due to inadequate secretion of endogenous growth hormone. In addition, three of our competitors have received approval to market their existing human growth hormone products in the United States for additional indications.

In December 1999, we received FDA approval for Nutropin Depot, the first long-acting dosage form of recombinant growth hormone for pediatric growth hormone deficiency. We launched the product in late June 2000. We are not aware of any competing sustained-release formulations of human growth hormone in clinical development.

Pulmozyme

Pulmozyme is used for the treatment of cystic fibrosis, including cystic fibrosis in children under the age of five. We are not aware of any directly competing products in development.

Stock Option Changes

In connection with the Redemption of our Special Common Stock, the following changes occurred with respect to our stock options that were outstanding as of June 30, 1999:

- Options for the purchase of approximately 27.2 million shares of Special Common Stock were canceled in accordance with the terms of the applicable stock option plans, and the holders received cash payments in the amount of \$20.63 per share, less the exercise price;
- Options for the purchase of approximately 16.0 million shares of Special Common Stock were converted into options to purchase a like number of shares of Common Stock at the same exercise price; and
- Options for the purchase of approximately 19.6 million shares of Special Common Stock were canceled in accordance with the terms of our 1996 Stock Option/Stock Incentive Plan, or the 1996 Plan. With certain exceptions, we granted new options for the purchase of 1.333 times the number of shares under the previous options with an exercise price of \$24.25 per share, which was the July 23, 1999 public offering price of the Common Stock. The number of shares that were the subject of these new options, which were issued under our 1999 Stock Plan, or the 1999 Plan, was approximately 20.0 million. Alternative arrangements were provided for certain holders of some of the unvested options under the 1996 Plan.

Of the approximately 16.0 million shares of converted options, options with respect to approximately 4.0 million shares were outstanding at December 31, 2000, all of which are currently exercisable except for options with respect to approximately 320,507 shares. These outstanding options are held by 1,420 employees; no non-employee directors hold these options.

Our board of directors and Roche, then our sole stockholder, approved the 1999 Plan on July 16, 1999. Under the 1999 Plan, we granted new options to purchase approximately 26.0 million shares (including the 20.0 million shares referred to above) of Common Stock to approximately 2,400 employees at an exercise price of \$24.25 per share, with the grant of such options made

Edgar Filing: GENENTECH INC - Form 10-K

effective as of July 16, 1999. Of the options to purchase these 26.0 million shares, options to purchase approximately 19.8 million shares were outstanding at December 31, 2000, of which options to purchase approximately 7.7 million shares are currently exercisable.

In connection with these stock option transactions, we recorded:

- (1) cash compensation expense of approximately \$284.5 million associated with the cash-out of such stock options and (2) non-cash compensation expense of approximately \$160.1 million associated with the remeasurement, for accounting purposes, of the converted options, which non-cash amount represents the difference between each applicable option exercise price and the redemption price of the Special Common Stock; and
- Over a two-year period beginning July 1, 1999, an aggregate of approximately \$27.4 million of deferred cash compensation available to be earned by a limited number of employees who elected the alternative arrangements described above. As of December 31, 2000, \$11.1 million and as of December 31 1999, \$7.3 million, of compensation expense has been recorded related to these alternative arrangements.

Relationship With Roche

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

Affiliation Arrangements

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

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

Edgar Filing: GENENTECH INC - Form 10-K

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 of our deferred compensation plans.

Licensing Agreement

In 1995, we entered into a licensing and marketing agreement with Hoffmann-La Roche and its affiliates granting it a ten-year option to license to use and sell our products in non-U.S. markets. In July 1999, we amended that agreement, the major provisions of which include:

- extending Hoffmann-La Roche's option until at least 2015;
- Hoffmann-La Roche may exercise its option to license our products upon the occurrence of any of the following: (1) our decision to file an IND for a product, (2) completion of a Phase II trial for a product or (3) if Hoffmann-La Roche previously paid us a fee of \$10.0 million to extend its option on a product, completion of a Phase III trial for that product;
- 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 with the FDA or completion of the Phase II trials, a royalty of 12.5% on the first \$100.0 million on its aggregate sales of that product and thereafter a royalty of 15% on its aggregate sales of that product in excess of \$100.0 million until the later in each country of the expiration of our last relevant patent or 25 years from the first commercial introduction of that product; and
- Hoffmann-La Roche will pay, for each product for which Hoffmann-La Roche exercises its option after completion of the Phase III trials, a royalty of 15% on its sales of that product until the later in each country of the expiration of our relevant patent or 25 years from the first commercial introduction of that product; however, \$5.0 million of any option extension fee paid by Hoffmann-La Roche will be credited against royalties payable to us in the first calendar year of sales by Hoffmann-La Roche in which aggregate sales of that product exceed \$100.0 million.

Tax Sharing Agreement

Since the redemption of our Special Common Stock, and until Roche completed

Edgar Filing: GENENTECH INC - Form 10-K

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

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

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

We expect from time to time to issue additional shares of common stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. The affiliation agreement provides that we will, among other things, establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. In addition, Roche has a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. In connection with that provision, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance is to be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche) divided by 509,194,352 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering adjusted for the two-for-one splits of our common stock in October 2000 and November 1999. As long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, Genentech has agreed to repurchase a sufficient number of shares of its common stock to provide that, immediately after its issuance of shares, Roche's percentage ownership will be greater than 50%. We have also agreed, upon request, to repurchase shares of our common stock to increase Roche's ownership to the Minimum Percentage.

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

The following section contains forward-looking information based on our current expectations. Because our actual results may differ materially from this and any other forward-looking statements made by or on behalf of Genentech, this section also 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 and net income.

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

Edgar Filing: GENENTECH INC - Form 10-K

including:

- The overall competitive environment for our products.

For example, sales of our Activase product decreased in 2000, 1999 and 1998 primarily due to competition from Centocor Inc.'s Retavase and more recently to a decreasing size of the thrombolytic marketplace as other forms of acute myocardial infarction treatment gain acceptance.

- The amount and timing of sales to customers in the United States.

For example, sales of our Growth Hormone products increased in 2000 and 1999 due to fluctuations in distributor ordering patterns.

- The amount and timing of our sales to Hoffmann-La Roche of products for sale outside of the United States and the amount and timing of its sales to its customers, which directly impact both our product sales and royalty revenues.

For example, in the third quarter of 2000, Hoffmann-La Roche's approval of Herceptin in Europe increased our sales of Herceptin product.

- The timing and volume of bulk shipments to licensees.
- The availability of third-party reimbursements for the cost of therapy.
- The effectiveness and safety of our various products as determined both in clinical testing and by the accumulation of additional information on each product after it is approved by the FDA for sale.
- The rate of adoption and use of our products for approved indications and additional indications.

For example, sales of Pulmozyme increased in 1998 due, in part, to new patients who were attracted to our product as a result of an FDA approval for a label extension to include cystic fibrosis patients under the age of five.

- The potential introduction of new products and additional indications for existing products in 2001 and beyond.
- The ability to successfully manufacture sufficient quantities of any particular marketed product.
- The number and size of any product price increases we may issue.

The Successful Development of Pharmaceutical Products Is Highly Uncertain

Successful pharmaceutical product development is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- Preclinical and clinical trial results that may show the product to be less effective than desired or to have harmful problematic side effects;

For example:

- In June 2000, we announced that the preliminary results from our 415-patient Phase II clinical trial of our recombinant humanized anti-CD18 monoclonal antibody fragment, which is known as rhuMAB CD18, for the treatment of myocardial infarction, more commonly known

Edgar Filing: GENENTECH INC - Form 10-K

as a heart attack, did not meet its primary objectives.

- In 1999, our Phase III clinical trial of recombinant human nerve growth factor, which is known as rhNGF, for use in diabetic peripheral neuropathy did not meet its objectives and we decided not to file for product approval with the FDA.
- In 1999, our Phase II clinical study of recombinant human vascular endothelial growth factor, which is known as VEGF, protein failed to meet the primary endpoints of the study.
- Failure to receive the necessary regulatory approvals or delay in receiving such approvals;
- Manufacturing costs or other factors that make the product uneconomical; or
- The proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

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

Factors affecting our research and development, or R&D, expenses include, but are not limited to:

- The number of and the outcome of clinical trials currently being conducted by us and/or our collaborators.
- The number of products entering into development from late-stage research.

For example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us. In the past, promising candidates have not yielded sufficiently positive preclinical results to meet our stringent development criteria.

- Hoffmann-La Roche's decisions whether to exercise its options to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
- In-licensing activities, including the timing and amount of related development funding or milestone payments.

For example, in February 2000, we entered into an agreement with Actelion Ltd. for the purchase of rights for the development and co-promotion in the United States of tezosentan and paid Actelion an upfront fee of \$15.0 million which was recorded as a R&D expense.

- As part of our strategy, we invest in R&D. R&D as a percent of revenues can fluctuate with the changes in future levels of revenue. Lower revenues can lead to more disciplined spending of R&D efforts.
- Future levels of revenue.

Roche, Our Controlling Stockholder, May Have Interests That Are Adverse to

Edgar Filing: GENENTECH INC - Form 10-K

Other Stockholders

Roche, as our majority stockholder, controls the outcome of actions requiring the approval of our stockholders. Our bylaws provide, among other things, that the composition of our board of directors shall consist of two Roche directors, three independent directors nominated by a nominating committee and one Genentech employee nominated by the nominating committee. As long as Roche owns in excess of 50% of our common stock, Roche directors will comprise two of the three members of the nominating committee. However, at any time until Roche owns less than 5% of our stock, Roche will have the right to obtain proportional representation on our board. Roche intends to continue to allow our current management to conduct our business and operations as we have done in the past. However, we cannot assure stockholders that Roche will not institute a new business plan in the future. Roche's interests may conflict with your interests.

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

The affiliation agreement between us and Roche contains provisions that:

- Require the approval of the directors designated by Roche to make any acquisition or any sale or disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues;
- Enable Roche to maintain its percentage ownership interest in our common stock; and
- Establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock.

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

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

Our certificate of incorporation includes provisions relating to:

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

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

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

Edgar Filing: GENENTECH INC - Form 10-K

Persons who are directors and/or officers of Genentech and who are also directors and/or officers of Roche may decline to take action in a manner that might be favorable to us but adverse to Roche. Two of our directors, Dr. Franz B. Humer and Dr. Jonathan K.C. Knowles, currently serve as directors, officers and employees of Roche Holding Ltd and its affiliates.

We May Be Unable to Retain Skilled Personnel and Maintain Key Relationships

The success of our business depends, in large part, on our continued ability to attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, and on our ability to develop and maintain important relationships with leading research institutions and key distributors. Competition for these types of personnel and relationships is intense.

Roche has the right to maintain its percentage ownership interest in our common stock. Our affiliation agreement with Roche provides that, among other things, we will establish a stock repurchase program designed to maintain Roche's percentage ownership in our common stock if we issue or sell any shares. This right of Roche may limit our flexibility as to the number of shares we are able to grant under our stock option plans. We therefore cannot assure you that we will be able to attract or retain skilled personnel or maintain key relationships.

We Face Growing and New Competition

We face growing competition in two of our therapeutic markets and expect new competition in a third market. First, in the thrombolytic market, Activase has lost market share and could lose additional market share to Centocor's Retavase, either alone or in combination with the use of another Centocor product, ReoPro, registered trademark, (abciximab) and to the use of other mechanical therapies to treat acute myocardial infarction; the resulting adverse effect on sales has been and could continue to be material. Retavase received approval from the FDA in October 1996 for the treatment of acute myocardial infarction. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow.

Second, in the growth hormone market, we continue to face increased competition from four other companies currently selling growth hormone and an additional company which may enter the market in the near future. As a result of that competition, we have experienced a loss in market share. The four competitors have also received approval to market their existing human growth hormone products for additional indications. As a result of this competition, sales of our Growth Hormone products may decline, perhaps significantly.

Third, in the non-Hodgkin's lymphoma market, Corixa Corporation, formerly Coulter Pharmaceutical, Inc., has filed and received an expedited review of a revised Biologics License Application, or BLA, in 2000 for Bexxar, trademark, (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan and IDEC has filed a BLA for Zevalin, trademark, (ibritumomab tiuxetan), a product which could also potentially compete with Rituxan. Both Bexxar and Zevalin are radiolabeled molecules while Rituxan is not. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

Other Competitive Factors Could Affect Our Product Sales

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

Edgar Filing: GENENTECH INC - Form 10-K

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

For example, in June 2000 one of our competitors, Novo, received FDA approval for a liquid formulation of its growth hormone product that will directly compete with our liquid formulation, Nutropin AQ. Also in June 2000, another of our competitors, Serono S.A., received FDA approval to deliver its competitive growth hormone product in a needle-free device.

- Our pricing decisions and the pricing decisions of our competitors.

For example, we raised the prices of Rituxan in May 2000 and Pulmozyme in June 2000 by approximately 5%.

- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.

For example, in January 2000, a federal court judge lifted a preliminary injunction that had been in effect since 1995 against Bio-Technology General Corporation, or BTG. Although an appeal of the judge's decision is pending, BTG is now permitted to sell its competitive growth hormone product in the United States.

- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products.

For example, as further described in "Protecting Our Proprietary Rights Is Difficult and Costly," in May 1999, June 2000 and September 2000, several companies filed patent infringement lawsuits against us alleging that we are infringing certain of their patents.

- The increasing use and development of alternate therapies.

For example, the overall size of the market for thrombolytic therapies, such as our Activase product, continues to decline as a result of the increasing use of mechanical reperfusion.

- The rate of market penetration by competing products.

For example, in the past, we have lost market share to new competitors in the thrombolytic and growth hormone markets.

In Connection With the Redemption of Our Special Common Stock, We Recorded Substantial Goodwill and Other Intangibles, the Amortization of Which May Adversely Affect Our Earnings

As a result of the redemption of our special common stock, Roche owned all of our outstanding common stock. Consequently, push-down accounting under generally accepted accounting principles was required. Push-down accounting required us to establish a new accounting basis for our assets and liabilities, based on Roche's cost in acquiring all of our stock. In other words, Roche's cost of acquiring Genentech was "pushed down" to us and reflected on our financial statements. Push-down accounting required us to record goodwill and other intangible assets of approximately \$1,685.7 million and \$1,499.0 million, respectively, on June 30, 1999. The amortization of this goodwill and other intangible assets will have a significant negative impact on our financial results in future years. In addition, we will continuously evaluate whether events and circumstances have occurred that indicate the remaining balance of this and other intangible assets may not be recoverable. If our assets need to be evaluated for possible impairment, we may have to reduce the carrying value of our intangible assets. This could

Edgar Filing: GENENTECH INC - Form 10-K

have a material adverse effect on our financial condition and results of operations during the periods in which we recognize a reduction. We may have to write down intangible assets in future periods. For more information about push-down accounting, see the "Redemption of Our Special Common Stock" note in the Notes to Consolidated Financial Statements (Part II, Item 8 of this Form 10-K).

Our Royalty and Contract Revenues Could Decline

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

- Hoffmann-La Roche's decisions whether to exercise its options and option extensions to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
- Variations in Hoffmann-La Roche's sales and other licensees' sales of licensed products.

For example, we began receiving royalty revenues from Immunex's sale of Enbrel in 1999.

- The conclusion of existing arrangements with other companies and Hoffmann-La Roche.

For example, royalty revenues decreased in 1999 from 1998 due to the expiration of royalty payments primarily on sales of human insulin, from Eli Lilly and Company in August 1998.

- The timing of non-U.S. approvals, if any, for products licensed to Hoffmann-La Roche and other licensees.

For example, we expect the approval of Herceptin outside the United States which occurred in third quarter of 2000 to have a continuing positive impact on royalties.

- Fluctuations in foreign currency exchange rates.
- The initiation of new contractual arrangements with other companies.

For example, license fees from Immunex and Schwarz Pharma increased contract revenues in 1999.

- Whether and when contract benchmarks are achieved.

For example, milestone payments from Pharmacia increased contract revenue in 1997.

- The failure of or refusal of a licensee to pay royalties.
- The expiration or invalidation of patents or licensed intellectual property.

Protecting Our Proprietary Rights Is Difficult and Costly

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be involved in material patent litigation. Patent litigation is costly in its own right and could subject us to significant

Edgar Filing: GENENTECH INC - Form 10-K

liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute. For example, in late 1999 we settled a patent infringement lawsuit brought against us by the Regents of the University of California in which the University alleged that the manufacture and sale of our Protropin and Nutropin growth hormone products infringed a patent owned by the University. In connection with that settlement we paid the University of California \$150.0 million and donated \$50.0 million for the construction of a new life sciences building on the University of California, San Francisco campus.

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

We believe that we have strong patent protection or the potential for strong patent protection for a number of our products that generate sales and royalty revenue or that we are developing. However, the courts will determine the ultimate strength of patent protection of our products and those on which we earn royalties.

Three lawsuits have been filed against us in which the companies involved allege that we have infringed their patents by the manufacture and sale of certain of our products:

- In May 1999, GlaxoSmithKline plc, or Glaxo, filed a complaint in which it appears to claim that our manufacture, use and sale of Rituxan and Herceptin antibody products infringe four Glaxo patents that relate to certain uses and preparations of antibodies.
- In June 2000, Chiron Corporation filed a complaint in which it claims that our manufacture and sale of Herceptin infringe a patent it owns.
- In September 2000, Glaxo filed another complaint in which it appears to claim that our manufacture, use and sale of Rituxan and Herceptin antibody products infringe a Glaxo patent that relates to certain cell culture methods.

We May Incur Material Litigation Costs

Litigation to which we are currently or have been subjected relates to, among other things, our patent and intellectual property rights, licensing arrangements with other persons, product liability and financing activities. We cannot predict with certainty the eventual outcome of pending litigation, and we might have to incur substantial expense in defending these lawsuits. We have in the past taken substantial special charges relating to litigation, including \$230.0 million in 1999.

We May Incur Material Product Liability Costs

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

We May Be Unable to Obtain Regulatory Approvals for Our Products

The pharmaceutical industry is subject to stringent regulation with respect to product safety and efficacy by various 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 pharmaceutical product cannot be marketed in the United

Edgar Filing: GENENTECH INC - Form 10-K

States until it has been approved by the FDA, and then can only be marketed for the indications and claims approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application, or NDA, or a BLA, are substantial and can require a number of years. In addition, after any of our products receive regulatory approval, they remain subject to ongoing FDA regulation, including, for example, changes to their label, written advisements to physicians and product recall.

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

- Significant delays in obtaining or failing to obtain required approvals.
- Loss of or changes to previously obtained approvals.

For example, in May 2000, we issued letters to physicians advising them of some serious adverse events associated with the administration of Herceptin. In October 2000, we issued a new package insert for Herceptin including this information.

- Failure to comply with existing or future regulatory requirements.

For example, in 1999, we paid a \$50.0 million settlement to the federal government in connection with a federal investigation of our former clinical, sales and marketing activities associated with our human growth hormone products.

Moreover, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development, which may affect our ability to obtain approval of our products.

Difficulties or Delays in Product Manufacturing Could Harm Our Business

We currently produce all of our products at our manufacturing facilities located in South San Francisco, California and Vacaville, California or through various contract manufacturing arrangements. Problems with any of our or our contractors' manufacturing processes could result in product defects, which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all.

For example, in March 2000, we issued an important drug notification regarding a defect in the packaging of our Pulmozyme product. During a quality assurance inspection, we had discovered that there was a defect in the packaging of Pulmozyme which occasionally caused a small puncture in ampules of that product. We suspended shipping the product while we determined the source and extent of the defect. We ultimately recalled some of the product.

On December 27, 2000, we received a Warning Letter from the FDA regarding our quality control at our South San Francisco manufacturing plant. The products cited were for cystic fibrosis, breast cancer and acute myocardial infarction. On February 7, 2001, we received a letter from the FDA accepting our responses and corrective actions with respect to the Warning Letter.

In addition, any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments. A number of factors could cause interruptions, including equipment malfunctions or failures, or damage to a facility due to natural

Edgar Filing: GENENTECH INC - Form 10-K

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

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

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. In addition, due to the absence of the put and call that were associated with our special common stock, the market price of our common stock has been and may continue to be more volatile than our special common stock was in the past.

In addition, the following factors may have a significant impact on the market price of our common stock:

- Announcements of technological innovations or new commercial products by us or our competitors.

For example, our stock increased by approximately 4% on the day we announced FDA approval for our Nutropin Depot product.

- Developments concerning proprietary rights, including patents.

For example, our stock price decreased by approximately 4% on the day one of our competitors, Chiron, announced a patent infringement suit against us.

- Publicity regarding actual or potential medical results relating to products under development by us or our competitors.

For example, our stock price increased by approximately 9% on the day we announced positive preliminary Phase III results from the Anti-IgE asthma clinic.

- Regulatory developments in the United States and foreign countries.

- Public concern as to the safety of biotechnology products.

For example, on May 8, 2000, we issued a warning concerning our Herceptin drug after 15 deaths resulted from the administration of Herceptin. Our stock price decreased by approximately 2% at that time.

- Economic and other external factors or other disaster or crisis.

For example, our stock reached a high of \$122.50 per share in March 2000 and decreased, as the biotech sector and stock market in general decreased, to a low of \$42.25 per share in late May 2000.

- Period-to-period fluctuations in financial results.

For example, our stock price has historically been affected by whether we met or exceeded analyst expectations.

Our Affiliation Agreement With Roche Could Adversely Affect Our Cash Position

Our affiliation agreement with Roche provides that we will establish a stock repurchase program designed to maintain Roche's percentage ownership interest

Edgar Filing: GENENTECH INC - Form 10-K

in our common stock. While the dollar amounts associated with these future purchases cannot currently be estimated, these stock repurchases could have a material adverse effect on our cash position and may have the effect of limiting our ability to use our capital stock as consideration for acquisitions.

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

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

As of December 31, 2000, Roche owned 306,594,352 shares of our common stock or approximately 58.4% of our outstanding shares. All of our shares owned by Roche are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Roche's request, we will file one or more registration statements under the Securities Act in order to permit Roche to offer and sell shares of our common stock. We have agreed to use our best efforts to facilitate the registration and offering of those shares designated for sale by Roche. 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.

We Are Exposed to Market Risk

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

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

The estimated exposures discussed below are intended to measure the maximum amount we could lose from adverse market movements in interest rates, foreign currency exchange rates and equity investment prices, given a specified confidence level, over a given period of time. Loss is defined in the value at risk estimation as fair market value loss. The exposures to interest rate, foreign currency exchange rate and equity investment price changes are calculated based on proprietary modeling techniques from a Monte Carlo simulation value at risk model using a 30-day holding period and a 95% confidence level. The value at risk model assumes non-linear financial returns and generates potential paths various market prices could take and tracks the hypothetical performance of a portfolio under each scenario to approximate its financial return. The value at risk model takes into account correlations and diversification across market factors, including interest rates, foreign currencies and equity prices. Market volatilities and correlations are based on J.P. Morgan Riskmetrics, trademark, dataset as of December 31, 2000.

Our Interest Income is Subject to Fluctuations in Interest Rates

Edgar Filing: GENENTECH INC - Form 10-K

Our material interest bearing assets, or interest bearing portfolio, consisted of cash equivalents, restricted cash, short-term investments, convertible preferred stock investments, convertible loans and long-term investments. The balance of our interest bearing portfolio was \$1,879.6 million or 28% of total assets at December 31, 2000. Interest income related to this portfolio was \$90.4 million or 5% of total revenues. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest bearing portfolio. To mitigate the impact of fluctuations in U.S. interest rates, for a portion of our portfolio, we have entered into swap transactions, which involve the receipt of fixed rate interest and the payment of floating rate interest without the exchange of the underlying principal.

Based on our overall interest rate exposure at December 31, 2000, 1999 and 1998, including derivative and other interest rate sensitive instruments, a near-term change in interest rates, within a 95% confidence level based on historical interest rate movements would not materially affect the fair value of interest rate sensitive instruments.

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

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

To mitigate our net foreign exchange exposure, we could hedge certain of our anticipated revenues by purchasing option contracts with expiration dates and amounts of currency that are based on 25% to 90% of probable future revenues so that the potential adverse impact of movements in currency exchange rates on the non-dollar denominated revenues will be at least partly offset by an associated increase in the value of the option. Currently, the term of these options is generally one to two years. We may also enter into foreign currency forward contracts to lock in the dollar value of a portion of these anticipated revenues. To hedge the non-dollar denominated investment portfolio, we enter into forward contracts.

Based on our overall currency rate exposure at December 31, 2000, 1999 and 1998, including derivative and other foreign currency sensitive instruments, a near-term change in currency rates within a 95% confidence level based on historical currency rate movements, would not materially affect the fair value of foreign currency sensitive instruments.

Edgar Filing: GENENTECH INC - Form 10-K

Our Investments in Equity Securities Are Subject to Market Risks

As part of our strategic alliance efforts, we invest in equity instruments of biotechnology companies. Our biotechnology equity investment portfolio totaled \$652.7 million or 10% of total assets at December 31, 2000. These investments are subject to fluctuations from market value changes in stock prices. To mitigate this risk, certain equity securities are hedged with costless collars and equity swaps. A costless 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). An equity swap is a derivative instrument where we pay the counterparty the total return of the security above the current spot price and receives interest income on the notional amount for the swap term. The equity swap 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. In addition, as part of our strategic alliance efforts, we hold dividend-bearing convertible preferred stock and have made interest-bearing loans that are convertible into the equity securities of the debtor.

Based on our overall exposure to fluctuations from market value changes in marketable equity prices at December 31, 2000, a near-term change in equity prices within a 95% confidence level based on historic volatilities could result in a potential loss in fair value of the equity securities portfolio of \$94.0 million. We estimated that the potential loss in fair value of the equity securities portfolio was \$43.2 million at December 31, 1999 and \$10.6 million at December 31, 1998.

Recent Accounting Pronouncements Could Impact Our Financial Position and Results of Operations

We will adopt Statement of Financial Accounting Standards 133, or FAS 133, "Accounting for Derivative Instruments and Hedging Activities," on January 1, 2001. FAS 133 establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. It requires companies to recognize all derivatives as either assets or liabilities on the balance sheet and measure those instruments at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting under FAS 133. Based on our derivative positions at December 31, 2000, we estimate that upon adoption, we will record a charge from the cumulative effect of a change in accounting principle of approximately \$9.0 million being recognized in the consolidated statement of operations and an increase of approximately \$8.0 million in other comprehensive income.

We Are Exposed to Credit Risk of Counterparties

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

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of our

Edgar Filing: GENENTECH INC - Form 10-K

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

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

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

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

We are also subject to various laws and regulations relating to safe working conditions, 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. We believe we are currently in compliance with all these laws and regulations. The extent of governmental regulation that might result from any legislative or administrative action cannot be accurately predicted.

Edgar Filing: GENENTECH INC - Form 10-K

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 United States there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. In addition, in the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. We cannot assure you that any of our products will be considered cost effective and that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

Research and Development

A major portion of our operating expenses to date are related to the R&D of products either on our own behalf or under contracts. During 2000, 1999 and 1998, our R&D expenses were \$489.9 million, \$367.3 million and \$396.2 million, respectively.

Our R&D efforts have been the primary source of our products. We intend to maintain our strong commitment to R&D as an essential component of our product development effort. Licensed technology developed by outside parties is an additional source of potential products.

Human Resources

As of December 31, 2000, we had 4,459 employees.

Environment

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

ITEM 2. Properties

Our primary facilities are located in a research and industrial park in South San Francisco, California in both leased and owned properties. We currently occupy 25 buildings for our research and development, manufacturing, marketing and administrative activities. Of the buildings, 14 are owned and 11 are leased. We have made and continue to make improvements to these properties to accommodate our growth. In addition, we own approximately 17 acres adjacent to our current facilities that may be used for future expansion. In 1995, we began development of a new manufacturing facility of approximately 300,000 square feet in Vacaville, California under an operating lease arrangement. The facility is operational and was granted FDA licensure in April 2000. In April 2000, we purchased a cell culture manufacturing facility in Porrino, Spain. The facility will supplement our existing bulk cell culture production capacity. We also have leases for certain additional office facilities in several locations in the United States.

Edgar Filing: GENENTECH INC - Form 10-K

We believe our facilities are in good operating condition and that the real property owned or leased are adequate for all present and near term uses. Additional manufacturing capacity may be added in the South San Francisco or on the Vacaville site dependent on the success of products in clinical trials. We believe any additional facilities could be obtained or constructed with our capital resources.

ITEM 3. Legal Proceedings

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

In 1990 and 1997, the Regents of the University of California, or UC, filed patent infringement lawsuits against Genentech, alleging that the manufacture, use and sale of our Protropin and Nutropin human growth hormone products infringe a patent known as the "Goodman patent" that is owned by UC. On November 19, 1999, we and UC announced a proposed settlement of those lawsuits, and on or about December 17, 1999, the parties entered into a definitive written agreement on the terms of the settlement. Under the terms of the settlement, Genentech agreed to pay UC \$150.0 million and agreed to make a contribution in the amount of \$50.0 million toward construction of the first biological sciences research building at the University of California, San Francisco Mission Bay campus, and Genentech and UC granted certain releases to one another and dismissed with prejudice the 1990 and 1997 patent infringement lawsuits and related appeals. Such amounts were included in other accrued liabilities at December 31, 1999. The settlement resolves all outstanding litigation between Genentech and UC relating to our growth hormone products.

On May 28, 1999, GlaxoSmithKline plc, or Glaxo, filed a patent infringement lawsuit against us in the U.S. District Court in Delaware. The suit asserts that we infringe four U.S. patents owned by Glaxo. Two of the patents relate to the use of specific kinds of antibodies for the treatment of human disease, including cancer. The other two patents asserted against us relate to preparations of specific kinds of antibodies which are made more stable and the methods by which such preparations are made. Glaxo's complaint fails to specify which of our products or methods of manufacture are allegedly infringing the four patents at issue. However, we believe that the suit relates to the manufacture, use and/or sale of our Herceptin and Rituxan antibody products. On July 19, 1999, we filed our answer to the complaint, and in our answer we also stated counterclaims against Glaxo. On or about October 27, 2000, Glaxo filed a motion for summary judgment that our Herceptin and Rituxan antibody products infringe two of the patents asserted against us in this suit, U.S. Patent Nos. 5,545,403 and 5,545,405. On November 21, 2000, we filed an opposition to that motion. The trial of this suit was previously scheduled to begin January 29, 2001, but has been rescheduled to begin April 16, 2001.

On September 14, 2000, Glaxo filed another patent infringement lawsuit against us in the U.S. District Court in Delaware, alleging that we are infringing U.S. Patent No. 5,633,162 owned by Glaxo. The patent relates to specific methods for culturing Chinese Hamster Ovary cells. Glaxo's complaint fails to specify which of our products or methods of manufacture are allegedly infringing that patent. However, the complaint makes a general reference to Genentech's making, using and selling "monoclonal antibodies," and so we believe that the suit relates to our Herceptin and Rituxan antibody products. On October 4, 2000, we filed our answer to the complaint, and in our answer we also stated counterclaims against Glaxo. The judge has

Edgar Filing: GENENTECH INC - Form 10-K

scheduled the trial for this suit to begin January 25, 2002. This lawsuit is separate from and in addition to the Glaxo suit mentioned above.

We and the City of Hope National Medical Center are parties to a 1976 agreement relating to work conducted by two City of Hope employees, Arthur Riggs and Keiichi Itakura, and patents that resulted from that work, which are referred to as the "Riggs/Itakura Patents." Since that time, Genentech has entered into license agreements with various companies to make, use and sell the products covered by the Riggs/Itakura Patents. On August 13, 1999, the City of Hope filed a complaint against us in the Superior Court in Los Angeles County, California alleging that we owe royalties to the City of Hope in connection with these license agreements, as well as product license agreements that involve the grant of licenses under the Riggs/Itakura Patents. The complaint states claims for declaratory relief, breach of contract, breach of implied covenant of good faith and fair dealing, and breach of fiduciary duty. On December 15, 1999, we filed our answer to the City of Hope's complaint, denying all the claims made by the City of Hope. On or about December 22, 2000, City of Hope filed a dismissal of its declaratory relief claims. On January 4, 2001, we filed a motion to dismiss the case. The judge denied the motion on February 1, 2001, but issued a temporary stay of proceedings to permit us to file a petition with the appellate court. We filed our petition on February 13, 2001, which was denied by the appellate court on February 22, 2001. The trial of this suit has been rescheduled to begin on August 22, 2001.

On December 1, 1994, Genentech filed suit against Bio-Technology General Corporation, or BTG, in the United States District Court in Delaware charging BTG with infringement of two Genentech patents applicable to its human growth hormone product. On February 28, 1995, Genentech filed an Amended Complaint against BTG alleging infringement of an additional Genentech patent. On January 6, 1995, BTG filed suit against Genentech in the United States District Court for the Southern District of New York seeking declaratory judgments that those patents and another Genentech patent are invalid and not infringed by BTG. Genentech's suit in Delaware was then transferred to New York and consolidated with BTG's suit there.

At the time of filing its suit and thereafter, BTG alleged various antitrust, abuse of process, civil rights, malicious prosecution and unfair competition claims against Genentech. All of those claims were dismissed by the District Court.

On August 10, 1995, the District Court issued a preliminary injunction which prohibited BTG, pending the Court's final determination of the action, from importing, making, using, selling, offering for sale or distributing in the United States BTG's human growth hormone products except for certain ongoing FDA approved clinical trials. BTG filed an appeal from the District Court's issuance of the preliminary injunction to the United States Court of Appeals for the Federal Circuit. On April 8, 1996, the Federal Circuit affirmed the preliminary injunction granted by the District Court. On May 20, 1996, the Federal Circuit denied BTG's petition for rehearing, and on October 7, 1996, the United States Supreme Court declined to review the case.

In 1999, the case was transferred to a different judge of the District Court for further proceedings. A jury trial of BTG's patent invalidity claim began on January 10, 2000. On January 18, 2000, the jury returned a verdict in Genentech's favor on a certain factual issue underlying BTG's invalidity claim, but the judge nevertheless entered judgment in favor of BTG and lifted the preliminary injunction that had been in effect against BTG since 1995. On February 23, 2000, we filed a motion with the Federal Circuit requesting that the injunction against BTG be reinstated pending appeal and for an expedited appeal. On May 8, 2000, the Federal Circuit denied our motion.

Edgar Filing: GENENTECH INC - Form 10-K

Genentech and BTG each filed appeals with the Federal Circuit relating to the proceedings in the District Court, and those appeals are now pending. Genentech filed its appeal brief with the Federal Circuit on May 15, 2000. BTG filed its appeal brief on July 11, 2000. In it, BTG included a request that its antitrust claims against Genentech (which previously had been dismissed by the District Court) be reinstated. The Federal Circuit held a hearing on the appeals on December 4, 2000, but has not yet given a decision on the appeals. At this time, and in the future if Genentech's appeal is not successful, BTG could enter the United States market with its human growth hormone product.

On June 7, 2000, Chiron Corporation filed a patent infringement suit against us in the U.S. District Court in the Eastern District of California (Sacramento), alleging that the manufacture, use, sale and offer for sale of our Herceptin antibody product infringes Chiron's U.S. Patent No. 6,054,561. This patent relates to certain antibodies that bind to breast cancer cells and/or other cells. On August 4, 2000, we filed our answer to Chiron's complaint, and in our answer we also stated counterclaims against Chiron. The judge has scheduled the trial of this suit to begin June 25, 2002.

We and Pharmacia AB are parties to a 1978 agreement relating to Genentech's development of recombinant human growth hormone products, under which Pharmacia is obligated to pay Genentech royalties on sales of Pharmacia's growth hormone products throughout the world. On January 5, 1999, Pharmacia filed a request for arbitration with the International Chamber of Commerce to resolve several disputed issues between Genentech and Pharmacia under the agreement. One of the claims made by Pharmacia is for a refund of some of the royalties previously paid to Genentech for sales of Pharmacia's growth hormone products in certain countries. Although the International Chamber of Commerce has not yet given a decision on that claim, we do not believe its decision is likely to have a material adverse effect on our financial position, result of operations or cash flows.

Based upon the nature of the claims made and the information available to date to us and our counsel through investigations and otherwise, we believe the outcome of these actions is not likely to have a material adverse effect on our financial position, result of operations or cash flows. However, were an unfavorable ruling to occur in any quarterly period, there exists the possibility of a material impact on the operating results of that period.

In addition to the above, in April 1999, we paid \$50.0 million to settle a federal investigation relating to our past clinical, sales and marketing activities associated with human growth hormone.

ITEM 4. Submission of Matters to a Vote of Security Holders

Not applicable.

GENENTECH, INC.

EXECUTIVE OFFICERS

The executive officers of the Company and their respective ages (ages as of December 31, 2000) and positions with the Company are as follows:

Name	Age	Position
------	-----	----------

Edgar Filing: GENENTECH INC - Form 10-K

-----	-----	-----
Arthur D. Levinson, Ph.D.	50	Chairman and Chief Executive Officer
Susan D. Desmond-Hellmann, M.D., M.P.H.	43	Executive Vice President-Development and Product Operations and Chief Medical Officer
Louis J. Lavigne, Jr.	52	Executive Vice President and Chief Financial Officer
Myrtle S. Potter	42	Executive Vice President-Commercial Operations and Chief Operating Officer
Robert L. Garnick, Ph.D.	51	Senior Vice President-Regulatory, Quality and Compliance
Dennis J. Henner, Ph.D	49	Senior Vice President-Research
Stephen G. Juelsgaard	52	Senior Vice President-General Counsel and Secretary
Kimberly J. Popovits	42	Senior Vice President-Marketing and Sales
W. Robert Arathoon, Ph.D.	48	Vice President-Global Manufacturing Operations
J. Joseph Barta	53	Vice President-Quality
Stephen G. Dilly, M.D., Ph.D.	41	Vice President-Medical Affairs
David A. Ebersman	31	Vice President-Product Development
Claudia M. Estrin	48	Vice President-Decision Support and Commercial Innovation
Roy C. Hardiman	41	Vice President-Corporate Law and Assistant Secretary
Paula M. Jardieu, Ph.D.	50	Vice President-Pharmacological Sciences
Sean A. Johnston, Ph.D.	42	Vice President-Intellectual Property and Assistant Secretary
R. Guy Kraines	50	Vice President-Finance
Joseph S. McCracken, D.V.M.	47	Vice President-Business and Commercial Development
Walter K. Moore	49	Vice President-Government Affairs
David Nagler	48	Vice President-Human Resources
Diane L. Parks	48	Vice President-Managed Healthcare and Commercial Support
Andrew R. Scherer	52	Vice President-Engineering, Facilities, Strategic Planning and Support
Daniel S. Sulzbach, Ph.D.	51	Vice President-Corporate Information Technology
John M. Whiting	45	Vice President, Controller and Chief Accounting Officer

All officers are elected annually by the Board of Directors. There is no family relationship between or among any of the officers or directors.

Business Experience

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

Edgar Filing: GENENTECH INC - Form 10-K

Susan D. Desmond-Hellmann, M.D., M.P.H. was appointed Executive Vice President, Development and Product Operations in September 1999. She has served as Chief Medical Officer since December 1996. She previously served as Senior Vice President, Development from December 1997 until September 1999, among other positions, since joining Genentech in March 1995 as a Clinical Scientist. Prior to joining Genentech, she held the position of Associate Director at Bristol-Myers Squibb from February 1993 to February 1995.

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

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

Robert L. Garnick, Ph.D. was appointed Vice President, Regulatory, Quality and Compliance on March 1, 2001. Previously, he served as Vice President, Regulatory Affairs from February 1998 to March, 2001. He previously served as Vice President, Quality from April 1994, 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 worked from 1980.

Dennis J. Henner, Ph.D. was appointed Senior Vice President, Research in May 1998. He previously served as Vice President, Research from April 1996 to May 1998, Vice President, Research Technology from July 1994 to April 1996, and as Senior Director, Research Technology from December 1990 to July 1994 and was Director and Senior Scientist, Cell Genetics from May 1990 to December 1990. He joined Genentech in 1981, as a Scientist in Research from Scripps Clinic and Research Foundation.

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

Kimberly J. Popovits was appointed Senior Vice President, Marketing and Sales in February 2001. Previously, she served as Vice President, Sales from October 1994 to February 2001, Director, Field Sales from January 1993 to October 1994 and Regional Manager, Northeast Region from October 1989 to January 1993. Prior to joining Genentech in November 1987, she served as Division Manager, Southeast Region for American Critical Care, a Division of American Hospital Supply.

W. Robert Arathoon, Ph.D. was appointed Vice President, Global Manufacturing Operations in September 2000. He previously served as Vice President, Process Sciences and Manufacturing from October 1999 through August 2000,

Edgar Filing: GENENTECH INC - Form 10-K

Vice President, Process Sciences from April 1996 through August 2000 and Senior Director, Process Sciences from November 1994 to April 1996, among other positions, since joining Genentech in 1983 from The Wellcome Foundation.

J. Joseph Barta was appointed Vice President, Quality in October 1998. He previously served as Senior Director, Quality from March 1998 to October 1998, Senior Director, Quality Assurance from January 1994 to February 1998, Senior Director, Pharmaceutical Manufacturing from September 1993 to December 1993, Director, Pharmaceutical Manufacturing from September 1989 to August 1993, and Associate Director, Validation and Technical Services from June 1989 to September 1989. He joined Genentech in March 1988 as Manager, Validation.

Stephen G. Dilly, M.D., Ph.D. joined Genentech as Vice President, Medical Affairs in December 1998. Prior to joining Genentech, he held various positions with GlaxoSmithKline plc, formerly SmithKline Beecham Pharmaceuticals, from August 1988, including Director and Vice President Neurosciences Therapeutic Unit from December 1996 to December 1998, Director and Vice President CardioPulmonary Therapeutic Team from December 1994 to December 1996 and Group Director Neurosciences Therapeutic Unit from April 1993 to December 1994.

David A. Ebersman was appointed Vice President, Product Development in February 1999. 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 and Senior Director, Product Development from March 1998 to February 1999. Prior to joining Genentech, he held the position of Research Analyst at Oppenheimer & Company, Inc. beginning in 1991.

Claudia M. Estrin was appointed Vice President, Decision Support and Commercial Innovation in November 2000. Prior to joining Genentech, she held the position of Executive Vice President, Customer Operations and Corporate Administration from December 1999 to October 2000 and Senior Vice President of Customer Operations from April 1998 to December 1999 at Boron, LePore & Associates, Inc. Previously, she held the position of Director of Strategic Marketing and Media from October 1996 to March 1998 at Bristol-Myers Squibb and Business Planning Manager from March 1996 to October 1996 and Manager of Database Marketing from August 1993 to March 1996 at Merck USHH.

Roy C. Hardiman was appointed Vice President of Corporate Law in May 2000 and Assistant Secretary in December 2000. He previously served as Director and Far East Representative, Business Development from July 1998 to April 2000, and Associate General Counsel from April 1998 to July 1998, Chief Corporate Counsel from April 1996 to March 1998, Senior Corporate Counsel from August 1993 to March 1996 and Corporate Counsel from November 1990 to July 1993.

Paula M. Jardieu, Ph.D. was appointed Vice President, Pharmacological Sciences in February 1997. She previously served as Senior Director, Pharmacological Sciences from 1996 to February 1997, Staff Scientist from 1992 to 1996, Senior Scientist from 1989 to 1992 and Scientist from 1986 to 1989.

Sean A. Johnston, Ph.D. was appointed Vice President, Intellectual Property in June 1998 and Assistant Secretary in December 2000. He joined Genentech in October 1990 as Patent Counsel and subsequently served as Senior Patent Counsel from October 1993 to October 1995, Senior Patent Counsel and Manager of Patent Litigation from October 1995 to April 1998, and Associate General Counsel, Patent Law from April 1998 to June 1998. Prior to joining Genentech, he served as a Law Clerk at the United States District Court for

Edgar Filing: GENENTECH INC - Form 10-K

the Central District of California from September 1989 to September 1990 and was a Research Scientist at International Genetic Engineering, Inc. from December 1984 to August 1986.

R. Guy Kraines was appointed Vice President of Finance in April 2000. Prior to joining Genentech, he held the position of Vice President and Treasurer of CNF Transportation Inc. from August 1996 through March 2000 and Assistant Treasurer from August 1994 to August 1996.

Joseph S. McCracken was appointed Vice President of Business and Commercial Development in February 2001. Previously, he served as Vice President of Business Development from July 2000 to February 2001. He held the positions of Vice President of Technology Licensing and Alliances at Aventis Pharmaceuticals from January 2000 to July 2000. Previously he held the position of Vice President of Worldwide Business and Technology Development from November 1998 to December 1999 and Vice President of Technology Licensing from November 1997 to November 1998 at Rhone-Poulenc Rorer Pharmaceuticals. He was the Founder of TPM Associates from April 1995 to November 1997. From October 1993 to April 1995, he held the position of Vice President of Business Development at Terrapin Technologies.

Walter K. Moore was appointed Vice President, Government Affairs in May 1998. He joined Genentech in September 1993 as Senior Director of Government Affairs. Prior to joining Genentech, Mr. Moore served as Manager of Governmental Relations at Eli Lilly and Company.

David Nagler was appointed Vice President of Human Resources in September 2000. He previously served as Senior Director of State Government Affairs from April 1995 to August 2000. Prior to joining Genentech, he held the position of Managing Associate at Nossaman, Guthner, Knox and Elliott from April 1988 to April 1995.

Diane L. Parks was appointed Vice President of Managed Healthcare and Commercial Support in February 2001. Previously, she served as Vice President, Marketing from June 1999 to February 2001. Prior to joining Genentech, she held various positions with Marion Laboratories, formerly Marion Merrell Dow and Hoeschst Marion Roussel, from 1982, including Vice President, Marketing from March 1998 to June 1999, Group Product Director, Respiratory and Metabolism from November 1994 to March 1998 and Director, U.S. Commercial Development from July 1993 to November 1994.

Andrew R. Scherer was appointed Vice President, Strategic Planning and Support in August 2000 and has served as Vice President, Engineering and Facilities since May 2000. He previously served as Senior Director of Engineering and Facilities Services from April 1998 to April 2000 and Senior Director of Facilities Services from January 1996 to April 1998 among other positions, since joining Genentech in 1988.

Daniel S. Sulzbach, Ph.D. was appointed Vice President, Corporate Information Technology in September 1999. He joined Genentech in March 1994 as Director of Scientific Computing and subsequently served as Head and Senior Director of Information Resources from March 1998 to September 1999. Prior to joining Genentech, he served as Executive Director of the San Diego Supercomputer Center from August 1985 to March 1994.

John M. Whiting was appointed Vice President in January 2001 and Controller and Chief Accounting Officer in October 1997. He previously served as Director, Financial Planning and Analysis from January 1997 to October 1997, Director, Operations, Financial Planning and Analysis from December 1999 to January 1997, Associate Director, Operations, Financial Planning and Analysis from March 1996 to December 1996, Plant Controller from April 1993 to March 1996, and Group Controller from July 1991 to April 1993.

Edgar Filing: GENENTECH INC - Form 10-K

PART II

ITEM 5. Market for the Registrant's Common Equity and Related Stockholder Matters

The section labeled "Redemption of Our Special Common Stock," "Stock Splits," and footnotes labeled "Relationship With Roche," "Roche's Right to Maintain its Percentage Ownership Interest in Our Stock" and "Capital Stock" in the Notes to Consolidated Financial Statements of our 2000 Annual Report to Stockholders are incorporated herein by reference.

ITEM 6. Selected Financial Data

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

	2000		1999		1998	
	New Basis (June 30 to December 31) Restated (6)		Old Basis (January 1 to June 30) Restated (6)			
Total revenues	\$ 1,736.4	\$ 703.8	\$ 697.2	\$ 1,150.9	\$ 1,150.9	\$ 1,150.9
Product sales	1,278.3	535.7	503.4	717.8	717.8	717.8
Royalties	207.2	96.7	92.6	229.6	229.6	229.6
Contract & other	160.4	26.4	56.8	114.8	114.8	114.8
Interest	90.4	45.0	44.4	88.7	88.7	88.7
Total costs and expenses	\$ 1,732.4	\$ 2,211.0	\$ 550.6	\$ 898.3	\$ 898.3	\$ 898.3
Cost of sales	364.9(1)	187.1(1)	98.5	138.6	138.6	138.6
Research & development	489.9	182.4	184.9	396.2	396.2	396.2
Marketing, general & administrative	497.0	253.4	214.5	358.9	358.9	358.9
Special charges	-	1,387.7(2)	50.0(2)	-	-	-
Recurring charges related to redemption	375.3(3)	197.7(3)	-	-	-	-
Interest	5.3	2.7	2.7	4.6	4.6	4.6
Income (loss) data						
Income (loss) before taxes and cumulative effect of accounting change	\$ 4.0	\$ (1,507.2)	\$ 146.6	\$ 252.6	\$ 252.6	\$ 252.6
Income tax (benefit) provision	20.4	(262.1)	59.0	70.7	70.7	70.7
Income (loss) before cumulative effect of accounting change	(16.4)	(1,245.1)	87.6	181.9	181.9	181.9
Cumulative effect of accounting change, net of tax	(57.8) (5)	-	-	-	-	-
Net income (loss)	(74.2)	(1,245.1)	87.6	181.9	181.9	181.9
Earnings (loss) per share:						
Basic	\$ (0.14)	\$ (2.43)	\$ 0.17	\$ 0.36	\$ 0.36	\$ 0.36
Diluted	(0.14)	(2.43)	0.16	0.35	0.35	0.35

Edgar Filing: GENENTECH INC - Form 10-K

Selected balance sheet data					
Cash, short-term investments					
& long-term marketable securities	\$ 2,459.4	\$ 1,957.4		\$1,604.6	\$1,
Accounts receivable	261.7	214.8		149.7	
Inventories	265.8	275.2		148.6	
Property, plant & equipment, net	752.9	730.1		700.2	
Goodwill	1,455.8	1,609.1		-	
Other intangible assets	1,280.4	1,453.3		65.0	
Other long-term assets	168.5	201.1		131.3	
Total assets	6,711.8	6,534.8		2,855.4	2,
Total current liabilities	448.7	477.4		291.3	
Long-term debt	149.7	149.7		150.0	
Total liabilities	1,037.6	1,264.9		511.6	
Total stockholders' equity	5,674.2	5,269.9(4)		2,343.8	2,

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

The section labeled "Financial Review" of our 2000 Annual Report to Stockholders is incorporated herein by reference.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

The section labeled "Financial Review-Forward-Looking Information and Cautionary Factors That May Affect Future Results-We Are Exposed to Market Risk" in this Form 10-K.

ITEM 8. Consolidated Financial Statements and Supplementary Data

The Consolidated Financial Statements and Notes to Consolidated Financial Statements, the Report of Ernst & Young LLP, Independent Auditors and the section labeled "Quarterly Financial Data (unaudited)" of our 2000 Annual Report to Stockholders are incorporated herein by reference.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

PART III

ITEM 10. Directors and Executive Officers of the Registrant

(a) The sections labeled "Nominees" and "Section 16(a) Beneficial Ownership Reporting Compliance" of our Proxy Statement in connection with the 2001 Annual Meeting of Stockholders are incorporated herein by reference.

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

Edgar Filing: GENENTECH INC - Form 10-K

ITEM 11. Executive Compensation

The sections labeled "Executive Compensation," "Compensation of Directors," "Compensation of Executive Officers," "Summary of Compensation," "Summary Compensation Table," "Stock Option Grants and Exercises," "Option Grants in Last Fiscal Year," "Aggregated Option Exercises in Last Fiscal Year and FY-End Option Values," "Change-In-Control Agreements," "Loans and Other Compensation," "Compensation Committee Report," "Compensation Committee Interlocks and Insider Participation," "Performance Graph" and "Total Stockholder Returns" of our Proxy Statement in connection with the 2001 Annual Meeting of Stockholders are incorporated herein by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management

The sections labeled "Relationship With Roche," "Security Ownership of Certain Beneficial Owners," "Security Ownership of Management" and "Amount and Nature of Beneficial Ownership" of our Proxy Statement in connection with the 2001 Annual Meeting of Stockholders are incorporated herein by reference.

ITEM 13. Certain Relationships and Related Transactions

The sections labeled "Relationship With Roche," "Loans and Other Compensation" and "Certain Relationships and Related Transactions" of our Proxy Statement in connection with the 2001 Annual Meeting of Stockholders is incorporated herein by reference.

PART IV

ITEM 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) 1. Index to Financial Statements

The following Financial Statements and supplementary data are included in our 2000 Annual Report to Stockholders and are incorporated herein by reference pursuant to Item 8 of this Form 10-K.

Consolidated Statements of Operations for the year ended December 31, 2000, the periods from June 30, 1999 to December 31, 1999 and January 1, 1999 to June 30, 1999, and for the year ended December 31, 1998

Consolidated Statements of Cash Flows for the year ended December 31, 2000, the periods from June 30, 1999 to December 31, 1999 and January 1, 1999 to June 30, 1999, and for the year ended December 31, 1998

Consolidated Balance Sheets at December 31, 2000 and 1999

Consolidated Statements of Stockholders' Equity for the year ended December 31, 2000, the periods from June 30, 1999 to December 31, 1999 and January 1, 1999 to June 30, 1999, and for the year ended December 31, 1998

Notes to Consolidated Financial Statements

Report of Ernst & Young LLP, Independent Auditors

Quarterly Financial Data (unaudited)

Edgar Filing: GENENTECH INC - Form 10-K

2. Financial Statement Schedule

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

Schedule II- Valuation and Qualifying Accounts for the year ended December 31, 2000, the periods from June 30, 1999 to December 31, 1999 and January 1, 1999 to June 30, 1999, and for the year ended December 31, 1999.

All other schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

Exhibit No.	Description
-----	-----
3.1	Amended and Restated Certificate of Incorporation.(1)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation.(14)
3.3	Restated By-Laws.(2)
4.1	Indenture, dated March 27, 1987 ("Indenture") for U.S. \$150,000,000 5% Convertible Subordinated Debentures due 2002.(3)
4.2	First Supplemental to Indenture, dated August 17, 1990.(4)
4.3	Second Supplemental to Indenture, dated October 18, 1995.(5)
4.4	Form of Common Stock Certificate.(2)
10.1	Patent License Agreement with Columbia University dated October 12, 1987.(6)
10.2	Form of Affiliation Agreement, dated as of July 22, 1999, between Genentech and Roche Holdings, Inc.(2)
10.3	Amendment No. 1, dated October 22, 1999, to Affiliation Agreement between Genentech and Roche Holdings, Inc.(13)
10.4	Form of Amended and Restated Agreement, dated as of October 25, 1995, between Genentech, Inc. and F. Hoffmann-La Roche Ltd regarding Commercialization of Genentech's Products outside the United States.(2)
10.5	Tax Sharing Agreement, dated as of July 22, 1999, between Genentech, Inc. and Roche Holdings, Inc.(2)
10.6	Amended and Restated Lease Agreement, dated December 8, 1995, between Genentech and BNP Leasing Corporation.(5)
10.7	Amended and Restated Purchase Agreement, dated December 8, 1995, between Genentech and BNP Leasing Corporation.(5)
10.8	Restated Relocation Loan Program.(7)

Edgar Filing: GENENTECH INC - Form 10-K

10.9	Genentech, Inc. Tax Reduction Investment Plan.(9)
10.10	Amendment No. 1 to the Genentech, Inc. Tax Reduction Investment Plan.(10)
10.11	Amendment No. 2 to the Genentech, Inc. Tax Reduction Investment Plan.(10)
10.12	Amendment No. 3 to the Genentech, Inc. Tax Reduction Investment Plan.(10)
10.13	Trust Agreement.(10)
10.14	Amendment No. 1 to Trust Agreement.(10)
10.15	Amendment No. 2 to Trust Agreement.(10)
10.16	Amendment No. 3 to Trust Agreement.(10)
10.17	Amendment No. 4 to Trust Agreement.(10)
10.18	Amendment No. 5 to Trust Agreement.(10)
10.19	Amendment No. 6 to Trust Agreement.(10)
10.20	Amendment No. 7 to Trust Agreement.(10)
10.21	Supplemental Plan to the 401(k) Plan.(7)
10.22	1990 Stock Option/Stock Incentive Plan, as amended and restated as of October 16, 1996.(11)
10.23	1994 Stock Option Plan, as amended and restated as of October 16, 1996.(11)
10.24	1996 Stock Option/Stock Incentive Plan, as amended and restated as of October 16, 1996.(11)
10.25	1999 Stock Plan, as amended and restated as of December 8, 2000.(14)
10.26	1991 Employee Stock Plan, as amended April 13, 1999.(12)
10.27	Long-Term Key Employee Incentive Program, effective as of July 1, 1999.(13)
13.1	Portions of the 2000 Annual Report to Stockholders.(14)
23.1	Consent of Ernst & Young LLP, Independent Auditors.(14)
28.1	Description of the Company's capital stock.(8)

* As required by Item 14(a)(3) of Form 10-K, Genentech identifies this Exhibit as a management contract or compensatory plan or arrangement of Genentech.

(1) Filed as an exhibit to our current report on Form 8-K filed with the

Edgar Filing: GENENTECH INC - Form 10-K

Commission on July 28, 1999 and incorporated herein by reference.

- (2) Filed as an exhibit to Amendment No. 3 to our Registration Statement (No. 333-80601) on Form S-3 filed with the Commission on July 16, 1999 and incorporated herein by reference.
 - (3) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 1987 filed with the Commission and incorporated herein by reference.
 - (4) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 1990 filed with the Commission and incorporated herein by reference.
 - (5) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 1995 filed with the Commission and incorporated herein by reference.
 - (6) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 1988 filed with the Commission and incorporated herein by reference.
 - (7) Filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 1991 filed with the Commission and incorporated herein by reference.
 - (8) Incorporated by reference to the description under the heading "Description of Capital Stock" relating to our Common Stock in the prospectus included in our Amendment No. 2 to the Registration Statement on Form S-3 (No. 333-88651) filed with the Commission on October 20, 1999, and the description under the heading "Description of Capital Stock" relating to the Common Stock in our final prospectus filed with the Commission on October 21, 1999 pursuant to Rule 424(b) under the Securities Act of 1933, as amended, including any amendment or report filed for the purpose of updating that description.
 - (9) Filed as an exhibit to our Registration Statement (No. 333-08055) on Form S-8 filed with the Commission on July 12, 1996 and incorporated herein by reference.
 - (10) Filed as an exhibit to our Registration Statement (No. 333-94749) on Form S-8 filed with the Commission on January 14, 2000 and incorporated herein by reference.
 - (11) Filed as an exhibit to our Registration Statement (No. 333-83157) on Form S-8 filed with the Commission on July 19, 1999 and incorporated herein by reference.
 - (12) Filed as an exhibit to our Post-Effective Amendment No. 1 to our Registration Statement on Form S-8 (No. 333-83989) filed with the Commission on November 2, 1999.
 - (13) Filed as an exhibit to Annual Report on Form 10-K for the year ended December 1999 and incorporate herein by reference.
 - (14) Filed with this document.
- (b) Reports on Form 8-K

On October 25, 2000, Genentech filed a current report on Form 8-K dated October 24, 2000. There were no other reports filed for the quarter ended December 31, 2000.

Edgar Filing: GENENTECH INC - Form 10-K

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENENTECH, INC.
Registrant

Date: March 9, 2001

By: /s/JOHN M. WHITING

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

POWER OF ATTORNEY

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

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

Signature	Title	Date
-----	-----	-----
Principal Executive Officer:		
/s/ARTHUR D. LEVINSON ----- Arthur D. Levinson	Chairman, Chief Executive Officer and Director	March 9, 2001
Principal Financial Officer:		
/s/LOUIS J. LAVIGNE, JR. ----- Louis J. Lavigne, Jr.	Executive Vice President and Chief Financial Officer	March 9, 2001

Edgar Filing: GENENTECH INC - Form 10-K

Director:

/s/HERBERT W. BOYER ----- Herbert W. Boyer	Director	March 9, 2001
/s/JONATHAN K.C. KNOWLES ----- Jonathan K.C. Knowles	Director	March 9, 2001
/s/FRANZ B. HUMER ----- Franz B. Humer	Director	March 9, 2001
/s/MARK RICHMOND ----- Mark Richmond	Director	March 9, 2001
/s/CHARLES A. SANDERS ----- Charles A. Sanders	Director	March 9, 2001

SCHEDULE II

GENENTECH, INC.
VALUATION AND QUALIFYING ACCOUNTS
Years Ended December 31, 2000, 1999 and 1998
(in thousands)

	Balance at Beginning of Period -----	Additions Charged to Costs and Expenses -----	Deductions (1) -----	Balance End of Period -----
Allowance for doubtful accounts and returns:				
Year Ended December 31, 2000:	\$ 18,951 =====	\$ 16,167 =====	\$ (17,808) =====	\$ 17,310 =====
Period from June 30 to December 31, 1999:	\$ 17,744 =====	\$ 4,318 =====	\$ (3,111) =====	\$ 18,951 =====
Period from January 1 to June 30, 1999:	\$ 17,418 =====	\$ 3,985 =====	\$ (3,659) =====	\$ 17,744 =====
Year Ended December 31, 1998:	\$ 14,535 =====	\$ 11,389 =====	\$ (8,506) =====	\$ 17,418 =====
Inventory reserves:				
Year Ended December 31, 2000:	\$ 16,384	\$ 14,500	\$ (19,067)	\$ 11,817

Edgar Filing: GENENTECH INC - Form 10-K

Period from June 30 to December 31, 1999:	=====	=====	=====	=====
	\$ 16,447	\$ 2,382	\$ (2,445)	\$ 16,3
Period from January 1 to June 30, 1999:	=====	=====	=====	=====
	\$ 14,904	\$ 10,901	\$ (9,358)	\$ 16,4
Year Ended December 31, 1998:	=====	=====	=====	=====
	\$ 12,055	\$ 5,405	\$ (2,556)	\$ 14,9
Reserve for nonmarketable equity securities and convertible equity loans:				
Year Ended December 31, 2000:	=====	=====	=====	=====
	\$ 29,045	\$ 3,740	\$ -	\$ 32,7
Period from June 30 to December 31, 1999:	=====	=====	=====	=====
	\$ 19,648	\$ 9,397	\$ -	\$ 29,0
Period from January 1 to June 30, 1999:	=====	=====	=====	=====
	\$ 12,143	\$ 7,505	\$ -	\$ 19,6
Year Ended December 31, 1998:	=====	=====	=====	=====
	\$ 5,490	\$ 7,958	\$ (1,305)	\$ 12,1

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

INDEX OF EXHIBITS FILED WITH FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2000

Exhibit No.	Description
-----	-----
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation
10.25	1999 Stock Plan, as amended and restated as of December 8, 2000
13.1	Portions of the 2000 Annual Report to Stockholders
23.1	Consent of Ernst & Young LLP, Independent Auditors