10-K 1 form10-k_2008.htm GENENTECH, INC. FORM 10-K FOR THE PERIOD ENDING DECEMBER 31, 2008

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

or

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

For the transition period from _____ to _____

Commission file number: 1-9813

GENENTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-2347624**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1 DNA Way, South San Francisco, California	**94080**
(Address of principal executive offices)	(Zip Code)

(650) 225-1000

(Registrant's telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.02 par value	New York Stock Exchange

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

None

(Title of class)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

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

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐

The aggregate market value of Common Stock held by non-affiliates as of June 30, 2008 was $35,103,983,241.[(A)] All executive officers and directors of the registrant and Roche Holdings, Inc. have been deemed, solely for the purpose of the foregoing calculation, to be "affiliates" of the registrant.

Number of shares of Common Stock outstanding as of February 6, 2009: 1,053,413,655

Documents incorporated by reference:

Portions of the Definitive Proxy Statement with respect to the 2009 Annual Meeting of Stockholders to be filed by Genentech, Inc. with the Securities and Exchange Commission (hereinafter referred to as "Proxy Statement")	Part III

[(A)] Excludes 587,253,150 shares of Common Stock held by directors and executive officers of Genentech and Roche Holdings, Inc.

GENENTECH, INC.

2008 Form 10-K Annual Report

Table of Contents

par value $0.02 per share, all of which was redeemed by Roche Holdings, Inc. (RHI) on June 30, 1999.

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Activase® (alteplase, recombinant) tissue-plasminogen activator; Avastin® (bevacizumab) anti-VEGF antibody; Cathflo® Activase® (alteplase for catheter clearance); Genentech®; Herceptin® (trastuzumab) anti-HER2 antibody; Lucentis® (ranibizumab) anti-VEGF antibody fragment; Nutropin® (somatropin [rDNA origin] for injection) growth hormone; Nutropin AQ® and Nutropin AQ Pen® (somatropin [rDNA origin] for injection) liquid formulation growth hormone; Pulmozyme® (dornase alfa, recombinant) inhalation solution; Raptiva® (efalizumab) anti-CD11a antibody; and TNKase® (tenecteplase) single-bolus thrombolytic agent. Rituxan® (rituximab) anti-CD20 antibody is a registered trademark of Biogen Idec Inc.; Tarceva® (erlotinib) is a registered trademark of OSI Pharmaceuticals, Inc.; and Xolair® (omalizumab) anti-IgE antibody is a registered trademark of Novartis AG. This report also includes other trademarks, service marks, and trade names of other companies.

PART I

Item 1. BUSINESS

Overview

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines for patients with significant unmet medical needs. A number of the currently approved biotechnology products originated from or are based on Genentech science. We commercialize multiple biotechnology products and also receive royalties from companies that are licensed to market products based on our technology. See "Marketed Products" and "Licensed Products" below. Genentech was organized in 1976 as a California corporation and was reincorporated in Delaware in 1987.

Marketed Products

We commercialize the pharmaceutical products listed below in the United States (U.S.):

Avastin (bevacizumab) is an anti-VEGF (vascular endothelial growth factor) humanized antibody approved for use in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first- or second-line metastatic cancer of the colon or rectum. It is also approved for use in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC). On February 22, 2008, we received accelerated approval from the U.S. Food and Drug Administration (FDA) to market Avastin in combination with paclitaxel chemotherapy for the treatment of patients who have not received prior chemotherapy for metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer (BC).

Rituxan (rituximab) is an anti-CD20 antibody that we commercialize with Biogen Idec Inc. It is approved for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) as a single agent. Rituxan is also approved for patients with previously untreated follicular, CD20-positive, B-cell NHL in combination with cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Rituxan is indicated for patients with non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent, after first-line CVP chemotherapy. Rituxan is also indicated for patients with previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Rituxan is also indicated for use in combination with methotrexate to reduce signs and symptoms and slow the progression of structural damage in adult patients with moderate-to-severe rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

Herceptin (trastuzumab) is a humanized anti-HER2 antibody approved for treatment of patients with node-positive or node-negative early-stage BC, whose tumors overexpress the HER2 protein, as part of an adjuvant treatment regimen containing 1) doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel or 2) docetaxel and carboplatin, and as a single agent following multi-modality anthracycline-based adjuvant therapy. It is also approved for use as a first-line metastatic BC therapy in combination with paclitaxel and as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease.

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

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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

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With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.