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

Form 10-K

(Mark One)  $\checkmark$ 

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Item 1.

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE **ACT OF 1934** For the fiscal year ended December 31, 2004 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: 0-19311

# **Biogen Idec Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

14 Cambridge Center, Cambridge,

Massachusetts

(Address of principal executive offices)

(Registrant's telephone number, including area code) (617) 679-2000

Securities registered pursuant to Section 12(b) of the Act: None

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

Common Stock, \$0.0005 par value and Series X Junior Participating Preferred Stock Purchase Rights

(Title of class)

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 o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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. 0

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes 🗹 No o

The aggregate market value of the Registrant's Common Stock held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter was \$21,197,833,965.

As of March 10, 2005, the Registrant had 344,027,240 shares of Common Stock, \$0.0005 par value, issued and outstanding.

# DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

# **BIOGEN IDEC INC.**

#### **ANNUAL REPORT ON FORM 10-K**

For the Fiscal Year Ended December 31, 2004

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33-0112644 (I.R.S. Employer Identification No.)

> 02142 (Zip code)

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# Item 1. Business

#### Overview

Biogen Idec creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. We currently have five products:

AVONEX® (interferon beta-1a). AVONEX is approved for the treatment of relapsing forms of multiple sclerosis, or MS, and is the most prescribed therapeutic product in MS worldwide. Globally over 130,000 patients have chosen AVONEX as their treatment of choice. In 2004, sales of AVONEX generated worldwide revenues of \$1.42 billion as compared to worldwide sales of \$1.17 billion in 2003.

*RITUXAN*® (*rituximab*). RITUXAN is approved worldwide for the treatment of certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs. We market RITUXAN in the U.S. in collaboration with Genentech, Inc., or Genentech. All U.S. sales of RITUXAN are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis. In 2004, RITUXAN generated U.S. net sales of \$1.57 billion of which we recorded \$469.5 million as our share of copromotion profits as compared to U.S. net sales of \$1.36 billion in 2003 of which we recorded \$419.2 million as our share of copromotion profits. F. Hoffmann-La Roche Ltd., or Roche, sells rituximab outside the U.S., except in Japan where it co-markets RITUXAN in collaboration with Zenyaku Kogyo Co. Ltd., or Zenyaku. We received royalties through Genentech on sales of rituximab outside of the U.S. of \$121.0 million in 2004 as compared to \$67.9 million in 2003. We are working with Genentech and Roche on the development of RITUXAN in additional oncology indications and rheumatoid arthritis, or RA. RITUXAN is the trade name for the compound rituximab in the U.S., Canada and Japan. MabThera is the tradename for rituximab in the EU. In this Form 10-K, we refer to rituximab, RITUXAN, and MabThera collectively as RITUXAN, except where we have otherwise indicated.

*TYSABRI*® (*natalizumab*), formerly known as ANTEGREN®. TYSABRI was approved by the United States Food and Drug Administration, or FDA, in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan Corporation, plc, or Elan, voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and RA. These decisions were based on reports of two serious adverse events that occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of progressive multifocal leukoencephalopathy, or PML, a rare and frequently fatal, demyelinating disease of the central nervous system. Both patients received more than two years of TYSABRI in combination with AVONEX. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability.

*ZEVALIN® (ibritumomab tiuxetan).* ZEVALIN was the first radioimmunotherapy approved by the FDA for the treatment of cancer. ZEVALIN, as part of the ZEVALIN therapeutic regimen, is approved in the U.S. as a treatment for relapsed or refractory low-grade, follicular, or transformed B-cell NHL including patients with RITUXAN refractory follicular non-Hodgkin's lymphoma. In 2004, sales of ZEVALIN in the U.S. generated revenues of \$18.7 million as compared to revenues of \$19.6 million in 2003. Outside the U.S., we have licensed our marketing rights in ZEVALIN to Schering AG. In January 2004, the European Medicines Agency, or EMEA, granted marketing approval of ZEVALIN in the EU for the treatment of adult

patients with CD20+ follicular B-cell NHL who are refractory to or have relapsed following RITUXAN therapy. Rest of world product sales for ZEVALIN for the year ended December 31, 2004 were \$4.3 million. The \$4.3 million relates to ZEVALIN sold to Schering AG in 2003 and 2004, recognition of which had been deferred.

*AMEVIVE*® (*alefacept*). AMEVIVE is approved in the U.S. for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. In 2004, AMEVIVE was approved for the same indication in Argentina, Australia, Canada, Israel, Kuwait and Switzerland. In 2004, sales of AMEVIVE generated worldwide revenues of \$43.0 million, substantially all of which were generated from sales in the U.S., as compared to sales of \$40.4 million in 2003.

We also receive royalty revenues on sales by our licensees of a number of products covered under patents that we control. In addition, we have a pipeline of research and development products in our core therapeutic areas and in other areas of interest.

We devote significant resources to research and development programs. Our research and development efforts are primarily focused on finding therapeutics in our focus areas of oncology, neurobiology and immunology. These efforts include our collaboration with Elan on the development of TYSABRI as a potential treatment for Crohn's disease and RA, our work with Genentech and Roche on the development of RITUXAN in additional oncology indications and RA, and our collaboration with Fumapharm AG, or Fumapharm, on development of an oral therapy as a potential treatment for psoriasis and MS. We supplement our internal research efforts to find novel therapeutics in these areas and in other areas of interest with genomics tools and other innovative technologies. We also seek to advance our research and development efforts through collaborations.

*Merger*. On November 12, 2003, Bridges Merger Corporation, a wholly owned subsidiary of IDEC Pharmaceuticals Corporation, was merged with and into Biogen, Inc. with Biogen, Inc. continuing as the surviving corporation and a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. At the same time, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc. The merger and name change were made under an Agreement and Plan of Merger dated as of June 20, 2003. As a result of the merger, each issued and outstanding share of Biogen, Inc. common stock was converted into the right to receive 1.15 shares of Biogen Idec common stock. Our stock trades on the Nasdaq National Market under the symbol "BIIB." The results of Biogen, Inc.'s operations from November 13, 2003, the day after the effective date of the merger, to December 31, 2003 have been included in the 2003 consolidated financial statements filed in this Annual Report on Form 10-K.

*Available Information.* We are a Delaware corporation with principal executive offices located at 14 Cambridge Center, Cambridge, Massachusetts 02142. Our telephone number is (617) 679-2000 and our website address is www.biogenidec.com. We make available free of charge through the Investor Relations section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC. We include our website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website.

# **Our Products — Approved Indications and Ongoing Development**

Our products are targeted to address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology. They are as follows:

Product	Product Indications	Status	Development and/or Marketing Collaborators
AVONEX	Certain forms of MS	Approved worldwide	None
	Chronic Inflammatory Demyelinating Polyradioneuropathy	Phase 2b — enrollment	None
RITUXAN	Certain B-cell NHLs	Approved worldwide	U.S. — Genentech Outside U.S. and Japan — Roche Japan — Roche and Zenyaku
	Relapsed chronic lymphocytic leukemia	Phase 3	U.S. — Genentech Outside U.S. and Japan — Roche Japan — Roche and Zenyaku
	RA	Phase 3 — TNF failures Phase 2b — DMARD failures	U.S. — Genentech Outside U.S. and Japan — Roche Japan — Roche and Zenyaku
	Lupus/MS	Phase 2	U.S. — Genentech Outside U.S. and Japan — Roche Japan — Roche and Zenyaku
ZEVALIN	Certain B-cell NHLs (radioimmunotherapy)	Approved — U.S. and EU	Outside U.S. — Schering AG
AMEVIVE	Moderate-to-severe chronic plaque psoriasis	Approved — U.S., Argentina, Australia, Canada, Israel, Kuwait and Switzerland Under regulatory review — New Zealand Application withdrawn — EU	None
TYSABRI	MS	Approved — U.S.; marketing, commercial distribution and dosing in clinical studies suspended in February 2005 Under regulatory review — EU	Elan
	Crohn's disease	Phase 3 — two Phase 3 trials completed; dosing in all clinical studies, including additional Phase 3 induction trial, suspended in February 2005 Under regulatory review — EU	Elan
	RA	Phase 2; dosing in all clinical studies suspended in February 2005	Elan

#### **AVONEX**

We currently market and sell AVONEX worldwide for the treatment of relapsing MS. In 2004, sales of AVONEX generated worldwide revenues of \$1.42 billion as compared to worldwide sales of \$1.17 billion in 2003. AVONEX was sold by Biogen, Inc. until November 12, 2003. Our consolidated financial statements include only the results of operations of Biogen, Inc. since November 13, 2003. Our revenues from AVONEX during the period from November 13, 2003 to December 31, 2003 were \$142.6 million.

MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis and, in some cases, death. Patients with active relapsing MS experience an uneven pattern of disease progression characterized by periods of stability interrupted by flare-ups of the disease after which the patient returns to a new baseline of functioning. AVONEX is a recombinant form of a protein produced in the body by fibroblast cells in response to viral infection. AVONEX has been shown in clinical trials in relapsing forms of MS both to slow the accumulation of disability and to reduce the frequency of flare-ups. AVONEX is approved to treat relapsing forms of MS, including MS patients with a first clinical episode and MRI features consistent with MS. Biogen, Inc. began selling AVONEX in the U.S. in 1996, and in the EU in 1997. AVONEX is on the market in more than 60 countries. Based on data from an independent third party research organization, information for our distributors and internal analysis, we believe that AVONEX is the most prescribed therapeutic product for the treatment of MS worldwide. Globally, over 130,000 patients have selected AVONEX as their treatment of choice.

As part of our commitment to AVONEX, we work to make treatment and delivery more convenient. For example, AVONEX is now available in a prefilled syringe formulation as well as a dry powder form. A syringe grip device to aid patients with compromised manual dexterity in injecting AVONEX was approved by the FDA in 2004.

We also continue to work to expand the data available about AVONEX. We have extended the Controlled High Risk AVONEX Multiple Sclerosis Prevention Study In Ongoing Neurological Surveillance, or CHAMPIONS. CHAMPIONS was originally designed to determine whether the effect of early treatment with AVONEX in delaying relapses and reducing the accumulation of MS brain lesions could be sustained for up to five years. The study results showed that AVONEX altered the long-term course of MS in patients who began treatment immediately after their initial MS attack compared to initiation of treatment more than two years after onset of symptoms. The five-year study extension is intended to determine if the effects of early treatment with AVONEX can be sustained for up to 10 years. We are conducting a study with Surromed, Inc. to investigate the biologic markers and phenotype of MS patients with and without AVONEX treatment. We also continue to support Phase 4 investigator-run studies evaluating AVONEX in combination with other therapies. In addition, we recently initiated enrollment into a Phase 2b study of AVONEX as a treatment for Chronic Inflammatory Demyelinating Polyradioneuropathy.

In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of our other MS drug TYSABRI and suspended dosing in all clinical studies of TYSABRI, including clinical studies of TYSABRI in combination with AVONEX. These decisions were based on reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX. These events involved two cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. Both patients received more than two years of TYSABRI in combination with AVONEX. For additional information related to TYSABRI and PML, see "Our Products – Approved Indications and Ongoing Development — TYSABRI."

# RITUXAN

*Overview.* RITUXAN is approved worldwide for the treatment of certain B-cell NHLs. We market RITUXAN in the U.S. in collaboration with Genentech. All U.S. sales of RITUXAN are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis. In 2004, RITUXAN generated U.S. net sales of \$1.57 billion of which we recorded \$469.5 million as our share of copromotion profits as compared to U.S. net sales of \$1.36 billion in 2003 of which we recorded \$419.2 million



as our share of copromotion profits. Roche sells RITUXAN outside the U.S., except in Japan where it co-markets RITUXAN in collaboration with Zenyaku. We received royalties through Genentech on sales of RITUXAN outside of the U.S. of \$121.0 million in 2004 as compared to \$67.9 million in 2003.

In the U.S., we copromote RITUXAN with Genentech and share responsibility with Genentech for continued development. Such continued development includes conducting supportive research and post-approval clinical studies and seeking potential approval for additional indications. Genentech provides the support functions for the commercialization of RITUXAN in the U.S. and has worldwide manufacturing responsibilities. See "Sales, Marketing and Distribution — RITUXAN and ZEVALIN" and "Manufacturing and Raw Materials." We also have the right to collaborate with Genentech on the development of other humanized anti-CD20 antibodies targeting B-cell disorders for a broad range of indications, and to copromote with Genentech any new products resulting from such development in the U.S.

RITUXAN is approved in the U.S. for single agent use in relapsed or refractory, low grade or follicular CD20-positive B-cell NHL, which comprise approximately half of the B-cell NHLs diagnosed in the U.S. RITUXAN is administered as outpatient therapy by personnel trained in administering chemotherapies or biologics. A standard course of RITUXAN therapy consists of four intravenous infusions given on days one, eight, 15 and 22, unlike chemotherapy which is given typically in repeating cycles for up to four to eight months. RITUXAN is also approved to be administered as an 8-dose regimen, for retreatment of patients with B-cell NHL who have previously responded to RITUXAN and for use in patients who have bulky tumors. RITUXAN is unique in the treatment of B-cell NHLs due to its specificity for the antigen CD20, which is expressed only on the surface of normal B cells and malignant B cells. Stem cells (including B-cell progenitors or precursor B-cells) in bone marrow lack the CD20 antigen. This allows healthy B-cells to regenerate after treatment with RITUXAN and to return to normal levels within several months. RITUXAN's mechanism of action utilizes the body's own immune system as compared to conventional lymphoma therapies.

*RITUXAN in Oncology.* In an effort to identify expanded applications for RITUXAN, we, in conjunction with Genentech and Roche, continue to support RITUXAN post-marketing studies. Ongoing and completed Phase 2 and 3 studies suggest that RITUXAN may have promise as a front-line therapy in combination with various chemotherapies in indolent and aggressive non-Hodgkin's lymphoma, as a single agent in the treatment of aggressive B-cell NHLs and relapsed chronic lymphocytic leukemia, or CLL, and as maintenance therapy in indolent B-cell NHLs. These studies include:

- A randomized Phase 3 study of the addition of RITUXAN to a chemotherapy regimen of cyclophosphamide, vincristine and prednisone, also known as CVP, in previously untreated, or front line patients with indolent non- Hodgkin's lymphoma. In this investigator-run study, 321 patients who had not received previous treatment for CD20 positive follicular or indolent non-Hodgkin's lymphoma were randomized to receive either CVP alone or CVP with RITUXAN. The initial results of the study indicated that the addition of RITUXAN to CVP prolonged time to treatment failure, the primary endpoint of the study, to 26 months compared to seven months for patients treated with CVP alone. Based on the results from this study, in August 2004, MabThera was approved by the EMEA as a first line treatment for indolent non-Hodgkin's lymphoma in combination with CVP.
- A randomized Phase 3 study, known as E4494, of patients age 60 or older with newly diagnosed, diffuse, large B-cell, or aggressive non-Hodgkin's lymphoma, comparing a chemotherapy regimen consisting of cyclophosphamide, doxorubicin, vincristine and prednisone, also known as CHOP, alone to a regimen of RITUXAN plus CHOP, also known as R-CHOP, as a front-line or induction therapy followed by RITUXAN maintenance therapy or observation for those patients who responded positively to either R-CHOP or CHOP alone. The study is a U.S. Intergroup study led by the Eastern Cooperative Oncology Group, or ECOG. The primary endpoint of the induction and maintenance phases of the study was time to treatment failure. Due to the observed interaction between RITUXAN maintenance and induction therapy, additional analyses were performed to compare induction therapy with R-CHOP versus CHOP alone, removing the effects of subsequent RITUXAN maintenance therapy. Based on these additional analyses, the investigators concluded that patients who received R-CHOP induction therapy experienced prolonged time to treatment failure and overall survival

compared to patients who received induction therapy with CHOP alone. In the maintenance phase of the study, patients treated with RITUXAN maintenance therapy for up to an additional two years after completing induction therapy had a statistically significant delay in time to treatment failure compared to patients who did not receive RITUXAN maintenance therapy following induction. At the time of the interim analysis, this advantage appears predominantly confined to patients who received CHOP alone during the induction phase.

- A multi-center, randomized Phase 2 study of 114 patients with relapsed indolent non-Hodgkin's lymphoma designed to compare the efficacy of RITUXAN maintenance therapy to retreatment with RITUXAN. Maintenance therapy was defined as treatment with RITUXAN every six months for two years with the objective of keeping lymphoma from returning or progressing. Retreatment was defined as waiting until the disease progressed prior to administering another course of RITUXAN. The initial results of this investigator-run study showed that patients who received RITUXAN maintenance therapy experienced 31 months of progression-free survival as compared to eight months of progression-free survival for those patients who received retreatment.
- A large Phase 3 randomized study of 824 patients, known as MinT, designed to evaluate RITUXAN in combination with chemotherapy as a front-line treatment for aggressive large, B-cell NHL in patients age 18 to 60. This study, which was conducted by an international cooperative group and sponsored by Roche, met its pre-specified primary efficacy endpoint early. Positive results from the study were announced in June 2004. The study authors concluded that data from the study demonstrated a significant improvement in time to treatment failure, the primary endpoint of the study. At two years, 81% of patients who received RITUXAN and chemotherapy did not experience treatment failure compared to 58% of patients who received chemotherapy alone.
- A Phase 3 study, known as E1496, designed to compare RITUXAN maintenance therapy versus observation in patients with previously untreated indolent non-Hodgkin's lymphoma who achieved stable disease or better after induction therapy with CVP. The study, which was led by ECOG, met its pre-specified primary efficacy endpoint early. Positive results from the study were announced in June 2004. The study authors concluded that there was a significant improvement in progression free survival, the primary endpoint of the study. The authors estimated that 73% of patients who received RITUXAN maintenance therapy were free of disease progression and alive at two years compared to 43% of patients who received no further treatment. In this trial, maintenance therapy began four weeks after the last cycle of chemotherapy and was defined as four doses of RITUXAN every six months for two years.

We, along with Genentech and Roche, are also conducting a multi-center global Phase 3 registrational study in patients with relapsed CLL comparing the use of fludarabine, cyclophosphamide and RITUXAN together, known as FCR, versus fludarabine and cyclophosphamide alone. This study is open at multiple sites worldwide. Additional clinical studies are ongoing in other B-cell malignancies such as lymphoproliferative disorders associated with solid organ transplant therapies, relapsed aggressive non-Hodgkin's lymphoma and mantle cell non-Hodgkin's lymphoma.

*RITUXAN in RA.* The positive results from a Phase 2a study of 161 patients with moderate-to-severe, active, long-standing RA who had previously failed one to five disease-modifying anti-rheumatic drugs (DMARDs) were announced in October 2003 and published in the New England Journal of Medicine in June 2004. The study was a four arm, placebo controlled trial in which patients were randomized to receive RITUXAN alone, RITUXAN in combination with cyclophosphamide, RITUXAN in combination with methotrexate, or methotrexate alone. All patients also received a brief course of corticosteroids. The study showed that two doses of RITUXAN, administered two weeks apart, improved symptoms for up to 48 weeks in all arms in which it was administered. Investigators followed-up with patients at 48 weeks in order to assess duration of response beyond the primary endpoint of 24 weeks. At 24 weeks, investigators found that patients receiving the combination of RITUXAN and methotrexate had the greatest improvement in symptoms as assessed by the American College of Rheumatology (ACR) response criteria: 73% of patients showed at least a 20% improvement, 43% showed at least a 50% improvement and 23% showed at least a 70% improvement.



At 48 weeks, 65% of the patients in the RITUXAN and methotrexate combination arm of the trial showed at least a 20% improvement, 35% showed at least a 50% improvement and 15% showed at least a 70% improvement.

Based on results from the Phase 2a study, we, along with Genentech and Roche, initiated additional studies evaluating RITUXAN in the treatment of RA. One of these studies is a Phase 3 study known as REFLEX, studying the use of RITUXAN in treating patients who have had an inadequate response to tumor necrosis factor (TNF) inhibitor therapies. Data from REFLEX is expected to be available in the first half of 2005. The other study, a multi-center, randomized, double-blind, placebo-controlled, Phase 2b dose optimization study, known as DANCER, is evaluating the efficacy and safety of varying doses of both RITUXAN and corticosteroids in combination with a stable dose of methotrexate in patients who have failed one to five DMARDs and are inadequately responding to methotrexate. In DANCER, a total of 465 patients were randomized to receive a stable dose of methotrexate and a varying dose of RITUXAN and corticosteroids. In November 2004, we, along with Genentech and Roche, announced that DANCER met its primary endpoint of a greater proportion of RITUXAN-treated patients achieving an ACR 20 response at week 24, compared to placebo, in patients who were also treated with methotrexate. Further analyses of the data from DANCER are ongoing.

*RITUXAN in Other Immunology Indications.* Based on results from the Phase 2a study of RITUXAN in RA, as well as other small investigator-sponsored studies in various autoimmune-mediated diseases, we, along with Genentech, have initiated early-stage clinical trials studying RITUXAN in MS and lupus.

### **TYSABRI**

Overview. The FDA granted accelerated approval for TYSABRI in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. The approval was based on one-year data from two Phase 3 clinical studies: AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) and SENTINEL (safety and efficacy of natalizumab in combination with AVONEX), each a two-year, randomized multi-center, placebo-controlled and double blinded study. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and RA. These decisions were based on reports of two serious adverse events that occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases (one confirmed and one suspected at the time of the decisions) of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. The suspected case of PML was subsequently confirmed. Both patients received more than two years of TYSABRI therapy in combination with AVONEX. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical trials and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability. We cannot predict the outcome of these evaluations. See "Forward-Looking Information and Risk Factors That May Affect Future Results - Safety Issues with TYSABRI Could Significantly Affect our Growth."

In June 2004, Elan submitted a Marketing Authorisation Application, or MAA, to the EMEA for approval of TYSABRI in MS. We are working closely with the EMEA in order to provide them with information regarding the status of our evaluation of the possible risk of PML with TYSABRI and any additional information that they may request so that they can conduct a risk/benefit assessment in accordance with regulatory requirements. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth."

TYSABRI binds to adhesion molecules on the immune cell surface known as alpha-4 integrin. Adhesion molecules on the surface of the immune cells play an important role in the migration of the immune cells in the inflammatory process. Research suggests that by binding to alpha-4 integrin, TYSABRI prevents immune cells from migrating from the bloodstream into tissue where they can cause inflammation and potentially damage nerve fibers and their insulation.

PHASE 3 Studies of TYSABRI in MS. Prior to the suspension of dosing in clinical studies of TYSABRI we, along with Elan, had completed the AFFIRM study and had substantially completed the SENTINEL study. The AFFIRM study was designed to evaluate the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses. The SENTINEL study was designed to evaluate the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing progression of disability and reducing the rate of clinical relapses. Both studies have protocols that included a one-year analysis of the data. The one-year data from the AFFIRM study showed that TYSABRI reduced the rate of clinical relapses by 66% relative to placebo, the primary endpoint at one year. AFFIRM also met all one-year secondary endpoints, including MRI measures. In the TYSABRI treated group, 60% of patients developed no new or newly enlarging T2 hyperintense lesions compared to 22% of placebo treated patients. On the one-year MRI scan, 96% of TYSABRI treated patients had no gadolinium enhancing lesions compared to 68% of placebo treated patients. The proportion of patients who remained relapse free was 76% in the TYSABRI treated group compared to 53% in the placebo treated group. The one-year data from the SENTINEL combination study also showed that the study achieved its one-year primary endpoint. The addition of TYSABRI to AVONEX resulted in a 54% reduction in the rate of clinical relapses over the effect of AVONEX alone. The annualized relapse rate was 0.36 for patients receiving TYSABRI when added to AVONEX versus 0.78 with AVONEX plus placebo. SENTINEL also met all secondary endpoints, including MRI measures. In the group treated with TYSABRI plus AVONEX, 67% of the patients developed no new or newly enlarging T2 hyperintense lesions compared to 40% in the AVONEX plus placebo group. On the one-year MRI scan, 96% of TYSABRI plus AVONEX treated patients had no gadolinium enhancing lesions compared to 76% of AVONEX plus placebo treated patients. The proportion of patients who remained relapse free was 67% in the TYSABRI plus AVONEX treated group compared to 46% in the AVONEX plus placebo treated group. In February 2005, we and Elan announced that the AFFIRM study also achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of MS. In the TYSABRI treated group, there was a 42% reduction in the risk of disability progression relative to placebo, and a 67% reduction in the rate of clinical relapses over two years, which was sustained and consistent with the oneyear results.

*TYSABRI in Crohn's Disease.* We, along with Elan, have completed two Phase 3 studies of TYSABRI in Crohn's disease. In February 2005, we suspended dosing in an additional fully enrolled Phase 3 induction study of TYSABRI in Crohn's disease until we complete our evaluation of the possible risk of PML in patients treated with TYSABRI. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported as malignant astrocytoma. The two completed Phase 3 studies are known as ENACT-2 (Evaluation of Natalizumab as Continuous Therapy-2) and ENACT-1 (Evaluation of Natalizumab as Continuous Therapy-1). In the double-blinded, placebo controlled ENACT-2, 428 patients who were responders in ENACT-1, the Phase 3 induction study, were re-randomized to one of two treatment groups, TYSABRI or placebo, both administered monthly for a total of 12 months. In ENACT-1, the primary endpoint of "response," as defined by a sustained CDAI score of less than 220 as well as no use of rescue intervention throughout six months of the study, was met. The primary endpoint of ENACT-2 looked at results through month six. Through month six, there was a significant treatment difference of greater than 30% in favor of patients taking TYSABRI compared to those taking placebo. In September 2004, we and Elan announced new 12-month data from ENACT-2 showing a sustained and clinically significant response throughout 12 months of extended TYSABRI infusion therapy, confirming findings in patients who had previously shown a sustained response throughout six months. Maintenance of response was defined by a CDAI score of less than 220, and less than 70-point increase from baseline, in the

absence of rescue intervention throughout the study. Response was maintained by 54% of patients treated with natalizumab compared to 20% of those treated with placebo. In addition, 39% of patients on TYSABRI maintained clinical remission during the study period, versus 15% of those on placebo. By the end of month 12, 49% of patients treated with TYSABRI who had previously been treated with corticosteroids were able to withdraw from steroid therapy compared to 20% of placebo-treated patients. In September 2004, Elan submitted an MAA to the EMEA for approval of TYSABRI as a treatment for Crohn's disease. This application is at an earlier stage than the MS application. However, as with the MAA for MS, we are working closely with the EMEA in order to provide them with information regarding the status of our evaluation of the possible risk of PML with TYSABRI and any additional information that they may request. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth."

*TYSABRI in RA*. In February 2005, we, along with Elan, suspended dosing in a recently fully enrolled Phase 2 study of TYSABRI in RA until we complete our evaluation of the possible risk of PML in patients treated with TYSABRI. The study is a multi-center, double-blind, placebo-controlled study of the efficacy, safety and tolerability of intravenous TYSABRI in patients with moderate-to-severe RA receiving concomitant treatment with methotrexate.

#### ZEVALIN

ZEVALIN was the first radioimmunotherapy approved by the FDA for the treatment of cancer. ZEVALIN, as part of the ZEVALIN therapeutic regimen, is indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma, including patients with RITUXAN relapsed or refractory non-Hodgkin's lymphoma. In 2004, sales of ZEVALIN in the U.S. generated revenues of \$18.7 million as compared to revenues of \$19.6 million in 2003. In January 2004, the EMEA granted marketing approval of ZEVALIN in the EU for the treatment of adult patients with CD20+ follicular B-cell NHL who are refractory to or have relapsed following RITUXAN therapy. We sell ZEVALIN to Schering AG for distribution in the EU, and receive royalty revenues from Schering AG on sales of ZEVALIN in the EU. Rest of world product sales for ZEVALIN for the year ended December 31, 2004 were \$4.3 million. The \$4.3 million relates to ZEVALIN sold to Schering AG in 2003 and 2004, recognition of which had been deferred.

Radiation therapy plays an important role in the management of B-cell lymphomas due to the sensitivity of B-cell tumors to radiation. Traditional radiation therapy consists of an external beam of radiation focused on isolated areas of the body or areas with high tumor burden. The ZEVALIN therapeutic regimen combines a monoclonal antibody with a radioisotope. Following intravenous infusion, the monoclonal antibody recognizes and attaches to the CD20 antigen. This allows ZEVALIN to specifically target B-cells, destroying the malignant NHL B-cells and also normal B-cells.

ZEVALIN therapy consists of two kits: an imaging kit for use with indium-111 and a therapeutic kit for use with yttrium-90. The ZEVALIN therapeutic regimen can be completed on an outpatient basis in approximately 7 to 9 days and includes:

- administration of one dose of RITUXAN to deplete peripheral blood B cells and improve ZEVALIN biodistribution;
- imaging with the ZEVALIN imaging kit using indium-111, followed by gamma camera images at two to 24 hours, 48 to 72 hours, and an optional image at 90 to 120 hours, to confirm biodistribution of ZEVALIN;
- if acceptable biodistribution of ZEVALIN is demonstrated, another dose of RITUXAN is administered; and
- infusion of the ZEVALIN therapeutic kit using yttrium-90.

We are working with third party investigators to expand the quality and quantity of data available about ZEVALIN. ZEVALIN is being investigated in a variety of lymphoma subtypes including diffuse B cell

lymphoma. ZEVALIN is also being studied in a number of different treatment strategies including combinations with front-line and salvage chemotherapy regimens and as part of autologous and allogeneic stem cell transplantation in both indolent and aggressive lymphoma subtypes. For example, in June 2004, we announced positive results from a Phase 2 study showing that the ZEVALIN therapeutic regimen may produce high complete remission rates in previously untreated patients with low-grade follicular lymphoma when used following RITUXAN and a short course of CHOP.

#### AMEVIVE

In February 2003, Biogen, Inc. began marketing and selling AMEVIVE in the U.S. for the treatment of patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. In 2004, AMEVIVE was approved for the same indication in Argentina, Australia, Canada, Israel, Kuwait and Switzerland. Our filing for approval in New Zealand is currently being reviewed. Our application for approval in the EU was withdrawn in February 2003.

In 2004, sales of AMEVIVE generated worldwide revenues of \$43.0 million, substantially all of which were generated from sales in the U.S., as compared to sales of \$40.4 million in 2003. AMEVIVE was sold by Biogen, Inc. until November 12, 2003. Our consolidated financial statements include only the results of operations of Biogen, Inc. since November 13, 2003. Our revenues from AMEVIVE during the period from November 13, 2003 to December 13, 2003 were \$9.4 million.

Psoriasis is an autoimmune skin disease in which skin cells multiply 10 times faster than the normal rate. The excess cells pile up on the skin's surface, forming red, raised, scaly plaques that can be painful and disfiguring. AMEVIVE is a systemic therapy that works by helping to rebalance the overactive cells in the immune system that cause psoriasis. These cells, called T-cells, are central to the immune response when working properly, but are directed inappropriately against the body's own tissues in psoriasis and other autoimmune disorders. AMEVIVE has a dual mechanism of action that is designed to interfere with T-cell activation and to reduce the number of so-called memory T-cells.

We continue to conduct clinical studies of AMEVIVE. We are investigating AMEVIVE in combination with other systemic therapies. We are conducting open label studies of AMEVIVE in combination with common psoriasis treatments, including topical steroids, methotrexate, cyclosporine and phototherapy. Interim analyses of these studies indicate that AMEVIVE in combination with common psoriasis treatments is well tolerated for patients with moderate-to-severe chronic plaque psoriasis. In February 2005, we announced preliminary results from a double-blind, placebo-controlled Phase 2 study of 185 patients with active psoriatic arthritis who were randomized to receive either methotrexate and AMEVIVE or methotrexate. Patients in the AMEVIVE group received 15 mg of AMEVIVE by intramuscular injection once a week for 12 weeks, followed by a 12-week observation period. In the study, 54% of patients who received AMEVIVE for 12 weeks achieved an ACR 20 response, or at least a 20 percent improvement in the signs and symptoms of psoriatic arthritis, at 24 weeks, in contrast to 23% of patients achieving at least a 20 percent improvement in the methotrexate alone group. As part of our post marketing commitments to the FDA, we have completed a Phase 3b international study designed to provide further safety data regarding the use of AMEVIVE and which also measured the efficacy of AMEVIVE over multiple courses.

# **Our Other Research and Development Programs**

We focus our research and development efforts on finding novel therapeutics in areas of high unmet medical need. Our focus areas are in oncology, neurobiology and autoimmune disease. Below is a brief summary of some of our research and development product candidates.

#### Oncology

• an adenoviral vector encoding the human IFN-β gene, designed to deliver high local concentrations of IFN-β to tumors

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- an anti-lymphotoxin beta receptor monoclonal antibody, which has shown activity in inhibiting tumor growth in animal models
- an antibody to tumor antigen TAG72, designed to deliver radioimmunotherapy to carcinomas that carry the antigen while minimizing the radiation to normal tissues such as bone marrow
- anti-CD80 and anti-CD23 antibodies using our Primatized® antibody technology
- a monoclonal antibody directed against Cripto, a novel cell surface signaling molecule that is over-expressed in solid tumors

# Autoimmune Disease

- an oral fumarate that is a second-generation fumarate derivative with an immunomodulatory mechanism of action which we licensed from Fumapharm AG. A first-generation product is currently marketed by Fumapharm as FUMADERM® in Germany, where it is the most prescribed oral systemic treatment for severe psoriasis. Fumapharm has completed a small Phase 3 double-blind, multi-center clinical study of the second-generation product in psoriasis and plans to seek approval in Germany based on the results of the Phase 3 study, and is currently conducting a safety extension study in psoriasis in the EU. We began a Phase 2b clinical study of the second generation product in patients with relapsing-remitting MS in November 2004
- in separate collaborations with Genentech, a new humanized anti-CD20 antibody targeting B-cell disorders for a broad range of indications, and a BR3 protein therapeutic as a potential treatment for disorders associated with abnormal B-lymphocyte activity, such as RA and lupus
- a monoclonal antibody directed against alpha-1/beta-1 integrin (VLA-1). VLA-1 is found on a variety of cells associated with tissue inflammation and fibrosis, including activated T-cells, macrophages and myofibroblasts. Reduction of VLA-1 activity is associated with sharply reduced inflammation and fibrosis in experimental models of disease

#### Neurobiology

- in collaboration with Vernalis plc, V2006, the lead compound in Vernalis' adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders
- neublastin, a protein therapeutic that appears to maintains the viability and physiology of peripheral sensory neurons. Neublastin has shown activity in animal models of neuropathic pain

Except as otherwise noted, all of these product candidates are in pre-clinical or earlier stage of development.

We supplement our internal research and development efforts to find novel therapeutics in these areas and in other areas of interest with genomics tools and other innovative technologies. We also seek to advance our research and development efforts through collaborations.

#### **Research and Development Costs**

For the years ended December 31, 2004, 2003 and 2002, our research and development costs were approximately \$686.7 million, \$233.3 million and \$100.9 million, respectively. Research and development costs in 2003 include the results of operations of Biogen, Inc. only for the period from November 13, 2003, the day after the effective date of the merger, through December 31, 2003.

#### **Principal Licensed Products**

As described above, we receive royalties on sales of RITUXAN outside the U.S. as part of our collaboration with Genentech and royalties on sales of ZEVALIN in the EU from Schering AG. We also

receive royalties from sales by our licensees of a number of other products covered under patents that we control. For example:

- We receive royalties from Schering-Plough Corporation on sales of its alpha interferon products in the U.S. and Italy under an exclusive license to our alpha interferon patents and patent applications. Schering-Plough sells its INTRON® A (interferon alfa-2b) brand of alpha interferon in the U.S. for a number of indications, including the treatment of chronic hepatitis B and hepatitis C. Schering-Plough also sells other alpha interferon products for the treatment of hepatitis C, including REBETRON® Combination Therapy containing INTRON A and REBETOL® (ribavirin, USP), PEG-INTRON® (peginterferon alfa-2b), a pegylated form of alpha interferon, and PEG-INTRON in combination with REBETOL. See "Patents and Other Proprietary Rights Recombinant Alpha Interferon."
- We hold several important patents related to hepatitis B antigens produced by genetic engineering techniques. See "Patents and Other Proprietary Rights Recombinant Hepatitis B Antigens." These antigens are used in recombinant hepatitis B vaccines and in diagnostic test kits used to detect hepatitis B infection. We receive royalties from sales of hepatitis B vaccines in several countries, including the U.S., from GlaxoSmithKline plc and Merck and Co. Inc. We have also licensed our proprietary hepatitis B rights, on an antigen-by-antigen and nonexclusive basis, to several diagnostic kit manufacturers, including Abbott Laboratories, the major worldwide marketer of hepatitis B diagnostic kits. For a discussion of the length of the royalty obligation of GlaxoSmithKline and Merck on sales of hepatitis B vaccines and the obligation of our other licensees on sales of hepatitis B-related diagnostic products, see "Patents and Other Proprietary Rights Recombinant Hepatitis B Antigens."
- We also receive ongoing royalties on sales of ANGIOMAX®(bivalirudin) by The Medicines Company, also known as TMC. TMC sells ANGIOMAX in the U.S., Europe, Canada and Latin America for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty.

#### **Patents and Other Proprietary Rights**

We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development, including a number of our processes and products. Patents have been issued on many of these applications. We have also obtained rights to various patents and patent applications under licenses with third parties, which provide for the payment of royalties by us. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. There is no certainty that our existing patents or others, if obtained, will afford us substantial protection or commercial benefit. Similarly, there is no assurance that our pending patent applications or patent applications licensed from third parties will ultimately be granted as patents or that those patents that have been issued or are issued in the future will prevail if they are challenged in court.

A substantial number of patents have already been issued to other biotechnology and biopharmaceutical companies. Competitors may have filed applications for, or have been issued patents and may obtain additional patents and proprietary rights that may relate to products or processes competitive with or similar to our products and processes. Moreover, the patent laws of the U.S. and foreign countries are distinct and decisions as to patenting, validity of patents and infringement of patents may be resolved differently in different countries. In general, we try to obtain licenses to third party patents which we deem necessary or desirable for the manufacture, use and sale of our products. We are currently unable to assess the extent to which we may wish to or may be required to acquire rights under such patents and the availability and cost of acquiring such rights, or whether a license to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder our ability to market our products.

We are aware that others, including various universities and companies working in the biotechnology field, have filed patent applications and have been granted patents in the U.S. and in other countries claiming



subject matter potentially useful to our business. Some of those patents and patent applications claim only specific products or methods of making such products, while others claim more general processes or techniques useful or now used in the biotechnology industry. There is considerable uncertainty within the biotechnology industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world, and, to date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products.

There has been, and we expect that there may continue to be, significant litigation in the industry regarding patents and other intellectual property rights. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Conversely, litigation may be necessary in some instances to determine the validity, scope and/or noninfringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Intellectual property litigation could therefore create business uncertainty and consume substantial financial and human resources. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights, or, conversely, hinder our ability to market our products. See "Item 3 — Legal Proceedings" for a description of our patent litigation.

Our trademarks RITUXAN, AVONEX, AMEVIVE, ZEVALIN and TYSABRI are important to us and are generally covered by trademark applications or registrations owned or controlled by us in the U.S. Patent and Trademark Office and in other countries.

#### **Recombinant Beta Interferon**

Third parties have pending patent applications or issued patents in the U.S., Europe and other countries with claims to key intermediates in the production of beta interferon. These are known as the Taniguchi patents. Third parties also have pending patent applications or issued patents with claims to beta interferon itself. These are known as the Roche patents and the Rentschler patents, respectively. We have obtained non-exclusive rights in various countries of the world, including the U.S., Japan and Europe, to manufacture, use and sell AVONEX, our brand of recombinant beta interferon, under the Taniguchi, Roche and Rentschler issued patents. The last of the Taniguchi patents expire in the U.S. in May, 2013 and have expired already in other countries of the world. The Roche patents expire in the U.S. in May, 2008 and also have generally expired elsewhere in the world. The Rentschler EU patent expires in July, 2012.

#### RITUXAN, ZEVALIN and Anti-CD20 Antibodies

We have several issued U.S. patents and U.S. patent applications, and numerous corresponding foreign counterparts directed to anti-CD20 antibody technology, including RITUXAN and ZEVALIN. We have also been granted patents covering RITUXAN and ZEVALIN by the European and Japanese Patent Offices. In the U.S. our principal patents covering the drugs or their uses expire between 2015 and 2018. With regard to the rest of the world, our principal patents covering the drug products expire in 2013 subject to potential patent term extensions in countries where such extensions are available. In addition Genentech, our collaborative partner for RITUXAN, has secured an exclusive license to five U.S. patents and counterpart U.S. and foreign patent applications assigned to Xoma Corporation that relate to chimeric antibodies against the CD20 antigen. These patents expire between 2006 and 2014. Genentech has granted us a non-exclusive sublicense to make, have made, use and sell RITUXAN under these patents and patent applications. We, along with Genentech, share the cost of any royalties due to Xoma in the Genentech/ Biogen Idec copromotion territory on sales of RITUXAN.

#### AMEVIVE

AMEVIVE is presently claimed in a number of patents granted in the U.S. and the EU which cover LFA-3 polypeptides and DNA, LFA-3 fusion proteins and DNA, host cells, manufacturing methods and pharmaceutical compositions. We have obtained composition of matter patent coverage for the commercial

product and important intermediates in the manufacturing process. Our patent portfolio also includes patents granted in the U.S. and the EU, which cover the use of LFA-3 polypeptides and LFA-3 fusion proteins in methods to inhibit T cell responses and use of LFA-3 polypeptides and fusion proteins to treat skin diseases, specifically including psoriasis. Our patent portfolio further includes pending patent applications, which seek coverage for the use of LFA-3 polypeptides and fusion proteins in the treatment of other indications of possible future interest as well for certain combination therapy treatments of potential interest and utility. Patents issued or which may be issued on these various patent applications expire between 2007 (for patents relating to manufacturing intermediates) and 2021 (in the case of recently filed patent applications). Our principal patents covering the drug product expire in 2013 subject to potential patent term extensions in countries where such extensions are available and by supplemental protection certificates in countries of the EU where such certificates may be obtained if and when approval of the product in the EU is obtained. Method of use patent protection for the product to treat skin diseases, including psoriasis, extends until 2017 in the U.S. and generally until 2015 in the rest of the world.

# **Recombinant Alpha Interferon**

In 1979, we granted an exclusive worldwide license to Schering-Plough under our alpha interferon patents. Most of our alpha interferon patents have since expired, including expiration of patents in the U.S., Japan and all countries of Europe other than Italy. We have obtained a supplementary protection certificate in Italy extending the coverage until 2007, although the Italian Legislature intends to implement legislation that may shorten this period to December 31, 2005. Schering-Plough pays us royalty payments on U.S. sales of alpha interferon products under an interference settlement entered into in 1998. Under the terms of the interference settlement, Schering-Plough agreed to pay us royalties under certain patents to be issued to Roche and Genentech in consideration of our assignment to Schering-Plough of the alpha interferon patent application that had been the subject of a settled interference with respect to a Roche/ Genentech patent. Schering-Plough entered into an agreement with Roche as part of settlement of the interference. The first of the Roche/ Genentech patents was issued on November 19, 2002 and has a seventeen-year term.

#### **Recombinant Hepatitis B Antigens**

We have obtained numerous patents in countries around the world, including in the U.S. and in European countries, covering the recombinant production of hepatitis B surface, core and "e" antigens. We have licensed our recombinant hepatitis B antigen patent rights to manufacturers and marketers of hepatitis B vaccines and diagnostic test kits, and receive royalties on sales of the vaccines and test kits by our licensees. See "Principal Licensed Products." The obligation of GlaxoSmithKline and Merck to pay royalties on sales of hepatitis B vaccines and the obligation of our other licensees under our hepatitis B patents to pay royalties on sales of diagnostic products will terminate upon expiration of our hepatitis B patents in each licensed country. Following the conclusion of a successful interference proceeding in the U.S., we were granted patents in the U.S. expiring in 2018. These patents claim hepatitis B virus polypeptides and vaccines and diagnostics containing such polypeptides. Our European hepatitis B patents expired at the end of 1999, except in those countries in which we have obtained supplementary protection certificates. Coverage under supplementary protection certificates still exists in France, Italy and Sweden. The additional coverage afforded by the supplementary protection certificates ranges from one to five years. See "Item 3 — Legal Proceedings" for a description of our litigation with Classen Immunotherapies, Inc.

#### **TYSABRI**

We are developing TYSABRI with Elan. TYSABRI is presently claimed in a number of pending patent applications and issued patents held by both companies in the U.S. and abroad. These patent applications and patents cover the protein, DNA encoding the protein, manufacturing methods and pharmaceutical compositions, as well as various methods of treatment using the product. In the U.S. the principal patents covering the product and methods of manufacturing the product generally expire between 2015 and 2020, subject to any available patent term extensions. In the remainder of the world patents on the product and methods of manufacturing the product generally expire between 2014 and 2016, subject to any supplemental protection

certificates that may be obtained. Both companies have method of treatment patents for a variety of indications including the treatment of MS and Crohn's disease and treatments of inflammation. These patents expire in the U.S. generally between 2012 and 2020 and outside the U.S. generally between 2010 and 2016, subject to any available patent term extensions and/or supplemental protection certificates extending such terms.

## Trade Secrets and Confidential Know-How

We also rely upon unpatented trade secrets, and we cannot assure that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect such rights. We require our employees, consultants, outside scientific collaborators, scientists whose research we sponsor and other advisers to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of our employees, the agreement provides that all inventions conceived by such employees shall be our exclusive property. These agreements may not provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

# Sales, Marketing and Distribution

# In General

Our sales and marketing efforts are generally focused on specialist physicians in private practice or at major medical centers. We utilize common pharmaceutical company practices to market our products and to educate physicians, including sales representatives calling on individual physicians and distributors, advertisements, professional symposia, direct mail, selling initiatives, public relations and other methods. We provide certain customer service and other related programs for our products, such as disease and product-specific websites, insurance research services and order, delivery and fulfillment services. We have also established programs in the U.S. which provide qualified uninsured or underinsured patients with commercial products at no charge. Specifics concerning the sales, marketing and distribution of each of our commercialized products are as follows:

# **AVONEX**

We continue to focus our marketing and sales activities on maximizing the potential of AVONEX in the U.S. and the EU in the face of increased competition. In the U.S., Canada, Australia and most of the major countries of the EU, we use our own sales forces and marketing groups to market and sell AVONEX. In these countries, we distribute AVONEX principally through wholesale distributors of pharmaceutical products, mail order specialty distributors or shipping service providers. In countries outside the U.S., Canada, Australia and the major countries of the EU, we sell AVONEX to distribution partners who are then responsible for most marketing and distribution activities.

#### **TYSABRI**

In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. See "Our Products – Approved Indications and Ongoing Development – TYSABRI." Prior to suspension of marketing and distribution of TYSABRI, we used our own sales force and marketing group to market TYSABRI in the U.S., and Elan distributed TYSABRI in the U.S.

# RITUXAN AND ZEVALIN

RITUXAN and ZEVALIN are complementary products for the management of B-cell NHLs. Most B-cell NHLs are treated today in community-based group oncology practices. RITUXAN fits well into the



community practice, as generally no special equipment, training or licensing is required for its administration or for management of treatment-related side effects. By contrast, ZEVALIN is administered by nuclear medicine specialists or radiation oncologists at medical or cancer centers that are licensed and equipped for the handling, administration and disposal of radioisotopes.

*RITUXAN.* We market and sell RITUXAN in the U.S. in collaboration with Genentech. Genentech has a sales and marketing staff dedicated to RITUXAN. Beginning in 2004, we also established a sales and marketing staff dedicated to RITUXAN. Sales efforts are focused on hematologists and medical oncologists in private practice, at community hospitals and at major medical centers in the U.S. RITUXAN is generally sold to wholesalers, specialty distributors and directly to hospital pharmacies. We rely on Genentech to supply marketing support services for RITUXAN including customer service, order entry, shipping, billing, insurance verification assistance, managed care sales support, medical information and sales training. Under our agreement with Genentech, all U.S. sales of RITUXAN are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis.

*ZEVALIN*. We use our own sales force and marketing group to market and sell ZEVALIN in the U.S. To date, we have focused our sales and marketing activities on educating physicians about ZEVALIN's efficacy in relapsed indolent lymphoma, its safety profile and patient tolerance. In the U.S., we sell ZEVALIN to radiopharmacies that radiolabel, or combine, the ZEVALIN antibody with an indium-111 isotope or an yttrium-90 radioisotope and then distribute the finished product to hospitals or licensed treatment facilities for administration. In the EU, we sell ZEVALIN to Schering AG, our exclusive licensee for ZEVALIN outside the U.S. Schering AG is responsible for sales, marketing and distribution activities for ZEVALIN in the EU. We have appointed MDS (Canada) Inc., or MDS (Canada), as our exclusive supplier of the yttrium-90 radioisotope required for therapeutic use of ZEVALIN to radiopharmacies. MDS (Canada) is the only supplier of the yttrium-90 radioisotope that is approved by the FDA. Radiopharmacies independently obtain the indium-111 isotope required for the imaging use of ZEVALIN from one of the two third party suppliers currently approved by the FDA to supply the indium-111 isotope.

## AMEVIVE

We use our own sales force and marketing group to market and sell AMEVIVE in the U.S. To date, we have focused our sales and marketing activities on physician education, payor coverage and acceptance, and improving physician and patient access to AMEVIVE through various initiatives including a sampling program. We distribute AMEVIVE in the U.S. principally through specialty distributors.

#### Competition

#### In General

Competition in the biotechnology and pharmaceutical industries is intense and comes from many and varied sources. We do not believe that any of the industry leaders can be considered dominant in view of the rapid technological change in the industry. We experience significant competition from specialized biotechnology firms in the U.S., the EU and elsewhere and from many large pharmaceutical, chemical and other companies. Certain of these companies have substantially greater financial, marketing, research and development and human resources than us. Most large pharmaceutical and biotechnology companies have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products.

We believe that competition and leadership in the industry will be based on managerial and technological superiority and establishing proprietary positions through research and development. Leadership in the industry may also be influenced significantly by patents and other forms of protection of proprietary information. A key aspect of such competition is recruiting and retaining qualified scientists and technicians. We believe that we have been successful in attracting skilled and experienced scientific personnel. The achievement of a leadership position also depends largely upon our ability to identify and exploit commercially the products resulting from research and the availability of adequate financial resources to fund facilities, equipment, personnel, clinical testing, manufacturing and marketing.

Many of our competitors are working to develop products similar to those that we are developing. The timing of the entry of a new pharmaceutical product into the market can be an important factor in determining the product's eventual success and profitability. Early entry may have important advantages in gaining product acceptance and market share. Moreover, under the Orphan Drug Act, the FDA is prevented for a period of seven years from approving more than one application for the "same" product for the same indication in certain diseases with limited patient populations, unless a later product is considered clinically superior. The EU has similar laws and other jurisdictions have or are considering such laws. Accordingly, the relative speed with which we can develop products, complete the testing and approval process and supply commercial quantities of the product to the market will have an important impact on our competitive position. An abbreviated process exists for approval of small molecule drugs in the U.S. that are comparable to existing products. It is possible that legislative bodies in the U.S. and the EU may provide a similar abbreviated process for comparable biologic products. Competition among products approved for sale may be based, among other things, on patent position, product efficacy, safety, convenience, reliability, availability and price.

# AVONEX AND TYSABRI

AVONEX, which generated \$1.42 billion of worldwide revenues in 2004 competes primarily with three other products:

- REBIF<sup>®</sup> (interferon-beta 1a), which is co-promoted by Serono, Inc. and Pfizer in the U.S. and sold by Serono AG in the EU. REBIF generated worldwide revenues of approximately \$1.09 billion in 2004.
- BETASERON® (interferon-beta 1a), sold by Berlex in the U.S. and sold under the name BETAFERON® by Schering A.G. in the EU. BETASERON and BETAFERON together generated worldwide revenues of approximately \$972 million in 2004.
- COPAXONE® (glatiramer acetate injection), sold by Teva Neuroscience, Inc. in the U.S. and co-promoted by Teva and Aventis Pharma in the EU. COPAXONE generated worldwide revenues of approximately \$936 million in 2004.

Along with us, a number of companies are working to develop products to treat MS that may in the future compete with AVONEX. For example, we are developing TYSABRI with Elan. TYSABRI was approved by the FDA in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. These decisions were based on reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. Both patients received more than two years of TYSABRI therapy in combination with AVONEX. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability. If we are able to reintroduce TYSABRI to the market, it would compete with the products listed above, including AVONEX. See "Our Products — Approved Indications

AVONEX also faces competition from off-label uses of drugs approved for other indications. Some of our current competitors are also working to develop alternative formulations for delivery of their products which may in the future compete with AVONEX.

## RITUXAN AND ZEVALIN

RITUXAN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low-grade or follicular, CD20+ B-cell NHLs. Marketing exclusivity resulting from this Orphan Drug designation expired in November 2004. ZEVALIN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell NHLs, including patients with RITUXAN refractory follicular NHL. Marketing exclusivity resulting from this Orphan Drug designation will expire in February 2009.

RITUXAN is typically used after patients fail to respond or relapse after treatment with traditional radiation therapy or standard chemotherapy regimes, such as CVP and CHOP. ZEVALIN is typically used after patients fail to respond or relapse following treatment with RITUXAN. ZEVALIN competes with BEXXAR® (tositumomab, iodine I-131 tositumomab), a radiolabeled molecule developed by Corixa Corporation which is now being developed and commercialized by GlaxoSmithKline. BEXXAR is approved to treat patients with CD20+, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to RITUXAN and has relapsed following chemotherapy.

A number of other companies, including us, are working to develop products to treat B-cell NHLs and other forms of non-Hodgkin's lymphoma that may ultimately compete with RITUXAN and ZEVALIN.

## AMEVIVE

AMEVIVE competes with several different types of therapies including:

- traditional therapies for moderate-to-severe chronic plaque psoriasis, such as oral retinoids, steroids, methotrexate, cyclosporin, PUVA and UVB radiation.
- RAPTIVA® (efalizumab), a drug co-developed by Genentech and Xoma Corporation that was approved by the FDA in November 2003 to treat moderate-to-severe psoriasis.
- ENBREL® (etanercept), a drug sold by Amgen, Inc. and Wyeth Pharmaceuticals, Inc. that was approved by the FDA to treat moderate-to-severe psoriasis in April 2004.
- drugs approved for other indications that are used to treat psoriasis. Among these drugs are REMICADE® (infliximab) and HUMIRA® (adalimumab). REMICADE, which is sold worldwide by Centocor, Inc., a subsidiary of Johnson & Johnson, as a treatment for other indications, including RA, is currently in clinical studies as a potential treatment for psoriasis. HUMIRA, which is sold by Abbott Laboratories, or Abbott, is approved to treat RA. Abbott is undertaking clinical studies in psoriasis and psoriatic arthritis.

In addition, a number of other companies, including us, are working to develop products to treat psoriasis that may ultimately compete with AMEVIVE.

#### Regulatory

Our current and contemplated activities and the products and processes that will result from such activities are subject to substantial government regulation.

Before new pharmaceutical products may be sold in the U.S. and other countries, clinical trials of the products must be conducted and the results submitted to appropriate regulatory agencies for approval. These clinical trial programs generally involve a three-phase process. Typically, in Phase 1, trials are conducted in volunteers or patients to determine the early side effect profile and, perhaps, the pattern of drug distribution and metabolism. In Phase 2, trials are conducted in groups of patients with a specific disease in order to determine appropriate dosages, expand evidence of the safety profile and, perhaps, determine preliminary efficacy. In Phase 3, large scale, comparative trials are conducted on patients with a target disease in order to generate enough data to provide the statistical proof of efficacy and safety required by national regulatory agencies. The results of the preclinical and clinical testing of a biologic product are then submitted to the FDA in the form of a Biologics License Application, or BLA, or a New Drug Approval Application, or NDA. In

response to a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide adequate basis for approval. The receipt of regulatory approval often takes a number of years, involving the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. On occasion, regulatory authorities may require larger or additional studies, leading to unanticipated delay or expense. Even after initial FDA approval has been obtained, further clinical trials may be required to provide additional data on safety and effectiveness and are required to gain clearance for the use of a product as a treatment for indications other than those initially approved. When approval is granted under the "accelerated approval" provisions of FDA's regulations, the BLA or NDA holder must conduct certain additional studies to verify the clinical benefit attributable to the product. Failure to conduct the required studies, or to comply with certain other conditions of accelerated approvals, may result, following a hearing, in FDA's withdrawing or modifying that part of the approval that was granted under the accelerated approval provisions. Approval of ZEVALIN and TYSABRI was granted under the accelerated approval, the FDA may take action to seek to withdraw that approval.

Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal or suspension of the product from the market. For example, in February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and RA. These decisions were based on reports of two serious adverse events that occurred in patients treated with TYSABRI in clinical studies. These events involved two cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. See "Our Products –Approved Indications and Ongoing Development — TYSABRI." Any adverse event, either before or after marketing approval, including the TYSABRI-related events described above, could result in product liability claims against us. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties.

If we seek to make certain changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components, we will need FDA review and approval before the change can be implemented.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years following marketing approval, except in certain very limited circumstances, including a showing of clinical superiority. ZEVALIN received orphan drug exclusivity in the U.S. Orphan Drug status for ZEVALIN will expire in February 2009.

The FDA, the EMEA and other regulatory agencies regulate and inspect equipment, facilities, and processes used in the manufacturing of pharmaceutical and biologic products prior to providing approval to market a product. If after receiving clearance from regulatory agencies, a material change is made in manufacturing equipment, location, or process, additional regulatory review and approval may be required. We also must adhere to current Good Manufacturing Practices, or cGMP, and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA, the EMEA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the

initial approval. If, as a result of these inspections, it is determined that our equipment, facilities, or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal, or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations. In addition, the FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. Companies must comply with all applicable FDA requirements. If they do not, they are subject to the full range of civil and criminal penalties available to the FDA.

In the EU, Canada, and Australia, regulatory requirements and approval processes are similar in principle to those in the U.S. Depending on the type of drug for which approval is sought, there are currently two potential tracks for marketing approval in EU countries: mutual recognition and the centralized procedure. These review mechanisms may ultimately lead to approval in all EU countries, but each method grants all participating countries some decision-making authority in product approval.

In the U.S., the federal government regularly considers reforming health care coverage and costs. For example, recent reforms to Medicare have reduced the reimbursement rates for many of our products and, beginning in 2006, added a prescription drug benefit for all Medicare beneficiaries. Resulting legislation or regulatory actions may have a significant effect on our business. Our ability to successfully commercialize products may depend in part on the extent to which reimbursement for the costs of our products and related treatments will be available in the U.S. and worldwide from government health administration authorities, private health insurers and other organizations. Substantial uncertainty exists as to the reimbursement status of newly approved health care products by third-party payors.

We are also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Antikickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege or convict us of violating these laws, our business could be harmed. For a description of litigation in this area in which we are currently involved, see "Item 3 — Legal Proceedings." Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

We also participate in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, and under amendments of that law that became effective in 1993. Under the Medicaid rebate program, we pay a rebate for each unit of product reimbursed by Medicaid. The amount of the rebate for each product is set by law as a minimum 15.1% of the average manufacturer price, or AMP, of that product, or if it is greater, the difference between AMP and the best price available from us to any commercial or non-governmental customer. The rebate amount also includes an inflation adjustment if AMP increases faster than inflation. The rebate amount is recomputed each quarter based on our reports of current average manufacturer price and best price for each of our products to the Centers for Medicare and Medicaid Services. The terms of our participation in the program impose an obligation to correct the prices reported in previous quarters, as may be necessary for up to three years. Any such corrections could result in an overage or underage in our rebate liability for past quarters, depending on the direction of the correction. In addition to retroactive rebates, if we were found to have knowingly submitted false information to the government, in addition to other penalties available to the government, the statute provides for civil monetary penalties in the amount of \$100,000 per item of false information. Participation in the Medicaid rebate program includes extending

discounts under the Public Health Service, or PHS, pharmaceutical pricing program. The PHS pricing program extends discounts to a variety of community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of poor Medicare beneficiaries.

We also make our products available for purchase by authorized users off of our Federal Supply Schedule (FSS) contract with the Department of Veterans Affairs. As a result of the Veterans Health Care Act of 1992, or the VHC Act, federal law requires that FSS contract prices for our products for purchases by the Veterans Administration, the Department of Defense, Coast Guard, and the PHS (including the Indian Health Service) be capped at "federal ceiling prices," or FCPs. FCPs are computed by taking, at a minimum, a 24% reduction off the "non-federal average manufacturer price," or non-FAMP. Our reported non-FAMPs and FCPs for our various products are used in establishing the FSS prices available to these government agencies. The accuracy of the reported non-FAMPs and FCPs may be audited by the government under applicable federal procurement laws. Among the remedies available to the government for infractions of these laws is recoupment of any overages paid by FSS users during the audited years. In addition, if we were found to have knowingly reported a false non-FAMP or FCP, the VHC Act provides for civil monetary penalties of \$100,000 per item of false information.

We are also subject to the U.S. Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

We conduct relevant research at all of our research facilities in the U.S. in compliance with the current U.S. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines, and all other applicable federal and state regulations. By local ordinance, we are required to, among other things, comply with the NIH Guidelines in relation to our facilities in Cambridge, Massachusetts, and are required to operate pursuant to certain permits.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights may be subject to national or supranational antitrust regulatory control, the effect of which also cannot be predicted. The extent of government regulation which might result from future legislation or administrative action cannot accurately be predicted.

# **Manufacturing and Raw Materials**

We currently produce all of our bulk AVONEX, AMEVIVE and TYSABRI at our manufacturing facilities located in Research Triangle Park, North Carolina and Cambridge, Massachusetts. We are in the process of transferring the process for manufacturing the commercial requirements of the antibody for ZEVALIN to Cambridge, Massachusetts from our pilot manufacturing facility in Oceanside, California. Genentech is responsible for all worldwide manufacturing activities for bulk RITUXAN and has sourced the manufacturing of certain bulk RITUXAN requirements to an independent third party. We manufacture clinical products in Cambridge. We are developing a large-scale manufacturing facility in Oceanside, California. We completed construction of this facility and obtained the certificate of occupancy in the fourth quarter of 2004. Commissioning and validation is expected to continue through 2005. We expect the facility to be licensed in 2006. In addition, we recently re-started construction of a large-scale manufacturing facility in Hillerod, Denmark which we expect to be licensed in 2008. For a discussion of the potential impact of the suspension of TYSABRI on our plans for these facilities, see "Forward-Looking Information and Risk Factors That May Affect Future Results — We are Subject to Risks Related to the Products That We Manufacture."

We source all of our fill-finish and the majority of final product storage operations for our products, along with a substantial part of our packaging operations, to a concentrated group of third party contractors. Raw

materials and supplies required for the production of AVONEX, ZEVALIN, AMEVIVE and TYSABRI, are generally available from various suppliers in quantities adequate to meet our needs, except for chelates and the radioisotope yttrium-90 used with ZEVALIN which are available from a limited number of suppliers. We source manufacturing of chelates to a concentrated group of third party manufacturers. We made MDS (Canada) our exclusive supplier of the radioisotope yttrium-90 used with ZEVALIN. If we were to lose the services of MDS (Canada) or our third party manufacturers of chelates, we would be forced to find other providers, which could delay our ability to sell ZEVALIN. In addition, radiopharmacies independently purchase the indium-111 isotope required for the imaging use of ZEVALIN. Currently, only two suppliers are approved by the FDA to supply the indium-111 isotope. Each of our third-party service providers, suppliers and manufacturers, along with the suppliers of the indium-111 isotopes, are subject to continuing inspection by the FDA or comparable agencies in other jurisdictions. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products, including as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection, could significantly impair our ability to sell our products. See "Forward-Looking Information and Risk Factors That May Affect Future Results — We Rely to a Large Extent on Third Parties in the Manufacturing of Our Products."

We believe that our existing manufacturing facilities and outside sources will allow us to meet our near-term and long-term manufacturing needs for our current commercial products and our other products currently in clinical trials. Our existing licensed manufacturing facilities operate under multiple licenses from the FDA, regulatory authorities in the EU and other regulatory authorities. For a discussion of risks related to our ability to meet our manufacturing needs for our commercial products and our other products currently in clinical trials, see "Forward-Looking Information and Risk Factors That May Affect Future Results — We are Subject to Risks Related to the Products That We Manufacturing of Our Products." Additional manufacturing facilities and outside sources may be required to meet our long term research, development and commercial production needs.

#### **Our Employees**

As of December 31, 2004, we had 4,266 employees.

#### **Our Executive Officers**

The following is a list of our executive officers, their ages as of March 10, 2005 and their principal positions. Executive officers are appointed and may be removed by the Board of Directors. We currently have employment agreements with Dr. Rastetter and Mr. Mullen.

Name	Age	Position
William H. Rastetter, Ph.D.	56	Executive Chairman
James C. Mullen	46	Chief Executive Officer and President
Burt A. Adelman, M.D.	52	Executive Vice President, Development
Anne Marie Cook, Esq.	43	Acting General Counsel
John M. Dunn, Esq.	53	Executive Vice President, New Ventures
Michael Gilman, Ph.D.	49	Executive Vice President, Research
Peter N. Kellogg	48	Executive Vice President, Finance and Chief Financial Officer
Connie L. Matsui	51	Executive Vice President, Corporate Strategy and Communication
Craig E. Schneier, Ph.D.	57	Executive Vice President, Human Resources
Mark C. Wiggins	49	Executive Vice President, Business Development
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Reference to "our" or "us" in the following descriptions of the background of our executive officers include Biogen Idec and Idec Pharmaceuticals Corporation.

*William H. Rastetter, Ph.D.* is our Executive Chairman and has served in that position since the merger in November 2003. Dr. Rastetter was formerly our Chairman and Chief Executive Officer. He was appointed Chairman of our Board of Directors in May 1996. He served as our President and Chief Executive Officer from December 1986 until January 2002 and served as our Chief Executive Officer from January 2002 until November 2003. Dr. Rastetter was also our Chief Financial Officer from 1988 to 1993. He has served as one of our Directors since 1986. From 1984 to 1986, Dr. Rastetter was Director of Corporate Ventures at Genentech. From 1982 to 1984, he served in a scientific capacity at Genentech, directing the Biocatalysis and Chemical Sciences groups. From 1975 to 1982, Dr. Rastetter held various faculty positions at the Massachusetts Institute of Technology. He received his Ph.D. in Chemistry from Harvard University in 1975. In addition to his position at Biogen Idec, Dr. Rastetter serves as Chairman of the Board of Directors of Illumina, Inc., a company that develops parallel, miniaturized and flexible biosensors. He also serves on board of the California Healthcare Institute (CHI), and is an R. B. Woodward Visiting Scholar of the Department of Chemistry and Chemical Biology at Harvard University.

*James C. Mullen* is our Chief Executive Officer and President and has served in these positions since the merger in November 2003. Mr. Mullen was formerly Chairman of the Board and Chief Executive Officer of Biogen, Inc. He was named Chairman of the Board of Directors of Biogen, Inc. in July 2002, after being named President and Chief Executive Officer of Biogen, Inc. in June 2000. Mr. Mullen joined Biogen, Inc. in 1989 as Director, Facilities and Engineering. He was named Biogen, Inc.'s Vice President, Operations, in 1992. From 1996 to 1999, Mr. Mullen served as Vice President, International, with responsibility for building all Biogen, Inc. operations outside North America. From 1984 to 1988, Mr. Mullen held various positions at SmithKline Beckman Corporation (now GlaxoSmithKline plc). He holds a B.S. in Chemical Engineering from Rensselaer Polytechnic Institute and a M.B.A. from Villanova University. Mr. Mullen is also a director of PerkinElmer, Inc., serves on the Board of Directors of the Biotechnology Industry Organization (BIO) and is co-chair of Cambridge Family and Children's Service Capital Campaign Steering Committee.

*Burt A. Adelman, M.D.* is our Executive Vice President, Development and has served in that position since the merger in November 2003. Dr. Adelman was previously Executive Vice President, Research and Development at Biogen, Inc., a position he attained in October 2001. Prior to that, he served as Vice President of Medical Research from January 1999 to October 2001 and Vice President of Development Operations from August 1996 to January 1999. He began his career with Biogen, Inc. in 1991, joining the company as Director of Medical Research, and has held positions of increasing responsibility including Vice President, Regulatory Affairs, and Vice President, Development Operations. In that role he oversaw the Preclinical Development, Medical Operations and Regulatory Affairs groups. Since 1992, Dr. Adelman has served as a lecturer at Harvard Medical School. He is a member of the Board of Directors for the New England Healthcare Institute and a New England Division Board of Directors member for the American Cancer Society.

Anne Marie Cook is our Acting General Counsel. Ms. Cook has served as Acting General Counsel since March 2005. From November 2003 to March 2005, Ms. Cook served as our Vice President, Chief Corporate Counsel. Prior to the merger, Ms. Cook was Vice President, Chief Corporate Counsel of Biogen, Inc., a position she held from October 2001 to November 2003. Before that, she served as Associate General Counsel, Chief Corporate Counsel of Biogen, Inc. from June 1999 to October 2001, Associate General Counsel of Biogen, Inc. from December 1995 to June 1999, and Assistant General Counsel of Biogen, Inc. from November 1992 to December 1995. Before joining Biogen, Inc., Ms. Cook was an associate in the corporate group of Testa, Hurwitz & Thibeault, LLP. She holds a B.S. from Tufts University and a J.D. from Notre Dame Law School.

*John M. Dunn* is our Executive Vice President, New Ventures and has served in that position since the merger in November 2003. Mr. Dunn was our Senior Vice President, Legal and Compliance, and General Counsel from January 2002 to November 2003. Prior to that, he was a partner at the law firm of Pillsbury Winthrop LLP specializing in corporate and business representation of public and private companies. Mr. Dunn received his B.S. and J.D. from the University of Wyoming.

*Michael Gilman, Ph.D.* is our Executive Vice President, Research and has served in that position since July 2004. Prior to that, Dr. Gilman has been our Senior Vice President, Research since the merger in November 2003 and served in that same capacity for Biogen, Inc. from October 2001 until November 2003. Dr. Gilman previously served as Vice President — Research of Biogen, Inc. from April 2000 until October 2001. Dr. Gilman joined Biogen, Inc. as Director of Molecular Biology in 1999 and served in that capacity until April 2000. Dr. Gilman spent the previous five years at ARIAD Pharmaceuticals in Cambridge, most recently as Executive Vice President and Chief Scientific Officer. Prior to that, Dr. Gilman spent eight years on the scientific staff of Cold Spring Harbor Laboratory in New York, where his research focused on mechanisms of signal transduction and gene regulation. Dr. Gilman holds a Ph.D. in Biochemistry from University of California, Berkeley, and a S.B. in Life Sciences from Massachusetts Institute of Technology.

*Peter N. Kellogg* is our Executive Vice President, Finance and Chief Financial Officer and has served in that position since the merger in November 2003. Mr. Kellogg was formerly Executive Vice President, Finance and Chief Financial Officer of Biogen, Inc. after serving as Vice President — Finance and Chief Financial Officer since July 2000. He joined Biogen, Inc. in 2000 from PepsiCo Inc., where he most recently served as Senior Vice President, PepsiCo E-Commerce from March to July 2000 and as Senior Vice President and Chief Financial Officer, Frito-Lay International, from March 1998 to March 2000. From 1987 to 1998, he served in a variety of senior financial, international and general management positions at PepsiCo and the Pepsi-Cola International, Pepsi-Cola North America, and Frito-Lay International divisions. Prior to joining PepsiCo, Mr. Kellogg was a senior consultant with Arthur Andersen & Co. and Booz Allen & Hamilton. He received a B.S.E. from Princeton University and an M.B.A. from The Wharton School.

*Connie L. Matsui* is our Executive Vice President, Corporate Strategy and Communications and has served in that position since the merger in November 2003. Ms. Matsui was previously our Senior Vice President, Planning and Resource Development. She joined us in November 1992 as Senior Director, Planning and Resource Development with primary responsibility for strategic planning and human resources. In December 1994, Ms. Matsui was promoted to Vice President, Planning and Resource Development. In 2000 Ms. Matsui was promoted to Senior Vice President, overseeing investor relations, corporate communications, human resources, project management and strategic planning. From 1977 to 1991, she served in a variety of marketing and general management positions at Wells Fargo Bank, including Vice President and Manager responsible for Consumer Retirement Programs and Vice President and Manager in charge of company-wide Employee Relations and Communications. Ms. Matsui has been active on a number of not-for-profit boards and served as National President of the Girl Scouts of the USA from 1999 to 2002. Ms. Matsui received her B.A. and M.B.A. from Stanford University.

*Craig E. Schneier, Ph.D.* is our Executive Vice President, Human Resources and has served in that position since the merger in November 2003. Dr. Schneier was previously Executive Vice President, Human Resources of Biogen, Inc., a position he has held since January 2003. He joined Biogen, Inc. in 2001 as Senior Vice President, Strategic Organization Design and Effectiveness, after having served as an external consultant to the company for eight years. Prior to joining Biogen, Inc., Dr. Schneier was president of his own management consulting firm in Princeton, NJ, where he provided consulting services to over 70 of the Fortune 100 companies, as well as several of the largest European and Asian firms. Dr. Schneier held a tenured professorship at the University of Maryland's Smith School of Business and has held teaching positions at the business schools of the University of Michigan and Columbia University. He currently teaches at the Tuck School of Business, Dartmouth College. He holds a Ph.D. in psychology and business strategy and an M.B.A. from the University of Colorado.

*Mark C. Wiggins* is our Executive Vice President, Business Development and has served in that capacity since July 2004. Prior to that, Mr. Wiggins served as our Senior Vice President, Business Development from November 2003 to July 2004, Vice President of Marketing and Business Development from November 2000 to November 2003, and Vice President of Business Development from May 1998 to November 2000. From 1986 to 1996 he held various positions at Schering-Plough, including Director of Business Development and from 1996 to 1998 he was Vice President of Business Development and Marketing for Hybridon. Mr. Wiggins received a B.S. from Syracuse University in finance and received his M.B.A from the University of Arizona.

#### Forward-Looking Information and Risk Factors That May Affect Future Results

The SEC encourages public companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking statements. Reference is made in particular to forward-looking statements regarding the anticipated level of future product sales, royalty revenues, expenses and profits, the timing of clinical trials, the potential outcome of clinical programs, regulatory approvals, our ability to continue development of TYSABRI and reintroduce TYSABRI into the market, the marketing of additional products, the impact of competitive products, the anticipated outcome of pending or anticipated litigation and patent-related proceedings, the completion and licensure of our large-scale manufacturing facilities and our ability to meet our manufacturing needs, and the value of investments in certain marketable securities. These and all other forward-looking statements are made based on our current belief as to the outcome and timing of such future events. Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. Although we believe that the risks described below represent all material risks currently applicable to our business, additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

## Our Revenues Rely Significantly on a Limited Number of Products

Our current and future revenues depend substantially upon continued sales of our commercial products. Revenues related to sales of two of our products, AVONEX and RITUXAN, represented approximately 92% of our total revenues in 2004. See "Our Products — Approved Indications and Ongoing Development — AVONEX" and "Our Products — Approved Indications and Ongoing Development — RITUXAN." We cannot assure you that AVONEX or RITUXAN will continue to be accepted in the U.S. or in any foreign markets or that sales of either of these products will not decline in the future. A number of factors may affect market acceptance of AVONEX, RITUXAN and our other products, including:

- the perception of physicians and other members of the health care community of their safety and efficacy relative to that of competing products;
- patient and physician satisfaction with these products;
- the effectiveness of our sales and marketing efforts and those of our marketing partners and licensees in the U.S., the EU and other foreign markets;
- the size of the markets for these products;
- unfavorable publicity concerning these products or similar drugs;
- the introduction, availability and acceptance of competing treatments;
- the availability and level of third-party reimbursement;
- adverse event information relating to any of these products, including additional reports or findings of progressive multifocal leukoencephalopathy, or PML, in patients treated with TYSABRI;
- · changes to product labels to add significant warnings or restrictions on use;
- the success of ongoing development work on RITUXAN;
- the continued accessibility of third parties to vial, label, and distribute these products on acceptable terms;
- the unfavorable outcome of patent litigation related to any of these products;
- the ability to manufacture commercial lots of products successfully and on a timely basis; and

• regulatory developments related to the manufacture or continued use of these products.

Any material adverse developments with respect to the commercialization of these products may cause our revenue to grow at a slower than expected rate, or even decrease, in the future.

# Safety Issues with TYSABRI Could Significantly Affect our Growth

TYSABRI was approved by the FDA in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI. We also suspended dosing in all clinical trials of TYSABRI. These decisions were based on reports of two serious adverse events that occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. This patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and consulting with leading experts to better understand the possible risk of PML. At this time, we cannot predict the outcome of these evaluations. The outcome of these evaluations, if unfavorable or inconclusive, could result in our permanently withdrawing TYSABRI from the market and terminating clinical studies of TYSABRI or could result in the need for additional testing, or, if, in consultation with the FDA, we are allowed to reintroduce TYSABRI to the market, could result in significantly restricted use with an ongoing extensive patient risk management program, or with blackbox or other significant safety warnings in the label. If the outcome of our evaluations are not satisfactory to regulatory authorities in the EU, we would likely be required to withdraw our applications for approval of TYSABRI as a treatment for MS and Crohn's disease in the EU. If we are able to reintroduce TYSABRI to the market, the success of such reintroduction will depend upon its acceptance by the medical community and patients, which cannot be certain given questions regarding its safety raised by these adverse events. Our inability to return TYSABRI to the market in the U.S. or to get TYSABRI approved in the EU or any significant restrictions or warnings on use or lack of acceptance of TYSABRI by the medical community or patients would materially affect our growth and impact various aspects of our business and our plans for the future. This impact could include, among other things, material write offs of inventory, intangible assets or goodwill, impairment and sale of capital assets, and could affect our workforce.

# Our Long-Term Success Depends Upon the Successful Development and Commercialization of Other Products from Our Research and Development Activities and Collaborations

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities and collaborations. We continue to expand our development efforts related to RITUXAN and other potential products in our pipeline. The expansion of our pipeline may include increases in spending on internal projects, the acquisition of third-party technologies or products or other types of investments. Product development and commercialization involve a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Many important factors affect our ability to successfully develop and commercialize other products, including the ability to:

- obtain and maintain necessary patents and licenses;
- demonstrate safety and efficacy of drug candidates at each stage of the clinical trial process;
- enroll patients in our clinical trials and complete clinical trials;
- overcome technical hurdles that may arise;



- successful manufacture of products in sufficient quantities to meet demand;
- meet applicable regulatory standards;
- obtain reimbursement coverage for the products;
- receive required regulatory approvals;
- produce drug candidates in commercial quantities at reasonable costs; and
- · compete successfully against other products and to market products successfully.

Success in early stage clinical trials or preclinical work does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies.

#### Competition in Our Industry and in the Markets for Our Products is Intensely Competitive

The biotechnology industry is intensely competitive. We compete in the marketing and sale of our products, the development of new products and processes, the acquisition of rights to new products with commercial potential and the hiring of personnel. We compete with biotechnology and pharmaceutical companies that have a greater number of products on the market, greater financial and other resources and other technological or competitive advantages. We cannot be certain that one or more of our competitors will not receive patent protection that dominates, blocks or adversely affects our product development or business; will benefit from significantly greater sales and marketing capabilities; or will not develop products that are accepted more widely than ours.

AVONEX competes with three other products:

- REBIF, which is co-promoted by Serono, Inc. and Pfizer Inc. in the U.S. and sold by Serono AG in the EU;
- BETASERON, sold by Berlex in the U.S. and sold under the name BETAFERON by Schering A.G. in the EU; and
- COPAXONE, sold by Teva Neuroscience, Inc. in the U.S. and co-promoted by Teva and Aventis Pharma in the EU.

In addition, a number of companies, including us, are working to develop products to treat MS that may in the future compete with AVONEX. If we are able to reintroduce TYSABRI to the market, it would compete with the products listed above, including AVONEX.

AVONEX also faces competition from off-label uses of drugs approved for other indications. Some of our current competitors are also working to develop alternative formulations for delivery of their products, which may in the future compete with AVONEX

RITUXAN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low-grade or follicular, CD20+ B-cell NHLs. Marketing exclusivity resulting from this Orphan Drug designation expired in November 2004. ZEVALIN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell non-Hodgkin's lymphoma, including patients with RITUXAN refractory follicular NHL. Marketing exclusivity resulting from this Orphan Drug designation expired in Sorphan Drug designation expires in February 2009. RITUXAN is typically used after patients fail to respond or relapse after treatment with traditional radiation therapy or standard chemotherapy regimes, such as CVP and CHOP. ZEVALIN is typically used after patients fail to respond or relapse following treatment with RITUXAN. ZEVALIN competes with BEXXAR, a radiolabeled molecule developed by Corixa Corporation which is now being developed and commercialized by GlaxoSmithKline. BEXXAR received FDA approval in June 2003 to treat patients with CD20+, follicular, NHL, with and without transformation, whose disease is refractory to RITUXAN and has relapsed following chemotherapy. A number of other

companies, including us, are working to develop products to treat B-cell NHLs and other forms of non-Hodgkin's lymphoma that may ultimately compete with RITUXAN and ZEVALIN.

AMEVIVE competes with several different types of therapies including:

- traditional therapies for moderate-to-severe chronic plaque psoriasis, such as oral retinoids, steroids, methotrexate, cyclosporin, PUVA and UVB radiation.
- RAPTIVA, a drug co-developed by Genentech and Xoma Corporation that was approved by the FDA in November 2003 to treat moderate-to-severe psoriasis.
- ENBREL, a drug sold by Amgen, Inc. and Wyeth Pharmaceuticals, Inc. that was approved by the FDA to treat moderate-to-severe psoriasis in April 2004.
- drugs approved for other indications that are used to treat psoriasis. Among these drugs are REMICADE and HUMIRA. REMICADE, which is sold worldwide by Centocor, Inc., a subsidiary of Johnson & Johnson, as a treatment for other indications, including RA, is currently in clinical studies as a potential treatment for psoriasis. HUMIRA, which is sold by Abbott is approved to treat RA. Abbott is undertaking clinical trials of HUMIRA in psoriasis and psoriatic arthritis.

In addition, a number of other companies, including us, are working to develop products to treat psoriasis that may ultimately compete with AMEVIVE.

#### We are Subject to Risks Related to the Products that We Manufacture

We manufacture and expect to continue to manufacture our own commercial requirements of bulk AVONEX, AMEVIVE, TYSABRI and the ZEVALIN bulk antibody. Our inability to successfully manufacture bulk product and to maintain regulatory approvals of our manufacturing facilities would harm our ability to timely produce sufficient quantities of commercial supplies of AVONEX, AMEVIVE, TYSABRI and ZEVALIN to meet demand. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. Any such problem would be exacerbated by unexpected demand for our products. We anticipate commissioning and validation of our large-scale manufacturing facility in Oceanside, California to continue through 2005 and expect the facility to be licensed for use in 2006. In addition, we initiated construction of a large-scale manufacturing facility and the Hillerod facility is dependent upon the commercial availability and potential market acceptance of TYSABRI. See "Our Products — Approved Indications and Ongoing Development — TYSABRI," and "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth." If TYSABRI is permanently withdrawn from the market, we would need to evaluate our long-term plans for these facilities. If we are able to reintroduce TYSABRI to the market, we would need to evaluate our requirements for existing inventory and additional manufacturing approval of TYSABRI in MS in the EU and other jurisdictions, and the probability of obtaining marketing approval of TYSABRI in additional indications in the U.S., EU and other jurisdictions.

If we cannot produce sufficient commercial requirements of bulk product of our products to meet demand, we would need to rely on third-party manufacturers, of which there are only a limited number capable of manufacturing bulk products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time. Our ability to supply products in sufficient capacity to meet demand is also dependent upon third party contractors to fill-finish, package and store such products. For a discussion of the risks associated with using third parties to perform manufacturing-related services for our products, see "Forward-Looking Information and Risk Factors That May Affect Future Results — We Rely to a Large Extent on Third Parties in the Manufacturing of Our Products."

expenses for products that failed to meet specifications. Similar charges may occur in the future. Any prolonged interruption in the operations of our existing manufacturing facilities could result in cancellations of shipments or loss of product in the process of being manufactured. Because our manufacturing processes 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.

#### We Rely to a Large Extent on Third Parties in the Manufacturing of Our Products

We rely on Genentech for all RITUXAN manufacturing. Genentech relies on a third party to manufacture certain bulk RITUXAN requirements. If Genentech or any third party upon which it relies does not manufacture or fill/finish RITUXAN in sufficient quantities and on a timely and cost-effective basis or if Genentech or any third party does not obtain and maintain all required manufacturing approvals, our business could be harmed. We also rely heavily upon third-party manufacturers and suppliers to manufacture and supply significant portions of the product components of ZEVALIN other than the bulk antibody, including chelates necessary for the ZEVALIN therapeutic regimen and the radioisotope yttrium-90 and the indium-111 isotope used with the therapeutic and imaging kits of ZEVALIN, respectively. The radioisotope yttrium-90 is only available from a limited number of suppliers. We made MDS (Canada) our exclusive supplier of the radioisotope yttrium-90 used with ZEVALIN. MDS (Canada) is the only manufacturer of the radioisotope yttrium-90 used with ZEVALIN approved by the FDA. If we were to lose the services of MDS (Canada) or our third party manufacturers of chelates, we would be forced to find other third party providers, which could delay our ability to manufacture and sell ZEVALIN. In addition, radiopharmacies independently purchase the indium-111 isotope required for the imaging use of ZEVALIN. Currently, only two suppliers are approved by the FDA to supply the indium-111 isotope. Our inability to find replacement suppliers for materials used in our marketed products and our primary product candidates that are available only from a single supplier or a limited number of suppliers could significantly impair our ability to sell our products.

We also source all of our fill-finish and the majority of our final product storage operations, along with a substantial portion of our packaging operations of the components used with our products, to a concentrated group of third party contractors. The manufacture of products and product components, fill-finish, packaging and storage of our products require successful coordination among ourselves and multiple third-party providers. Our inability to coordinate these efforts, the lack of capacity available at the third party contractor or any other problems with the operations of these third party contractors could require us to delay shipment of saleable products, recall products previously shipped or could impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share and damage our reputation. Any third party we use to fill-finish, package or store our products to be sold in the U.S. must be licensed by the FDA. As a result, alternative third party providers may not be readily available on a timely basis.

# The Manufacture of Our Products is Subject to Government Regulation

We and our third party providers are generally required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm this compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and ultimate amendment acceptance by the FDA prior to release of product to the market place. Our inability or the inability of our third party service providers to demonstrate ongoing cGMP compliance could require us to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

## Royalty Revenues Contribute to Our Overall Profitability and Are Not Within Our Control

Royalty revenues contribute to our overall profitability. Royalty revenues may fluctuate as a result of disputes with licensees, collaborators and partners, future patent expirations and other factors such as pricing

reforms, health care reform initiatives, other legal and regulatory developments and the introduction of competitive products that may have an impact on product sales by our licensees and partners. In addition, sales levels of products sold by our licensees, collaborators and partners may fluctuate from quarter to quarter due to the timing and extent of major events such as new indication approvals or government-sponsored programs. Since we are not involved in the development or sale of products by our licensees, collaborators and partners, we cannot be certain of the timing or potential impact of factors which may affect their sales. In addition, the obligation of licensees to pay us royalties generally terminates upon expiration of the related patents. For a further discussion of future patent expirations affecting certain royalty revenues, see "Principal Licensed Products" and "Patents and Other Proprietary Rights."

# **Our Operating Results Are Subject to Significant Fluctuations**

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, including:

- demand and pricing for our products;
- physician and patient acceptance of our products;
- amount and timing of sales orders for our products;
- our achievement of product development objectives and milestones;
- research and development and manufacturing expenses;
- clinical trial enrollment and expenses;
- our manufacturing performance and capacity and that of our partners;
- percentage of time that our manufacturing facilities are utilized for commercial versus clinical manufacturing;
- rate and success of product approvals;
- costs related to obtain product approvals, launching new products and maintaining market acceptance for existing products;
- timing of regulatory approval, if any, of competitive products and the rate of market penetration of competing products;
- new data or information, positive or negative, on the benefits and risks of our products or products under development;
- expenses related to protecting our intellectual property;
- expenses related to litigation and settlement of litigation;
- payments made to acquire new products or technology;
- write-downs and write offs of inventories, intangible assets, goodwill or investments;
- impairment of assets, such as buildings and manufacturing facilities;
- government or private healthcare reimbursement policies;
- collaboration obligations and copromotion payments we make or receive;
- timing and nature of contract manufacturing and contract research and development payments and receipts;
- interest rate fluctuations;
- foreign currency exchange rates; and
- overall economic conditions.

Our operating results during any one quarter do not necessarily suggest the anticipated results of future quarters.

# Our Sales Depend on Payment and Reimbursement from Third-Party Payors, and a Reduction in Payment Rate or Reimbursement Could Result in Decreased Use or Sales of Our Products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors such as state and federal governments, under programs such as Medicare and Medicaid in the U.S., and private insurance plans. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the U.S., there have been, there are, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. Recent Medicare reforms have lowered the reimbursement rate for many of our products. We are not able to predict the full impact of these reforms and its regulatory requirements on our business. However, we believe that legislation that reduces reimbursement for our products could adversely impact our business. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions in response to such legislation. Reduction in reimbursement for our products could have a material adverse effect on our results of operations. Also, we believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, when a new therapeutic product is approved, the availability of governmental and/or private reimbursement for our approved products or product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time.

Recent Medicare reforms also added a prescription drug reimbursement beginning in 2006 for all Medicare beneficiaries. In the meantime, a temporary drug discount card program is being established for Medicare beneficiaries. The federal government, through its purchasing power under these programs, is likely to demand discounts from pharmaceutical and biotechnology companies that may implicitly create price controls on prescription drugs. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, Managed Care Organizations, or MCOs, Health Maintenance Organizations, or HMOs, Preferred Provider Organizations, or PPOs, institutions and other government agencies continue to seek price discounts. MCOs, HMOs and PPOs and private health plans will administer the Medicare drug benefit, leading to managed care and private health plans influencing prescription decisions for a larger segment of the population. In addition, certain states have proposed and certain other states have adopted various programs to control prices for their seniors' and low income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada, and bulk purchasing of drugs.

If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products.

In 2003, Congress revised the statutory provisions governing Medicare payment for drugs and biologicals furnished in hospital outpatient departments, including many of our products. These revisions included a transitional change to the payment methodology in 2004 and 2005, which has lowered payment rates for our products in these years. The methodology will change in 2006, when the statute provides that rates are to be set based on hospital acquisition cost surveys, or some other means if survey data are not available. Some of our products, such as RITUXAN, are not frequently provided in hospital outpatient departments such that the majority of patients receiving the products should not be affected by the rates for 2005. Other products, such as ZEVALIN, are used primarily in the hospital outpatient setting and we are uncertain as to whether hospitals will view the 2005 rates favorably and therefore choose to provide ZEVALIN to their patients.

We encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides health care at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored health care system. This international patchwork of price regulation may lead to inconsistent prices and some third-party trade in our products from markets with lower prices. Such trade exploiting price differences between countries could undermine our sales in markets with higher prices.

## We May Be Unable to Adequately Protect or Enforce Our Intellectual Property Rights or Secure Rights to Third-Party Patents

We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development, including a number of our processes and products. Patents have been issued on many of these applications. We have also obtained rights to various patents and patent applications under licenses with third parties, which provide for the payment of royalties by us. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. There is no certainty that our existing patents or others, if obtained, will afford us substantial protection or commercial benefit. Similarly, there is no assurance that our pending patent applications or patent applications licensed from third parties will ultimately be granted as patents or that those patents that have been issued or are issued in the future will prevail if they are challenged in court.

A substantial number of patents have already been issued to other biotechnology and biopharmaceutical companies. Competitors may have filed applications for, or have been issued patents and may obtain additional patents and proprietary rights that may relate to products or processes competitive with or similar to our products and processes. Moreover, the patent laws of the U.S. and foreign countries are distinct and decisions as to patenting, validity of patents and infringement of patents may be resolved differently in different countries. In general, we obtain licenses to third party patents, which we deem necessary or desirable for the manufacture, use and sale of our products. We are currently unable to assess the extent to which we may wish or be required to acquire rights under such patents and the availability and cost of acquiring such rights, or whether a license to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder our ability to market our products.

We are aware that others, including various universities and companies working in the biotechnology field, have filed patent applications and have been granted patents in the U.S. and in other countries claiming subject matter potentially useful to our business. Some of those patents and patent applications claim only specific products or methods of making such products, while others claim more general processes or techniques useful or now used in the biotechnology industry. There is considerable uncertainty within the biotechnology industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world, and, to date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products

There has been, and we expect that there may continue to be significant litigation in the industry regarding patents and other intellectual property rights. Litigation, including our current patent litigation with Columbia University and Classen Immunotherapies, and other proceedings concerning patents and other intellectual property rights may be protracted, expensive and distracting to management. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners, may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or noninfringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the

outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights, or, conversely, hinder our ability to market our products. See "Item 3 — Legal Proceedings" for a description of litigation regarding our patents and other proprietary rights.

# Legislative or Regulatory Changes Could Harm Our Business

Our business is subject to extensive government regulation and oversight. As a result, we may become subject to governmental actions which could adversely affect our business, operations or financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery and payment for health care products and services;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- new laws, regulations and judicial decisions affecting pricing or marketing; and
- changes in the tax laws relating to our operations.

#### Failure to Comply with Government Regulations Regarding Our Products Could Harm Our Business

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, Anti-Kickback Act, the Prescription Drug Marketing Act or other violations in connection with Medicare and/or Medicaid reimbursement or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws. For example, we and a number of other major pharmaceutical and biotechnology companies are named defendants in certain Average Wholesale Price litigation pending in the U.S. District Court for the District of Massachusetts alleging, among other things, violations in connection with Medicaid reimbursement. See "Item 3 — Legal Proceedings" for a description of this litigation.

Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). We cannot predict with certainty the eventual outcome of any pending litigation. If we were to be convicted of violating laws regulating the sale and marketing of our products in the current proceedings or in new lawsuits or claims brought against us, our business could be materially harmed.

#### Failure to Prevail in Litigation or Satisfactorily Resolve a Third Party Investigation Could Harm Our Business

Pharmaceutical and biotechnology companies have been the target of lawsuits relating to product liability claims and disputes over intellectual property rights (including patents). See "Forward-Looking Information and Risk Factors That May Affect Future Results — We May Be Unable to Adequately Protect or Enforce Our Intellectual Property Rights or Secure Rights to Third-Party Patents." Additionally, the administration of drugs in humans, whether in clinical studies or commercially, can result in product liability claims whether or not the drugs are actually at fault in causing an injury. Our products or product candidates may cause, or may appear to have caused, injury or dangerous drug interactions that we may not learn about or understand until the product or product candidate has been administered to patients for a prolonged period of time. For example, we may face product liability claims by patients treated with TYSABRI that have developed PML, a rare and frequently fatal, demyelinating disease of the central nervous system, while using TYSABRI, whether or not TYSABRI is at fault in causing the disease.



Public companies may also be the subject of certain other types of claims, including those asserting violations of securities laws and derivative actions. For example, we face several stockholder-derivative actions and class action lawsuits related to our announcement of the suspension of marketing and commercial distribution of TYSABRI. See "Item 3 — Legal Proceedings" for a description of these matters. In addition, we are providing the SEC with information in connection with the SEC's informal inquiry into the suspension of marketing and commercial distribution of TYSABRI and trading in our securities by certain of our directors, officers and employees.

We cannot predict with certainty the eventual outcome of any pending litigation or third-party inquiry. We may not be successful in defending ourselves or asserting our rights in the litigation or informal inquiry to which we are currently subject, or in new lawsuits, investigations or claims brought against us, and, as a result, our business could be materially harmed. These lawsuits, investigations or claims may result in large judgments or settlements against us, any of which could have a negative effect on our financial performance and business. Additionally, lawsuits and investigations can be expensive to defend, whether or not the lawsuit or investigation has merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in running our business.

We maintain product liability and director and officer insurance that we regard as reasonably adequate to protect us from potential claims, however we cannot assure you that it will. Also, the costs of insurance have increased dramatically in recent years, and the availability of coverage has decreased. As a result, we cannot assure you that we will be able to maintain its current product liability insurance at a reasonable cost, or at all.

#### **Our Business Involves Environmental Risks**

Our business and the business of several of our strategic partners, including Genentech and Elan, involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Biologics manufacturing is extremely susceptible to product loss due to microbial or viral contamination, material equipment failure, or vendor or operator error. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards, there will always be the risk of accidental contamination or injury. In addition, microbial or viral contamination may cause the closure of a manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. We currently store radioactive materials from our California operation on-site because the approval of a disposal site in California for all California-based companies has been delayed indefinitely. If and when a disposal site is approved, we may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business.

#### We Rely Upon Key Personnel

Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers and key scientific personnel. If we lose the services of any of these individuals, our business could be harmed. We currently have employment agreements with William H. Rastetter, Ph.D., our Executive Chairman, and James C. Mullen, our Chief Executive Officer and President. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales and manufacturing personnel and our ability to develop and maintain relationships with qualified clinical researchers. Competition to obtain the services of these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel or develop and maintain relationships with clinical researchers.

# Future Transactions May Harm Our Business or the Market Price of Our Stock

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers;
- acquisitions;
- strategic alliances;
- · licensing agreements; and
- copromotion agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations to the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also harm the market price of our stock.

#### We are Subject to Market Risk

We have exposure to financial risk in several areas including changes in foreign exchange rates and interest rates. We attempt to minimize our exposures by using certain financial instruments, for purposes other than trading, in accordance with our overall risk management guidelines. See "Critical Accounting Estimates" in "Management's Discussion and Analysis of Financial Condition and Results of Operations" for information regarding our accounting policies for financial instruments and disclosures of financial instruments.

#### Our Financial Position, Results of Operations and Cash Flows can be Affected by Fluctuations in Foreign Currency Exchange Rates

We have operations in Europe, Japan, Australia and Canada in connection with the sale of AVONEX. We also receive royalty revenues based on worldwide product sales by our licensees and through Genentech on sales of RITUXAN outside of the U.S.. As a result, our financial position, results of operations and cash flows can be affected by fluctuations in foreign currency exchange rates (primarily Euro, Swedish krona, British pound, Japanese yen, Canadian dollar and Swiss franc).

We use foreign currency forward contracts to manage foreign currency risk and do not engage in currency speculation. We use these forward contracts to hedge certain forecasted transactions denominated in foreign currencies. A hypothetical adverse 10% movement in foreign exchange rates compared to the U.S. dollar across all maturities (for example, a strengthening of the Euro) would result in a hypothetical loss in fair value of approximately \$35 million. Our use of this methodology to quantify the market risk of such instruments should not be construed as an endorsement of its accuracy or the accuracy of the related assumptions. The quantitative information about market risk is necessarily limited because it does not take into account operating transactions.

#### We are Exposed to Risk of Interest Rate Fluctuations

The fair value of our cash, cash equivalents and marketable securities are subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. We estimate that such hypothetical adverse 100 basis point movement would not have materially impacted net income or materially affected the fair value of interest rate sensitive instruments.

# Volatility of Our Stock Price

The market prices for our common stock and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. For example, the closing selling price of our common stock fluctuated between \$36.94 per share and \$67.92 per share during 2004, and between \$37.53 per share and \$67.80 per share from January 3, 2005 and March 15,

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2005. The market price of our common stock likely will continue to fluctuate due to a variety of factors, including:

- material public announcements;
- the announcement and timing of new product introductions by us or others;
- material developments relating to TYSABRI, including the outcome of our evaluations of the risk of PML in patients treated with TYSABRI;
- events related to our products or those of our competitors, including the withdrawal or suspension of products from the market;
- technical innovations or product development by us or our competitors;
- regulatory approvals or regulatory issues;
- availability and level of third-party reimbursement;
- developments relating to patents, proprietary rights and orphan drug status;
- results of late-stage clinical trials with respect to our products under development or those of our competitors;
- new data or information, positive or negative, on the benefits and risks of our products or products under development;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic and other external factors, disaster or crisis;
- hedge and/or arbitrage activities by holders of our convertible promissory notes;
- period-to-period fluctuations in our financial results or results which do not meet or exceed analyst expectations; and
- market trends relating to or affecting stock prices throughout our industry, whether or not related to results or news regarding us or our competitors.

# Our Outstanding Convertible Promissory Notes Leverage Us Considerably

As a result of issuing our subordinated notes due 2019 in February 1999 and issuing our senior notes due 2032 in April and May 2002, we incurred indebtedness of approximately \$345.0 million at maturity in 2019 and approximately \$1.2 billion at maturity in 2032. As of December 31, 2004, our remaining indebtedness under the subordinated notes was approximately \$219.2 million at maturity, due to conversion of subordinated notes into common stock in accordance with the conversion features of the notes. Holders of the subordinated notes may require us to purchase all or a portion of the notes on February 16, 2009 and 2014 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, common stock or a combination of cash and stock. Holders of the senior notes may require us to purchase all or a portion of the notes in cash on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase. The aggregate purchase price of our outstanding senior notes on April 29, 2005 is approximately \$753 million. Based on the range of stock prices since the announcement of the suspension of the marketing and commercial distribution of TYSABRI on February 28, 2005, it is highly probable that we will be required to repurchase all or a substantial portion of the senior notes on April 29, 2005.

The degree to which we are leveraged could harm our ability to obtain future financing and could make us more vulnerable to industry downturns and competitive pressures. Our ability to meet our debt obligations will be dependent upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.



# We Have Adopted Several Anti-takeover Measures As Well As Other Measures to Protect Certain Members of Our Management Which May Discourage or Prevent a Third Party From Acquiring Us

A number of factors pertaining to our corporate governance discourage a takeover attempt that might be viewed as beneficial to stockholders who wish to receive a premium for their shares from a potential bidder. For example:

- we are subject to Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;
- our stockholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors;
- our board of directors has the authority to issue, without vote or action of stockholders, up to 8,000,000 shares of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of common stock;
- our collaboration agreement with Genentech provides Genentech with the option to buy the rights to RITUXAN and retain control of any additional anti-CD20 products developed under the collaboration in the event that we undergo a change of control, which may limit our attractiveness to potential acquirors;
- our collaboration agreement with Elan provides Elan with the option to buy the rights to TYSABRI in the event that we undergo a change of control, which may limit our attractiveness to potential acquirors;
- under the terms of our senior notes we would be required to repurchase the notes for cash if we undergo a change of control before 2007;
- our directors are elected to staggered terms, which prevents the entire board from being replaced in any single year; and
- our bylaws provide that, until November 12, 2006, the affirmative vote of at least 80% of our board of directors (excluding directors who are serving as an officer or employee) will be required to remove William H. Rastetter, Ph.D. from his position as our Executive Chairman and to remove James C. Mullen as our Chief Executive Officer and President.

# Item 2. Properties

# Cambridge, Massachusetts

Our principal executive offices are located in Cambridge, Massachusetts. In Cambridge, we own approximately 537,292 square feet of real estate space, consisting of a 150,000 square foot building that houses laboratory and office space; an approximately 259,000 square foot building that primarily contains research and development and process development operations; and two other buildings, consisting of an aggregate of approximately 128,292 square feet, which primarily contain laboratories, purification, aseptic bottling facilities, office space, and 6,130 square feet which we lease to a third party under a lease which expires in 2008. We have also started construction of an approximately 96,500 square foot building that will primarily house laboratory and office space. We also have development options for additional property in Cambridge. We lease a total of approximately 415,900 square feet, consisting of additional office, manufacturing, and research and development space, in all or part of five other buildings in Cambridge. One of the leases expired on December 31, 2004. We are leasing this space on a month-to-month basis while we negotiate a new lease. The lease expiration dates for the other leased sites range from 2005 to 2015.

#### San Diego and Oceanside, California

We also own approximately 42.6 acres of land in San Diego, California. In September 2004, we opened our new research and corporate campus on this property. The campus consists of five interconnected buildings and substantially all of our San Diego employees now work at this campus. The transition of our San Diego employees from our four leased sites in San Diego to this new campus was completed in October 2004. We have sublet or are in the process of subletting the vacated lease sites for which we have outstanding obligations. We also own approximately 90 acres of land in Oceanside, California where we have completed construction of a large-scale manufacturing facility, and obtained the certificate of occupancy in the fourth quarter of 2004. Commissioning and validation is expected to continue through 2005. We expect the facility to be licensed for use in 2006. We discontinued operations at our Oceanside pilot manufacturing facility in July 2004. For a discussion of the potential impact of the suspension of TYSABRI on our plans for the Oceanside large-scale manufacturing facility discussed below, see "Forward-Looking Information and Risk Factors That May Affect Future Results — We are Subject to Risks Related to the Products That We Manufacture."

#### **Research Triangle Park, North Carolina**

We own a 108,000 square foot biologics manufacturing facility, a 232,000 square foot large scale manufacturing plant and a second large scale purification facility of 42,000 square feet, and a 150,000 square foot laboratory office building in Research Triangle Park, North Carolina. We manufacture bulk AVONEX at the biologics manufacturing facility. We manufacture bulk AMEVIVE and TYSABRI at the large-scale manufacturing facility. We plan to use this facility to manufacture other products in our pipeline. We are continuing further expansion in Research Triangle Park with ongoing construction of several projects to increase our manufacturing flexibility, including the construction of a clinical aseptic fill-finish facility.

#### International

We lease office space in Zug, Switzerland, our international headquarters, the United Kingdom, Germany, Austria, France, Belgium, Spain, Portugal, Denmark, Sweden, Finland, Norway, Japan, Australia and Canada. In addition, we lease approximately 29,200 square feet of real estate in Hoopddorf, The Netherlands, which consists of office space, a storage facility, a packaging facility where we perform some of our AVONEX packaging operations, and quality control operations. We also lease 9,015 square meters of real estate space in Lijnden in the Netherlands consisting of office space and warehouse space. In addition, we own approximately 60 acres of property in Hillerod, Denmark. We recently re-started construction of a large-scale manufacturing facility at the Hillerod site.

# Item 3. Legal Proceedings.

On March 2, 2005, we, along with William H. Rastetter, our Executive Chairman, and James C. Mullen, our Chief Executive Officer, were named as defendants in a purported class action lawsuit, captioned Brown v. Biogen Idec Inc., et al., filed in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. The plaintiff alleges that the defendants made materially false and misleading statements regarding potentially serious side effects of TYSABRI in order to gain accelerated approval from the FDA for the product's distribution and sale. The plaintiff alleges that these materially false and misleading statements harmed the purported class by artificially inflating our stock price during the purported class period and that company insiders benefited personally from the inflated price by selling our stock. The plaintiff seeks unspecified damages, as well as interest, cost and attorneys' fees. A substantially similar action, captioned Grill v. Biogen Idec Inc., et al., was filed on March 10, 2005 in the same court by another purported class representative. We believe that the actions are without merit and intend to contest them vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss.



On March 4, 2005, a purported shareholder derivative action, captioned Halpern v. Rastetter, et al., was filed in the Court of Chancery for the State of Delaware, in New Castle County, on our behalf of Biogen Idec Inc., against us as nominal defendant, our Board of Directors and our former general counsel. The plaintiff derivatively claims breaches of fiduciary duty by our Board of Directors for inadequate oversight of our policies, practices, controls and assets, and for recklessly awarding executive bonuses despite alleged awareness of potentially serious side effects of TYSABRI and the potential for related harm to our financial position. The plaintiff also derivatively claims that our Executive Chairman, former general counsel and a director misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI, and alleges that our Board of Directors did not ensure that appropriate policies were in place regarding the control of confidential information and personal trading in our securities by officers and directors. The plaintiff seeks unspecified damages, profits, the return of all bonuses paid by us, costs and attorneys' fees. A substantially similar action, captioned Golaine v. Rastetter, et al., was filed on March 14, 2005 in the same court. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. As required by applicable law, we and our Board of Directors are considering the derivative claims in the complaints and will respond in a time and manner consistent with applicable Delaware statutory and common law. These purported derivative actions do not seek affirmative relief from the Company.

On March 9, 2005, two additional purported shareholder derivative actions, captioned Carmona v. Mullen, et al. and Fink v. Mullen, et al., were brought in the Superior Court of the State of California, County of San Diego, on our behalf, against us as nominal defendant, our Board of Directors and our chief financial officer. The plaintiffs derivatively claim breach of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment against all defendants. The plaintiffs also derivatively claim insider selling in violation of California Corporations Code § 25402 and breach of fiduciary duty and misappropriation of information against certain defendants who sold our securities during the period of February 18, 2004 to the date of the complaints. The plaintiffs allege that the defendants caused and/or allowed us to issue, and conspired, aided and abetted and acted in concert in concealing that we were issuing, false and misleading press releases about the safety of TYSABRI and its financial prospects which resulted in legal claims being asserted against us, irreparable harm to our corporate image, depression of our stock price and impairment of our ability to raise capital. The plaintiffs also allege that certain defendants sold personally owned shares of our stock while in possession of material, undisclosed, adverse information. The plaintiffs seek unspecified damages, treble damages for the purported insider trading in violation of California Corporate Code § 25402, equitable relief including restriction of the defendants' trading proceeds or other assets, restitution, disgorgement and costs, including attorneys' fees and expenses. Neither of the plaintiffs made presuit demand on the Board of Directors prior to filing their respective actions. As required by applicable law, we and our Board of Directors are considering the derivative claims in the complaints and will respond in a time and manner consistent with applicable statutory and common law. These purported derivati

Our Board of Directors has received letters, dated March 1 and 15, 2005, respectively, on behalf of purported owners of our securities purportedly constituting demands under Delaware law. A supplement to the March 1 letter was received on March 2, 2005. The letters generally allege that certain of our officers and directors breached their fiduciary duty to us by selling personally held shares our securities while in possession of material, non-public information about potential serious side effects of TYSABRI. The letters generally request that our Board of Directors take action on our behalf to recover compensation and profits from the officers and directors, consider enhanced corporate governance controls related to the sales of securities by insiders, and pursue other such equitable relief, damages, and other remedies as may be appropriate. As required by applicable law, our Board of Directors is currently considering the letters and will respond in a time and manner consistent with Delaware law.

We are providing information to the SEC regarding the SEC's informal inquiry into the suspension of marketing and commercial distribution of TYSABRI and trading in our securities by certain of our directors, officers and employees.

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York, or Columbia, in the U.S. District Court for the District of Massachusetts, contending that we no longer have any obligation to pay royalties to Columbia on sales of our products under a 1993 license agreement between us and Columbia related to U.S. Patent Nos. 4,399,216, 4,634,665, and 5,179,017, also referred to as the Original Patents, or under a newly issued patent, U.S. Patent No. 6,455,275, also referred to as the '275 patent (the 2003 action). Based, in part, on the court's subsequent finding that we had made a strong showing that we might prevail in proving the '275 patent is invalid under the doctrine of non-statutory double patenting, Columbia has since covenanted not to sue Biogen Idec MA, Inc. on any claim of the '275 patent and any claim that is the same or substantially the same as the claims of the '275 patent if such claim(s) emerge from the reexamination or reissue proceedings currently pending before the U.S. Patent and Trademark Office, or USPTO, with respect to the '275 patent. As a result of Columbia's covenant not to sue, and Columbia's assertion that Biogen Idec MA, Inc. is a licensee in good standing, the court issued an order on November 5, 2004, in which it dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction. At this time, we are unable to predict whether any claims will issue from the USPTO on the reexamination or reissue proceedings concerning the '275 patent, or whether, if any claims do issue, such claims will pose a risk of infringement with respect to our activities.

On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation, filed suit against Columbia in the U.S. District Court for the District of Massachusetts (the 2004 action). In the 2004 action we reasserted some of the contentions made in our complaint in the action filed in 2003 action. For example, that we are seeking a declaratory judgment that we have no obligation to pay any further royalties under the license agreement because the Original Patents have expired and the '275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based on the '275 patent or on any pending continuations, continuations-in-part, or divisional applications of the Original Patents. We have also asserted claims for relief based on abuse of process, breach of contract, violation of Massachusetts laws concerning unfair and deceptive trade practices, prosecution laches and inequitable conduct. To date, Columbia has refused to extend its covenant not to sue on the '275 patent to Biogen Idec Inc. In the event that we are unsuccessful in the present litigation and Columbia asserts a claim for infringement against Biogen Idec Inc., we may be liable for damages suffered by Columbia with respect to unpaid royalties and such other relief as Columbia may seek and be granted by the Court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, GlaxoSmithKline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of infringement claims are based on allegations that we "provided instructions and/or recommendations on a proper immunization schedule for vaccines" to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. Under our 1988 license agreement with GlaxoSmithKline, GlaxoSmithKline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that GlaxoSmithKline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in certain cases, Biogen Idec Inc., was named as a defendant in lawsuits filed by the County of Suffolk, New York, the County of Westchester, New York, the County of Rockland, New York, the County of Nassau, New York, the County of Onondaga, New York, the County of Chenango, New York, the County of Erie, New York, the City of New York and the County of Chautauqua, New York. All of the cases are pending in the U.S. District Court for the District of Massachusetts, with the exception of the Onondaga, Chenango and Chautauqua lawsuits, which are expected

to be transferred to the U.S. District Court for the District of Massachusetts, and the Erie lawsuit, which is pending in the Supreme Court of the State of New York for the County of Erie. The complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs; marketed and promoted the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs; and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaints allege violations of New York state law and advance common law claims for unfair trade practices, fraud, and unjust enrichment. In addition, all of the complaints, with the exception of the County of Erie, allege that the defendants failed to accurately report the "best price" on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services, and excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the "best price." The Suffolk, Westchester, Rockland, and Nassau County complaints also claim that Biogen violated the Racketeering Influence and Corrupt Organizations Act (RICO) 18 U.S.C. § 1962(c). In September 2003, Biogen joined other named defendants in filing a motion to dismiss the Suffolk County complaint. Biogen also separately filed a motion on its own behalf arguing that the plaintiffs made no specific factual allegations against Biogen to connect it with the alleged scheme. In September 2004, the court, in ruling on defendants' joint motion to dismiss, allowed the motion, in part, and dismissed the RICO claim, the Medicaid best price claim, the breach of contract claim, and the common law fraud claim. The court did not dismiss the claims brought under the New York State Medicaid and Social Services statutes, the unfair trade practices claim, or the claim for unjust enrichment. In October 2004, the court issued a partial decision on Biogen's individual motion to dismiss. The court dismissed all of the state law claims against Biogen based on the alleged failure to report best price, but deferred ruling on the fraud-based claims and ordered Suffolk County to produce all documents in support of its fraud-based claims. Suffolk County subsequently produced documents in response to the court's request and Biogen renewed its motion to dismiss. Neither Biogen nor the other defendants have answered or responded to the other complaints, as all of the plaintiffs except Erie County have agreed to stay the time to respond until the resolution of the pending motion to dismiss the Suffolk County complaint. Biogen Idec intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

#### Item 4. Submission of Matters to a Vote of Security Holders.

Not Applicable.

# PART II

# Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Market Information

Our common stock trades on The Nasdaq Stock Market under the symbol "BIIB." Prior to changing our name to Biogen Idec in November 2003, we traded on The Nasdaq Stock Market under the symbol "IDPH."

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The following table shows the high and low sales price for our common stock as reported by The Nasdaq Stock Market for each quarter in the years ended December 31, 2004 and 2003.

		Common S	tock Price	
	2	004	200	3
	High	Low	High	Low
irst Quarter	\$ 59.63	\$ 36.60	\$ 37.14	\$ 27.80
econd Quarter	64.00	54.56	42.15	30.01
hird Quarter	63.50	53.06	38.95	31.73
ourth Quarter	68.13	54.30	39.41	31.63

# Holders

As of March 10, 2005, there were approximately 4,158 stockholders of record of our common stock. In addition, 871 stockholders of record of Biogen, Inc. common stock have yet to exchange their shares of Biogen common stock for our common stock as contemplated by the merger.

# Dividends

We have not paid cash dividends since our inception. We currently intend to retain all earnings, if any, for use in the expansion of our business and therefore do not anticipate paying any cash dividends in the foreseeable future.

#### **Recent Sales of Unregistered Securities**

None.

# **Issuer Purchases of Equity Securities**

#### **Issuer Purchases of Equity Securities**

Period	Total Number of Shares Purchased (#)(a)	Average Price Paid per Share (\$)	Total Number of Shares Purchased as Part of Publicly Announced Program (#)(a)	Number of Shares that may yet be Purchased under Our Program (#)
October 1 — October 31,				
2004		\$ —	—	20,000,000
November 1 —				
November 30, 2004	200,582	58.66	200,000	19,800,000
December 1 —				
December 31, 2004	406,993	60.22	403,600	19,396,400
Total	607,575(b)	59.71	603,600	19,396,400

(a) In October 2004, our Board of Directors authorized the repurchase of up to 20 million shares of our common stock. This repurchase program will expire no later than October 4, 2006. We publicly announced the repurchase program in our press release dated October 27, 2004 which was furnished to (and not filed with) the SEC as Exhibit 99.1 of our Current Report of Form 8-K filed on October 27, 2004.

(b) 603,600 of these shares were repurchased as part our publicly announced repurchase program. The remaining shares are shares that were used by certain employees to pay the exercise price of their stock options in lieu of paying cash or utilizing our cashless option exercise program. In our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2004, we incorrectly reported that an aggregate of 11,199 shares were used by employees to pay the exercise price of their stock options during the third quarter when only 370 shares were so used.

# Item 6. Selected Consolidated Financial Data

The following financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K, beginning on page F-1.

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# SELECTED FINANCIAL DATA

	Years Ended December 31,							
	2004	2003(2)	2002	2001	2000			
			sands, except per share amou	nts)				
Product revenues	\$ 1,486,344	\$ 171,561	\$ 13,711	\$ —	\$ —			
Revenues from unconsolidated joint business	615,743	493,049	385,809	251,428	132,782			
Royalties	98,945	12,010	—	—	—			
Corporate partner revenue	10,530	2,563	4,702	21,249	21,900			
Total revenues	2,211,562	679,183	404,222	272,677	154,682			
Total costs and expenses(1)	2,168,146	1,548,852	190,346	141,540	98,823			
Income (loss) before income taxes (benefit)	64,093	(880,624)	231,522	161,604	69,347			
Net income (loss)	25,086	(875,097)	148,090	101,659	48,145			
Diluted earnings (loss) per share	0.07	(4.92)	0.85	0.58	0.30			
Shares used in calculating diluted earnings (loss)								
per share	343,475	177,982	176,805	178,117	152,616			
Cash, cash equivalents and marketable securities								
available-for-sale	2,167,566	2,338,286	1,447,865	866,607	750,526			
Total assets	9,165,758	9,503,945	2,059,689	1,141,216	856,406			
Notes payable, less current portion	101,879	887,270	866,205	135,977	128,888			
Shareholders' equity	6,826,401	7,053,328	1,109,690	956,479	694,619			

(1) Included in total costs and expenses in 2003 is a charge of \$823.0 million for in-process research and development.

(2) Includes the impact of our Merger with Biogen, Inc. on November 12, 2003.

# Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K, beginning on page F-1.

#### Overview

Biogen Idec creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. We currently have five products:

- AVONEX® (interferon beta-1a) for the treatment of relapsing forms of multiple sclerosis, or MS.
- RITUXAN® (rituximab) and ZEVALIN®(ibritumomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs. We collaborate with Genentech Inc., or Genentech, on the development and commercialization of RITUXAN. RITUXAN is the trade name in the United States, or U.S., Canada and Japan for the compound rituximab. MabThera is the tradename for rituximab in the European Union, or EU. In this Form 10-K, we refer to rituximab, RITUXAN and MabThera collectively as RITUXAN, except where we have otherwise indicated.
- TYSABRI® (natalizumab), formerly known as ANTEGREN®, which was approved by the U.S. Food and Drug Administration, or FDA, in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan Corporation plc, or Elan, voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and rheumatoid arthritis, or RA. These decisions were based on reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of progressive multifocal leukoencephalopathy, or PML, a rare and frequently fatal, demyelinating disease of the central nervous system. Both patients received more than two years of TYSABRI in combination with AVONEX. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability. See "Forward-Looking Information and Risk Factors That May
- AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

We also receive royalty revenues on sales by our licensees of a number of products covered under patents that we control, including on sales by Schering AG of ZEVALIN in the EU. In addition, we have a number of ongoing research and development programs in our core therapeutic areas and in other areas of interest.

#### Merger

On November 12, 2003, IDEC Pharmaceuticals Corporation and Biogen, Inc. completed a merger transaction, or the Merger, resulting in Biogen, Inc. becoming a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. The business combination was treated as an acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation for accounting purposes. In connection with the Merger, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc.



As a result of the Merger, Biogen, Inc. stockholders received 1.15 shares of Biogen Idec common stock for each share of Biogen, Inc. common stock. As a result, Biogen Idec issued approximately 171.9 million shares of common stock at a fair value of approximately \$6.48 billion (based on the average of the closing price of IDEC Pharmaceuticals Corporation's common stock for the period from two days before through two days after the public announcement of the Merger on June 23, 2003). In addition, options to purchase Biogen, Inc. common stock outstanding at November 12, 2003 were assumed by Biogen Idec and converted into options to purchase approximately 20.7 million shares of Biogen Idec common stock at a fair value of approximately \$295 million (based on the Black-Scholes option pricing model, as described in more detail below). We paid approximately \$19.9 million in fees for banking, legal, accounting and tax related services related to the Merger. Merger related fees of \$21.5 million paid by Biogen, Inc. prior to completion of the Merger are not included in this amount as they were expensed as incurred. The total Merger purchase price was approximately \$6.8 billion. The Merger qualified as a tax-free reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

The fair value of Biogen Idec's shares used in determining the purchase price was \$37.69 per share based on the average of the closing price of IDEC Pharmaceuticals Corporation's common stock for the period two days before through two days after public announcement of the Merger on June 23, 2003. The fair value of stock options assumed by Biogen Idec in the Merger was determined using the Black-Scholes option pricing model with the following assumptions: stock price of \$37.69, which is the value ascribed to IDEC shares in determining the purchase price; volatility of 40%; risk-free interest rate of 1.8%; and an expected life of 4.0 years.

The purchase price is as follows (table in thousands):

Fair value of Biogen Idec common stock	\$ 6,480,339
Fair value of replacement stock options	295,399
Cash paid for fractional shares	27
Acquisition related costs	19,872
Total purchase price	\$ 6,795,637

The purchase price has been allocated to the acquired tangible and intangible assets and liabilities based on their fair values as of November 12, 2003, the date that the Merger was consummated (table in thousands):

Inventory	\$ 706,957
Accounts receivable	216,221
Property, plant and equipment	713,719
Acquired identifiable intangible assets	3,664,000
Goodwill	1,151,105
In-process research and development	823,000
Deferred stock-based compensation	2,261
Other current and long-term assets	1,106,112
Assumed liabilities	(424,648)
Increase benefit plan liability to fair value	(26,650)
Deferred tax liabilities arising from fair value adjustments	(1,136,440)
Total purchase price	\$ 6,795,637

The allocation of the purchase price was based, in part, on a third-party valuation of the fair value of in-process research and development, identifiable intangible assets, and certain property, plant and equipment. The excess of the purchase price over the fair value of assets and liabilities acquired is allocated to goodwill. See "Biogen, Inc. Purchase Price Allocation" under Critical Accounting Estimates.

The discussions for the year ended December 31, 2004 in this Form 10-K represent our financial condition and results of operations for the year ended December 31, 2004 and include the results of operations of the merged companies. The discussions for the year ended December 31, 2003 in this Form 10-K, unless indicated otherwise, represent our financial condition and results of operations for the year ended December 31, 2003 and include the results of operations of Biogen, Inc. for the period commencing November 13, 2003 through December 31, 2003 only. The results of operations of Biogen, Inc. (revenues and expenses) for the period commencing January 1, 2003 through November 12, 2003, unless indicated otherwise, are excluded from this Form 10-K. Comparisons are made to our results of operations for the year ended December 31, 2002, which only include the historical results of IDEC Pharmaceuticals Corporation.

#### **Results of Operations**

#### Revenues

		2004	2003 (In thousands)			2002
Product sales						
United States	\$	986,050	\$	121,589	\$	13,711
Rest of world		500,294		49,972		
Total product sales		1,486,344		171,561		13,711
Revenues from unconsolidated joint business		615,743		493,049		385,809
Royalties		98,945		12,010		
Corporate partner revenue		10,530		2,563		4,702
Total revenues	\$	2,211,562	\$	679,183	\$	404,222
Product Sales						
	_	2004 2003 (In thousands)			-	2002
AVONEX	\$	1,417,157	\$	142,603	\$	
AMEVIVE		43,030		9,356		—
ZEVALIN		23,036		19,602		13,711
TYSABRI		3,121			_	
Total product sales	\$	1,486,344	\$	171,561	\$	13,711

AVONEX is the most prescribed therapeutic product in MS worldwide. Globally over 130,000 patients have chosen AVONEX as their treatment of choice. During 2004, sales of AVONEX generated worldwide revenues of \$1.4 billion, of which \$922.6 million was generated in the U.S. and \$494.6 million was generated outside the U.S., primarily in the EU. Product sales from AVONEX represent approximately 64% of our total revenues in 2004. Our results of operations for 2003 include sales of AVONEX for the period from November 13, 2003 through December 31, 2003. During that period, sales of AVONEX generated worldwide revenues of \$142.6 million, of which \$92.6 million was generated in the U.S. and \$50.0 million in the rest of the world, primarily the EU. Product sales from AVONEX represented approximately 21% of our total revenues in 2003. We expect to face increasing competition in the MS marketplace in and outside the U.S. from existing and new MS treatments, including TYSABRI if it is reintroduced to the market, that may impact sales of AVONEX. We expect future growth in AVONEX revenues to be dependent to a large extent on our ability to compete successfully.

AMEVIVE was approved in the U.S. in 2003 for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. During 2004, sales of AMEVIVE generated revenues of \$43.0 million, substantially all in the U.S. Our results of operations for 2003 include sales of AMEVIVE for the period from November 13, 2003 through December 31, 2003. During

that period, sales of AMEVIVE generated revenues of \$9.4 million, substantially all in the U.S. Product sales from AMEVIVE represent approximately 2% and 1% of our total revenues in 2004 and 2003, respectively.

In February 2002, ZEVALIN became the first radioimmunotherapy approved by the FDA for the treatment of certain B-cell NHLs. ZEVALIN, as part of the ZEVALIN therapeutic regimen, is approved as a treatment for relapsed or refractory low-grade, follicular, or transformed B-cell NHL including patients with RITUXAN refractory follicular NHL. We launched ZEVALIN in the U.S. in April 2002. In 2004, sales of ZEVALIN generated revenues of \$18.7 million in the U.S. as compared to \$19.6 million in 2003. Outside the U.S., we have licensed our marketing rights in ZEVALIN to Schering AG. In January 2004, the European Medicines Agency, or EMEA, the regulatory authority in the EU, granted marketing approval of ZEVALIN in the EU for the treatment of adult patients with CD20+ follicular B-cell NHL who are refractory to or have relapsed following treatment with RITUXAN. Rest of world product sales for ZEVALIN for the year ended December 31, 2004 were \$4.3 million. The \$4.3 million relates to ZEVALIN sold to Schering AG in 2003 and 2004, recognition of which had been deferred. The revenue was recognized in the fourth quarter of 2004 when an amendment to the license agreement was executed and the price of ZEVALIN became determinable. Product sales from ZEVALIN represented approximately 1% and 3% of our total revenues in 2004 and 2003, respectively.

In November 2004, TYSABRI was approved by the FDA as treatment for relapsing forms of MS to reduce the frequency of clinical relapses. In the U.S., prior to the suspension, we sold TYSABRI to Elan who then distributed TYSABRI to third party distributors and other customers. In 2004, our revenue associated with sales of TYSABRI was \$3.1 million, which represents less than 1% of our total revenues in 2004. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. The voluntary suspension will not affect 2004 revenue. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine the possibility of re-initiation of dosing in clinical studies and future commercial availability. See also "Revenue Recognition and Accounts Receivable" under Critical Accounting Estimates for our method of recording revenue from TYSABRI sales.

See also the risks affecting revenues described in "Forward-Looking Information and Risk Factors That May Affect Future Results — Our Revenues Rely Significantly on a Limited Number of Products" and "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth."

#### **Unconsolidated Joint Business Revenue**

RITUXAN is currently marketed and sold worldwide for the treatment of certain B-cell NHLs. We copromote RITUXAN in the U.S. in collaboration with Genentech under a collaboration agreement between the parties. Under the collaboration agreement, we granted Genentech a worldwide license to develop, commercialize and market RITUXAN in multiple indications. In exchange for these worldwide rights, we have copromotion rights in the U.S. and a contractual arrangement under which Genentech shares a portion of the pretax U.S. copromotion profits of RITUXAN with us. This collaboration agreement with Genentech to include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to RITUXAN, for a broad range of indications.

In the U.S., we contribute resources to selling and the continued development of RITUXAN. Genentech is responsible for worldwide manufacturing of RITUXAN. Genentech also is responsible for the primary support functions for the commercialization of RITUXAN in the U.S. including selling and marketing, customer service, order entry, distribution, shipping and billing. Genentech also incurs the majority of

continuing development costs for RITUXAN. Under the arrangement, we have a limited sales force as well as limited development activity.

Under the terms of separate sublicense agreements between Genentech and Roche, commercialization of RITUXAN outside the U.S. is the responsibility of Roche, except in Japan where Roche copromotes RITUXAN in collaboration with Zenyaku. There is no direct contractual arrangement between Biogen Idec and Roche or Zenyaku.

Revenue from unconsolidated joint business consists of our share of pretax copromotion profits which is calculated by Genentech, and includes consideration of our RITUXAN-related sales force and development expenses, and royalty revenue from sales of RITUXAN outside the U.S. by Roche and Zenyaku. Copromotion profit consists of U.S. sales of RITUXAN to third-party customers net of discounts and allowances and less the cost to manufacture RITUXAN, third-party royalty expenses, distribution, selling and marketing expenses, and joint development expenses incurred by Genentech and us.

Under the amended and restated collaboration agreement, our current pretax copromotion profit-sharing formula has two tiers. We earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of 2004, 2003 and 2002. Upon approval of the first new anti-CD20 product, the pretax copromotion profit-sharing formula for RITUXAN and other anti-CD20 products sold by us and Genentech will change over a period of time to a fixed annual profit-sharing percentage at the lower tier.

Copromotion profits for the years ended December 31, 2004, 2003 and 2002, consist of the following (table in thousands):

		2004		2003		2002
Product revenues, net	\$	1,573,228	\$	1,360,537	\$	1,080,240
Costs and expenses	_	418,190		299,398		256,496
Copromotion profits	\$	1,155,038	\$	1,061,139	\$	823,744
Biogen Idec's share of copromotion profits	\$	457,025	\$	419,197	\$	324,498

Net sales of RITUXAN to third-party customers in the U.S. recorded by Genentech for 2004 were \$1.6 billion compared to \$1.4 billion in 2003 and \$1.1 billion in 2002. The increase in 2004 from 2003 and 2002 was primarily due to increased market penetration in treatments of B-cell NHLs and chronic lymphocytic leukemia, and increases in the wholesale price of RITUXAN effective September 2004, March 2003 and March 2002.

We received royalties on sales of RITUXAN outside of the U.S. of \$121.0 million in 2004 as compared to \$67.9 million in 2003 and \$45.4 million in 2002, which we include under "Revenue from unconsolidated joint business" in our consolidated statements of income.

Revenues from unconsolidated joint business for the years ended December 31, 2004, 2003 and 2002, consist of the following (table in thousands):

	2004	2003	2002
Copromotion profits	\$ 457,025	\$ 419,197	\$ 324,498
Reimbursement of selling and development expenses	37,710	18,400	15,879
Royalty revenue on sales of RITUXAN outside the U.S.	121,008	67,869	45,432
RITUXAN clinical data purchased from Roche	—	(9,353)	—
Columbia patent royalty and interest payment	—	(3,064)	—
	\$ 615,743	\$ 493,049	\$ 385,809

Our royalty revenue on sales of RITUXAN outside the U.S. is based on Roche and Zenyaku's net sales to third-party customers and is recorded on a cash basis. The increase in royalty revenues in 2004 and 2003 is due to increased sales of RITUXAN outside the U.S. Under the amended and restated collaboration agreement, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products and will only receive such royalty revenues for the first eleven years from the date of first commercial sale of such new anti-CD20 products.

During 2003, Genentech purchased certain clinical data from Roche that supported a potential label expansion of RITUXAN. Additionally, in 2003, we, along with Genentech, agreed that payments were owed to Columbia University for royalties related to past sales of RITUXAN in the U.S. As a result, we recognized \$2.6 million in royalty payments and \$0.5 million in interest charges related to these royalties.

Revenues from unconsolidated joint business represented 28%, 73% and 95% of our total revenues in 2004, 2003 and 2002, respectively. The decreases in 2004 and 2003 are primarily due to former Biogen, Inc. revenue included in our results of operations for all of 2004 and for the period of November 12, 2003 through December 31, 2003.

#### **Royalty Revenue**

We receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control. During 2004 and 2003, we received approximately \$98.9 million and \$12.0 million, respectively, in royalty revenues representing 4% and 2% of total revenues. The increase in royalty revenue is primarily due to a full year of the former Biogen, Inc. royalty revenue being included in our results of operations in 2004 compared to the period from November 12, 2003 through December 31, 2003. Our royalty revenues on sales of RITUXAN outside the U.S. are included in "Revenue from unconsolidated joint business."

We receive royalties from Schering-Plough Corporation, or Schering-Plough, on sales of its alpha interferon products in the U.S. and Italy under an exclusive license to our alpha interferon patents and patent applications. Schering-Plough sells its INTRON® A (interferon alfa-2b) brand of alpha interferon in the U.S. for a number of indications, including the treatment of chronic hepatitis B and hepatitis C. Schering-Plough also sells other alpha interferon products for the treatment of hepatitis C, including REBETRON® Combination Therapy containing INTRON A and REBETOL® (ribavirin, USP), PEG-INTRON® (peginterferon alfa-2b), a pegylated form of alpha interferon, and PEG-INTRON in combination with REBETOL.

We hold several important patents related to hepatitis B antigens produced by genetic engineering techniques. These antigens are used in recombinant hepatitis B vaccines and in diagnostic test kits used to detect hepatitis B infection. We receive royalties from sales of hepatitis B vaccines in several countries, including the U.S., from GlaxoSmithKline plc and Merck and Co. Inc. We have also licensed our proprietary hepatitis B rights, on an antigen-by-antigen and nonexclusive basis, to several diagnostic kit manufacturers, including Abbott Laboratories, the major worldwide marketer of hepatitis B diagnostic kits.

We also receive ongoing royalties on sales of ANGIOMAX® (bivalirudin) by The Medicines Company, or TMC. TMC sells ANGIOMAX in the U.S. for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. TMC sells ANGIOMAX through distributors in Europe, Canada and Latin America.

We anticipate that total royalty revenues in 2005 will be slightly higher as compared to our total royalty revenues in 2004. Royalty revenues may fluctuate as a result of fluctuations in sales levels of products sold by our licensees from quarter to quarter due to the timing and extent of major events such as new indication approvals or government-sponsored programs.

#### **Corporate Partner Revenues**

Corporate partner revenues consist of contract revenues and license fees. Corporate partner revenues totaled \$10.5 million in 2004 compared to \$2.6 million in 2003 and \$4.7 million in 2002. Corporate partner

revenues represented less than 1% of total revenues in 2004 and 2003 and approximately 1% of total revenues in 2002. In 2004, we received a \$10.0 million payment from Schering AG for the EMEA grant of marketing approval of ZEVALIN in the EU. The payment represented, in part, a milestone payment to compensate us for preparing, generating, and collecting data that was critical to the EMEA marketing approval process and, to which we have no continuing involvement. The decrease in corporate partner revenues in 2003 is primarily due to decreased research and development funding in 2002 under our collaborations with Taisho Pharmaceutical Co. Ltd. of Tokyo, or Taisho, as a result of the termination of our collaboration with Taisho, and under our collaborations with Seikagaku Corporation, or Seikagaku. Contract revenues and license fees are, in part, dependent upon the achievement of certain research and development and commercialization objectives and, accordingly, may vary from year to year.

## **Operating Costs and Expenses**

	2004		(In th	2003 ousands)	 2002
Cost of product and royalty revenues	\$	554,319	\$	284,739	\$ 1,457
Research and development		687,663		233,337	100,868
Selling, general and administrative		578,487		174,596	88,021
Write-off of acquired in-process research and development		_		823,000	_
Amortization of acquired intangibles		347,677		33,180	_
Total operating costs and expenses	\$	2,168,146	\$	1,548,852	\$ 190,346

#### **Cost of Product and Royalty Revenues**

In 2004, total cost of product and royalty revenues was \$554.3 million and consisted of product cost of revenues of \$548.7 million and cost of royalty revenues of \$5.6 million. Product cost of revenues consisted of \$480.0 million related to AVONEX, \$27.8 million related to AMEVIVE, \$19.0 million related to ZEVALIN and \$17.3 million related to TYSABRI. Approximately \$295.1 million in cost of product revenues represents the difference between the cost of AVONEX and AMEVIVE inventory recorded at the Merger date and its historical manufacturing cost, which was recognized as cost of product revenues when the acquired inventory was sold or written-down in 2004. All AVONEX inventory acquired in the Merger was sold or written off as of December 31, 2004. We expect that product cost of revenues in 2005 related to AMEVIVE will include approximately \$16 million related to the difference between the cost of AMEVIVE inventory recorded at the Merger and its historical manufacturing cost, as the acquired inventory is sold or written-down.

In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of two serious adverse events that occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases, of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine future commercial availability. We cannot predict the outcome of these evaluations. An unfavorable or inconclusive outcome could result in the permanent withdrawal of TYSABRI from the market and termination of clinical studies of TYSABRI, or the re-introduction of TYSABRI to the market with significant restrictions on its permissible uses, blackbox or other significant safety warnings in its label and such other restrictions, requirements and limitations as the FDA may require. While we presently believe that we will be able to find a path forward for TYSABRI, there are no assurances as to the likelihood of success. In

light of our inability to predict to the required degree of certainty that our TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we have written down all of the \$19.1 million of TYSABRI inventory that had been included on the balance sheet as of December 31, 2004, which was charged to cost of product revenues. We are continuing to manufacture TYSABRI. Because of the uncertainty described above, in the first quarter of 2005, we also expect to expense between \$22 million to \$25 million of TYSABRI that was manufactured in the first quarter of 2005. In subsequent periods, we will continue to assess TYSABRI to determine if it needs to be expensed in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards. See "Forward Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect Our Growth."

We periodically review our inventories for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-offs may be required. This periodic review led to the write-downs of TYSABRI inventory as of December 31, 2004 and the expensing of TYSABRI expected to occur in the first quarter of 2005, as described above, and may lead us to expense TYSABRI in subsequent periods. Also included in product cost of revenues were write-downs of commercial inventory that did not meet quality specifications or became obsolete due to dating expiration, in all cases this product inventory was written-down to its net realizable value. In 2004, we wrote-down \$16.2 million, \$9.7 million, \$1.7 million and \$19.1 million of unmarketable inventory related to AVONEX, ZEVALIN, AMEVIVE and TYSABRI, respectively, which was charged to cost of product revenues. The AVONEX and AMEVIVE inventory was written-down when it was determined that the inventory did not meet quality specifications. The ZEVALIN inventory was written-down when it was determined that the inventory did not meet quality specifications.

In 2003, total cost of revenues was \$284.7 million and consisted of product cost of revenues of \$283.8 million and cost of royalty revenues of \$0.9 million. In November 2003, we recorded the inventory that we acquired from Biogen, Inc. at its estimated fair value. Product cost of revenues consisted of \$254.3 million related to AVONEX, \$18.7 million related to ZEVALIN and \$8.7 million related to AMEVIVE. In 2003, included in product cost of revenues was approximately \$231.6 million in fair market value purchase accounting adjustments related to AVONEX and AMEVIVE, which represents the difference between the cost of inventory recorded at the acquisition date and its historical manufacturing cost. The increase to fair market value was recognized as cost of product revenues when the acquired inventory was sold or written-down. Included in product cost of revenues were write-downs of commercial inventory that did not meet quality specifications or became obsolete due to dating expiration. In all cases this product inventory was written-down to its net realizable value. In 2003, we wrote-down \$160.8 million related to AVONEX, \$1.0 million related to AMEVIVE and \$12.1 million related to ZEVALIN. Of the \$160.8 million write-down related to AVONEX, \$149.6 million represented the increase to fair market value of inventory acquired at the Merger and \$11.2 million represented the historical manufacturing costs.

The AVONEX inventory that was written-down had been assessed as commercially viable and saleable and there were no known contingent issues at the acquisition date. This inventory was recorded at the estimated selling price less the costs to complete, costs of disposal and a reasonable distribution profit allowance. Our products are required to meet numerous stringent quality specifications that are agreed upon with the FDA at various times prior to and after approval. Based on quality testing performed subsequent to the Merger date, we became aware of certain lots of our pre-filled syringe formulation of AVONEX that previously had been approved for sale, but after additional testing no longer met the established quality specifications. Substantially all of the AVONEX inventory write-down was related to our pre-filled syringe formulation of AVONEX, in which certain lots had aggregate levels that exceeded the approved specifications. As a result of extensive discussions with the FDA, a new set of testing protocols were agreed to and certain lots were deemed unmarketable. Upon management's determination that the inventory was unmarketable, we wrote off the carrying value of the inventory in the fourth quarter of 2003 because the cost of the inventory would not be recoverable. In 2004, we developed a new pre-filled syringe formulation of AVONEX,

which was approved by the EMEA in November 2004 and the FDA in March 2005. We do not expect to experience interruption in the supply of AVONEX. However, we expect to write-down between \$6 million and \$8 million of the remaining supplies of the older formulation in the first quarter of 2005, related to the FDA approval.

Non-GAAP gross margin on product revenues, which includes inventory written-down to its net realizable value, was approximately 63% and (65)% in 2004 and 2003, respectively. The large fluctuation of gross margin on product revenues is due primarily to inventory acquired from Biogen, Inc. through the Merger. During 2003, we recorded the inventory that we acquired from Biogen, Inc. at its estimated fair value. The increase in fair market value was recognized as cost of product revenues when the acquired inventory was sold or written-down. During the first half of 2004, we sold or wrote-down all remaining AVONEX inventory acquired through the Merger. As a result, we expect that gross margins will increase during 2005. Excluding the increase in fair market value related to purchase accounting and the effects of write-downs of commercial inventory to net realizable value, gross margins of product revenues would have been 86% and 84% in 2004 and 2003, respectively. We expect that gross margins will fluctuate in the future based on changes in product mix, write-downs of excess or obsolete inventories and new product initiatives. Gross margin on royalty revenues were approximately 94% and 92% in 2004 and 2003, respectively. We expect that gross margin on royalty revenues were approximately 94% and 92% in 2004 and 2003, respectively. We expect that gross margin on changes in sales volumes for specific products from which we receive royalties.

# **Research and Development Expenses**

Research and development expenses totaled \$687.7 million in 2004 compared to \$233.3 million in 2003 and \$100.9 million in 2002. The increase in research and development expenses in 2004 over 2003 primarily related to a full year of the former Biogen, Inc. expenses in 2004 compared to the period from November 12, 2003 through December 31, 2003. The increase related to the former Biogen, Inc. was \$432.8 million and consisted primarily of \$74.3 million of expenses related to pre-clinical research activities, \$144.0 million of development research activities, including clinical trials, related to TYSABRI and AMEVIVE, \$84.2 million of biopharmaceutical operations expenses mainly attributable to manufacturing and supply chain functions, \$96.1 million of increased depreciation and infrastructure costs related to the expansion of our manufacturing and research facilities, and \$17.5 million for our joint development collaboration agreements.

The increase in research and development expenses in 2003 over 2002 primarily related to the acquisition of Biogen, Inc. which contributed \$63.6 million in research and development expenses for the period from November 13, 2003 through December 31, 2003, a \$20 million payment to Genentech in conjunction with entering into an amended and restated collaboration agreement in June 2003, a \$17.6 million increase in personnel expenses resulting from the expansion of our manufacturing and research functions, a \$12.8 million increase in contract research and manufacturing expenses primarily related to oncology development and a \$22.8 million increase in manufacturing expenses recorded as research and development.

Research and development expenses are expected to increase in 2005. We expect to continue incurring additional research and development expenses due to: work with clinical investigators and neurological experts related to our evaluations of TYSABRI resulting from the suspension of TYSABRI from the market in February 2005; preclinical and clinical testing of our various products under development; the expansion or addition of research and development programs and facilities; technology in-licensing; and regulatory-related expenses.

# Selling, General and Administrative Expenses

Selling, general and administrative expenses totaled \$578.5 million in 2004 compared to \$174.6 million in 2003 and \$88.0 million in 2002. The increase in selling, general and administrative expenses for the year ended December 31, 2004 primarily related to a full year of the former Biogen, Inc. expenses in 2004 compared to the period from November 12, 2003 through December 31, 2003. The increase related to the former Biogen, Inc. was \$410.1 million and consisted primarily of \$192.9 million of expenses related to neurology and dermatology sales and marketing activities, primarily due to the launch of TYSABRI, \$112.9 million of

expenses related to our international selling, general and administrative initiatives, \$64.2 million of expenses related to our finance and information technology infrastructure, and \$34.6 million of expenses related to the expansion of our global medical affairs Phase IV initiatives.

The increase in selling, general and administrative expenses for the year ended December 31, 2003 primarily related to the acquisition of Biogen, Inc. which contributed \$73.9 million in selling, general and administrative expenses for the period from November 13, 2003 through December 31, 2003, including \$10.2 million related to restructuring costs associated with the relocation of our European headquarters, a \$4.5 million increase in personnel expenses resulting from the expansion in sales and marketing expenses to support the commercialization of ZEVALIN, a \$2.5 million increase in legal fees to protect our intellectual property rights, a \$2.2 million increase in insurance expenses due to higher premiums, a \$1.3 million increase in travel expenses primarily related to integration efforts associated with the Merger with Biogen, Inc., and a \$1.3 million increase in information technology expenses with the remaining increase due to the expansion of our administrative function to support growth in manufacturing and research.

In 2004, we recorded charges of \$4.4 million related to severance obligations for certain employees affected by the Merger in our San Diego facilities. At December 31, 2004, we had a remaining accrual of approximately \$0.4 million related to the San Diego severance obligations. In 2004, we accrued approximately \$2.3 million of restructuring costs related to the relocation of our European headquarters. Our remaining liability related to these European headquarters restructuring costs was \$1.1 million at December 31, 2004. In 2003, we accrued \$2.1 million of restructuring costs related to severance obligations for certain employees affected by the Merger in our Cambridge facilities, and accrued an additional \$1.0 million of charges in 2004. At December 31, 2004, our remaining liability related to the Cambridge severance obligations was \$0.2 million.

We anticipate that total selling, general, and administrative expenses in 2005 will be higher than 2004 due to sales and marketing and other general and administrative expenses to primarily support AVONEX and TYSABRI, despite the voluntary suspension of the marketing and commercial distribution of TYSABRI in February 2005, and legal expenses related to lawsuits, investigations and other matters resulting from the suspension of TYSABRI.

#### Other Income (Expense), Net

	December 31,								
	2004		2003			2002			
			(In	thousands)					
Interest income	\$	57,225	\$	33,610	\$	34,528			
Interest expense		(18,898)		(15,182)		(16,073)			
Other expense		(17,650)		(29,383)		(809)			
Total other income (expense), net	\$	20,677	\$	(10,955)	\$	17,646			

Interest income totaled \$57.2 million in 2004 compared to \$33.6 million in 2003 and \$34.5 million in 2002. The increase in interest income in 2004 as compared to 2003 is primarily due to higher cash levels and higher yields on our marketable securities portfolio. The decrease in interest income in 2003 as compared to 2002 is primarily due to lower rates of return on marketable securities available-for-sale on our investments. Interest income levels that may be achieved in the future are, in part, dependent upon market conditions.

Interest expense totaled \$18.9 million in 2004 compared to \$15.2 million in 2003 and \$16.1 million in 2002. The increase in interest expense in 2004 compared to 2003 related to an updated estimation of the life of the senior notes due in 2032, which we expect holders will require us to repurchase in April 2005. As a result, amortization of the issuance costs related to the senior notes increased \$7.1 million. This was offset by lower noncash interest expense due to conversions throughout 2004 of our subordinated notes issued in February 1999, and higher capitalized interest expense in 2004. The decrease in interest expense in 2003 compared to 2002 is due to the capitalization of \$6.8 million in 2003 and \$0.4 million in 2002 of interest costs largely related to the development of a consolidated west coast research and development and administration campus

in San Diego, California and our large-scale manufacturing facility in Oceanside, California, offset by higher noncash interest expense from our senior notes.

Other expense as set forth in the preceding table included the following (table in thousands):

		December 31,				
	2004		2003	2002		
Impairments of marketable securities	\$ (18)	,482) \$	5 —	\$ —		
Foreign exchange remeasurement gains	5,	,353	1,319	_		
Loss on sale of marketable securities available-for-sale	(4	,090)		_		
Gain on investments in executive deferred compensation plan	1,	,029		—		
Donation to Biogen Idec Foundation			(10,000)			
Settlement of patent disputes		—	(20,668)	—		
Miscellaneous	(1	,460)	(34)	(809)		
Total other expense	\$ (17)	,650) \$	6 (29,383)	\$ (809)		

In 2004, we recorded charges totaling \$18.5 million to other expense when it was determined that certain marketable securities were impaired on an otherthan-temporary basis.

In October 2002, Biogen, Inc. established The Biogen Foundation, a private, U.S. based, non-profit philanthropic organization. In December 2002, Biogen, Inc. made a charitable contribution of \$15.0 million to fund the Biogen Foundation. As a result of the Merger, we changed the name of the foundation to The Biogen Idec Foundation and, in December 2003 contributed an additional \$10.0 million. The foundation is to operate exclusively for the benefit of charitable, educational and scientific purposes. Certain executive officers and other employees serve as directors and officers of the foundation. We classify charitable contributions to other income (expense).

In December 2003, we recorded charges of \$2.5 million and \$18.2 million related to the final settlement of patent infringement disputes with Apoxis S.A. and Corixa Corporation, respectively. These payments were charged to other expense in the fourth quarter of 2003.

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

In the fourth quarter of 2003, we incurred a charge of \$823.0 million related to the write-off of acquired in-process research and development, or IPR&D, related to the Merger. The amount expensed as IPR&D represents the estimated fair value of purchased in-process technology for projects that, as of the acquisition date, had not reached technological feasibility and had no alternative future use. The estimated fair value of these projects was determined based on the use of a discounted cash flow model. For each project, the estimated after-tax cash flows were probability weighted to take into account the stage of completion and the risks surrounding the successful development and commercialization. These cash flows were then discounted to present value using a discount rate of 16%.

As of December 31, 2004, we estimated future research and development expenses of approximately \$65 million, \$34 million, and \$177 million, respectively, would be incurred to complete the purchased neurology, dermatology, and rheumatology research projects. Since the date of the Merger, November 12, 2003, we have discontinued certain clinical trials. Additionally, in connection with the voluntary suspension of marketing and commercial distribution of TYSABRI in February 2005, we suspended dosing in clinical trials of TYSABRI in MS, Crohn's disease and RA. Estimates of expenses are net of any research and development expenses that were shared under collaborations with corporate partners. The projects, which were in various stages of development, from preclinical through Phase III clinical trials, are, unless they have been discontinued, expected to reach completion at various dates ranging from 2005 through 2009.

The major risks and uncertainties associated with the timely and successful completion of these projects are that we will not be able to confirm the safety and efficacy of the technology with data from clinical trials and that we will not be able to obtain necessary regulatory approvals. No assurance can be given that the

underlying assumptions used to forecast the cash flows or the timely and successful completion of such projects will materialize, as estimated. For these reasons, among others, actual results may vary significantly from estimated results.

# **Amortization of Intangible Assets**

In 2004 and 2003, we recorded amortization expense of \$347.7 million and \$33.2 million, respectively, related to the intangible assets of \$3.7 billion acquired in the Merger with Biogen, Inc. Intangible assets consist of \$3.0 billion in core technology, \$578.0 million in patents and \$64.0 million in trademarks. Amortization of the core technology is provided over the estimated useful lives of the technology ranging from 15 to 20 years, based on the greater of straight-line basis or economic consumption each period. Amortization of the out-licensed patents for which we receive royalties is provided over the remaining lives of the patents of 11 years. Trademarks have an indefinite life and, as such, are not amortized.

We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In the third quarter of 2004, management determined that certain clinical trials would not continue which indicated that the carrying value of certain core technology intangible assets related to AMEVIVE may not be recoverable. As a result, in the third quarter of 2004, we recorded an impairment charge of approximately \$27.8 million to amortization of acquired intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AMEVIVE. If future events or circumstances indicate that the carrying value of these assets may not be recoverable, we may be required to record additional charges to our results of operations.

#### **Income Tax Provision**

Our effective tax rate in 2004 was approximately 61% compared to 1% in 2003 and 36% in 2002. Our effective tax rate for 2004 varied substantially from the U.S. federal statutory rate and prior years primarily due to the IPR&D write-off in 2003, the acquisition-related intangible amortization and inventory fair value adjustments arising from purchase accounting related to foreign jurisdictions offset, in part, by the effect of lower income tax rates (less than the 35% U.S. statutory corporate rate) in certain non-U.S. jurisdictions in which we operate and tax credits allowed for research and experimentation expenditures in the U.S. Excluding the effect of purchase accounting adjustments, our adjusted 2004 effective tax rate would have been approximately 32%. Our effective tax rate for 2003 varied substantially from the U.S. federal statutory rate and prior years primarily due to the pre-tax loss resulting from the write-off of nondeductible IPR&D and other costs in connection with the Merger with Biogen, Inc. which were not deductible for income tax purposes. Excluding the effect of our write-off of IPR&D, our 2003 effective tax rate would have been approximately 35%. Our effective tax rate for 2002 was higher than the federal statutory rate primarily because of state taxes. We have tax credit carryforwards for federal and state income tax purposes available to offset future taxable income. The utilization of our tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate that this annual limitation will result only in a slight deferral in the utilization of our net tax credits. During 2002, we decreased our valuation allowance for deferred tax assets to zero. Each reporting period we evaluate the realizability of our deferred tax assets based upon the level of historical taxable income and income tax liabilities and projections for future taxable income over the periods that our deferred tax assets are either tax deductible or to which our tax credits may be carried. Based on the evaluation performed as of December 31, 2004, we believe it is more likely than not that we will realize the entire benefits of our deferred tax assets. In the event that actual results differ from our estimates of future taxable income or we adjust our estimates in future periods, we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

#### **Financial Condition**

We have financed our operating and capital expenditures principally through profits and other revenues from our joint business arrangement with Genentech related to the sale of RITUXAN, sales of AVONEX, AMEVIVE, and ZEVALIN, royalty revenues, corporate partner revenues, debt financing transactions and

interest income. We expect to finance our current and planned operating requirements principally through cash on hand, which includes the proceeds from the April and May 2002 issuance of our senior notes, funds from our joint business arrangement with Genentech related to the sale of RITUXAN, commercial sales of AVONEX, AMEVIVE and ZEVALIN, royalties and existing collaborative agreements and contracts, and sales of TYSABRI if we are able to relaunch this product which is dependent on the results of our evaluation of the risk of PML and discussions with regulatory authorities. We believe that these funds will be sufficient to meet our operating requirements for the foreseeable future. However, we may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources. Our working capital and capital requirements will depend upon numerous factors, including: the continued commercial success of AVONEX and RITUXAN and, to a lesser extent, AMEVIVE and ZEVALIN; the future commercial availability of TYSABRI if we are able to re-launch this product; the timing and expense of obtaining regulatory approvals for products in development; the cost of launching new products, and the success of those products; funding and timing of payments related to several significant capital projects, the progress of our preclinical and clinical testing; fluctuating or increasing manufacturing requirements and research and development programs; levels of resources that we need to devote to the development of manufacturing, sales and marketing capabilities, including resources devoted to the marketing of AVONEX, RITUXAN, AMEVIVE, and ZEVALIN and future products, as well as the future marketing and manufacturing of TYSABRI if we are able to re-launch this product; technological advances; status of products being developed by competitors; our ability to establish collaborative arrangements with other organizations; and working c

Until required for operations, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, foreign and U.S. government instruments and other readily marketable debt instruments in accordance with our investment policy.

Cash, cash equivalents and marketable securities available-for-sale decreased to \$2.2 billion at December 31, 2004 from \$2.3 billion at December 31, 2003. Our operating activities generated \$728.0 million of cash for the year ended December 31, 2004 as compared to \$170.0 million for the year ended December 31, 2003. Net cash from operating activities includes our net income of \$25.1 million, noncash charges of \$439.4 million for depreciation and amortization, \$289.5 million of impact on sales of stepped-up inventory, and \$144.6 million of tax benefits related to stock options offset by \$135.6 million for deferred income taxes. Our investing activities utilized \$382.4 million of cash in 2004 compared to \$256.4 million in 2003, and included \$361.0 million to fund construction projects and purchase real property and equipment, including our research and development and administration campus in San Diego and manufacturing facility in Oceanside. Cash generated from financing activities included \$273.5 million from the issuance of common and treasury stock under employee stock option and stock purchase plans offset by \$734.4 million used for the repurchase of shares under our repurchase programs in 2004.

In April and May 2002, we raised through the issuance of our senior notes, approximately \$696 million, net of underwriting commissions and expenses of \$18.4 million. Simultaneously with the issuance of the senior notes, we used a portion of the proceeds to fund the repurchase of \$135.0 million of our outstanding common stock. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. We will pay contingent cash interest to the holders of these senior notes during any nine-month period commencing on or after April 30, 2007 if the average market price of the senior notes for a five-trading-day measurement period preceding such nine-month period equals 120% or more of the sum of the issue price and accrued original issue discount for such senior note. The contingent interest payable per senior note with respect of any quarterly period within such nine-month period where contingent interest is determined to be payable will equal the greater of (1) the amount of regular cash dividends paid by us per share on our common stock during that quarterly period multiplied by the then applicable conversion rate or (2) 0.0625% of the average market price of a senior note for the five-trading-day measurement period preceding such nine-month period, provided that if we do not pay regular cash dividends during a semiannual period, we will pay contingent

interest semiannually at a rate of 0.125% of the average market price of a senior note for the five-trading-day measurement period immediately preceding such nine-month period.

Upon maturity, the senior notes will have an aggregate principal face value of \$1.2 billion. Each \$1,000 aggregate principal face value senior note is convertible at the holder's option at any time through maturity into 7.1881 shares of our common stock at an initial conversion price of \$82.49, resulting in total potential common shares to be issued upon conversion of 8.7 million shares. In addition, holders of the senior notes may require us to purchase all or a portion of the senior notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable in cash. We expect that on April 29, 2005, holders of the senior notes will require us to purchase all or a substantial portion of the notes which could result in a cash outflow of up to approximately \$809 million. This outflow includes payment of the aggregate purchase price of the notes of approximately \$753 million plus the payment of tax for which deferred tax liabilities have been previously established related to additional deductible interest expense. As a result, these senior notes are included in notes payable under current liabilities in our consolidated balance sheets. We would be required to liquidate a portion of our marketable securities portfolio to purchase the notes. In addition, if a change in control in our company occurs on or before April 29, 2007, holders may require us to purchase all or a portion of their senior notes for cash. We have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the senior notes for cash at any time on or after April 29, 2007.

In February 1999, we raised through the issuance of our subordinated notes, approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The subordinated notes are zero coupon and were priced with a yield to maturity of 5.5% annually. Upon maturity, the subordinated notes will have an aggregate principal face value of \$345.0 million. As of December 31, 2004, our remaining indebtedness under the subordinated notes was approximately \$219.2 million at maturity, due to conversion of subordinated notes into common stock. Each \$1,000 aggregate principal face value subordinated notes may require us to purchase the subordinated notes of our common stock at an initial conversion price of \$8.36 per share. The holders of the subordinated notes may require us to purchase the subordinated notes on February 16, 2009 or 2014 at a price equal to the issue price plus accrued original issue discount to the date of purchase with us having the option to repay the subordinated notes plus accrued original issue discount to the date of purchase with us have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the subordinated notes for cash at any time. During 2004, holders of subordinated notes with a face value of approximately \$125.7 million elected to convert their subordinated notes to approximately 5.1 million shares of our common stock. To date, in the first quarter of 2005, holders of subordinated notes with a face value of approximately 0.7 million shares of our common stock.

In August 2004, we restarted construction of our large-scale biologic manufacturing facility in Hillerod, Denmark to be used to manufacture TYSABRI and other products in our pipeline. The cost of the project is estimated to be \$372.0 million. As of December 31, 2004, we had committed approximately \$129.0 million to the project, of which \$17.3 million has been paid. We expect this facility to be substantially complete in 2007 and available for commercial production in 2008. As of March 31, 2005, we determined that we would no longer proceed with the fill-finish component of our large-scale biologic manufacturing facility in Hillerod. As a result, we expect to write-off in the first quarter of 2005 to research and development expense approximately \$6.5 million of engineering costs which had previously been capitalized.

In September 2000, we purchased a 60-acre site in Oceanside, California for approximately \$18.9 million in cash. In December 2002, we purchased an additional 27 acres of land at the Oceanside site for \$7.9 million. We are building a large-scale manufacturing facility at this location, which we anticipate using to manufacture TYSABRI and other commercial products. We have completed construction of this facility and obtained the certificate of occupancy in the fourth quarter of 2004. Commissioning and validation is expected to continue through 2005. We expect the facility to be licensed in 2006. Including start-up costs, total costs of this facility upon completion are estimated to be \$480.0 million. As of December 31, 2004, we have committed

approximately \$413.0 million to the construction of this large-scale manufacturing facility, of which \$388.4 million has been paid.

The timing of the anticipated completion, licensing and use of the Oceanside facility and the Hillerod facility is dependent upon the commercial availability and potential market acceptance of TYSABRI. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth." If TYSABRI is permanently withdrawn from the market, we would need to evaluate our long-term plans for these facilities. If we are able to reintroduce TYSABRI to the market, we would need to evaluate our requirements for TYSABRI inventory and additional manufacturing capacity in light of the approved label and our judgment of the potential U.S. market acceptance of TYSABRI in MS, the probability of obtaining marketing approval of TYSABRI in MS in the EU and other jurisdictions, and the probability of obtaining marketing approval of TYSABRI in additional indications in the U.S., EU and other jurisdictions.

In June 2004, we commenced construction to add additional research facilities and administrative space to one of our existing buildings in Cambridge, Massachusetts. The cost of the project is estimated to be \$65.0 million. As of December 31, 2004, we had committed approximately \$29.0 million to the project, of which \$18.5 million had been paid. The project is expected to be substantially complete in late 2005.

In September 2001, we purchased approximately 42.6 acres of land in San Diego, California for approximately \$31.7 million in cash where we are building a consolidated research and development and administration campus. We substantially completed construction and took occupancy in the building in the fourth quarter of 2004. The estimated total cost of the project is \$169.0 million. As of December 31, 2004, we have committed approximately \$168.0 million to the construction of this campus, of which \$167.0 million has been paid.

In February 2004, our Board of Directors authorized the repurchase of up to 12.0 million shares of our common stock. During 2004, we repurchased all 12.0 million shares at a cost of \$698.4 million, completing this program. The repurchased stock provided us with treasury shares to be used for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans.

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program will expire no later than October 4, 2006. During the fourth quarter of 2004, we repurchased 0.6 million shares at a cost of \$36.0 million. Approximately 19.4 million shares remain authorized for repurchase under this program at December 31, 2004. To date, in the first quarter of 2005, we repurchased approximately 3.5 million shares under this program, at a cost of \$168.5 million.

In May 1999, we entered into an arrangement with MDS (Canada) Inc., MDS Nordion Division, successor to MDS Nordion, Inc., or MDS (Canada), under which MDS (Canada) agreed to supply us yttrium-90, a radioisotope used in connection with administering ZEVALIN. MDS (Canada) initially supplied product for use in the ZEVALIN clinical trials. In anticipation of commercial launch of ZEVALIN, we subsequently determined that additional commercial production capacity for yttrium-90 would be necessary. To obtain a commitment from MDS (Canada) that sufficient commercial supply would be available, we agreed to minimum purchase commitments of \$55.0 million, and to make periodic cash payments totaling \$25.0 million into an escrow account. The supply agreement was amended in November 2001 to give effect to these mutual commitments.

In December 2003, in light of the reduced expectations for ZEVALIN sales levels, we agreed to release the \$25.0 million of escrowed funds to MDS (Canada), and MDS (Canada) agreed to eliminate the minimum purchase commitments from the supply arrangement. MDS (Canada)'s obligation to supply yttrium-90 remains in effect. We are amortizing the prepayment over the economic life of the agreement.

In connection with the Merger, we assumed Biogen, Inc.'s Retirement Plan, a tax-qualified defined benefit pension plan. Prior to November 13, 2003, we did not have a pension plan. Prior to the Merger, the Retirement Plan covered substantially all of Biogen, Inc.'s regular U.S. employees and provided compensation

credits and interest credits to participants' Retirement Plan accounts using a cash balance method. We also assumed Biogen, Inc.'s unfunded Supplemental Executive Retirement Plan, or SERP, which covered a select group of highly compensated U.S. employees. The plans are noncontributory. The Retirement Plan's benefit formula was based on employee earnings and age. The SERP provided benefits for covered executives in excess of those permitted under the tax-qualified Retirement Plan. Biogen, Inc.'s funding policy for the plans has been to contribute amounts deductible for federal income tax purposes. Funds contributed to the plans have been invested in fixed income and equity securities. At October 31, 2003, Biogen, Inc. ceased allowing new participants into the plans. Effective December 31, 2003, Biogen, Inc. amended the plans so that no further benefits would accrue to participants.

We credited participants' cash balance accounts under the Retirement Plan for compensation and interest earned through December 31, 2003. After that date, no further compensation credits will be made, but interest credits will be made until the Retirement Plan benefits have been distributed to participants.

We credited participants' accounts under the SERP for compensation and interest earned through December 31, 2003. No further compensation credits will be made, but interest credits will be made until the SERP is terminated.

In connection with the termination of the Retirement Plan, we requested an Internal Revenue Service, or IRS, ruling that the Plan's termination did not adversely affect its tax-qualified status. During 2004, our management decided to accelerate the payment and to pay out participants' benefits as soon as administratively possible. In December 2004, we began distributing to employees their respective Retirement Plan benefits. Participants had the following options with respect to the value of their Plan distribution: (a) to receive an immediate lump sum payment which may be rolled over into the Biogen Idec 401(k) Savings Plan (401(k) plan) or other designated qualified plan, or (b) to receive an annuity that would begin either immediately or at a deferred date.

During 2004, we incurred charges of approximately \$2.1 million related to transition benefits associated with the termination of the plans, and plan curtailment costs and additional premium costs related to the annuity transfer of approximately \$3.0 million, which are included in our results of operations for 2004. At December 31, 2004, we had a liability of \$14.1 million related to these plans, including \$7.7 million related to transition benefits associated with the plan terminations. In January 2005, we funded approximately \$1.2 million to cover the remaining lump sum benefit payments under the Retirement Plan.

#### **Use of Non-GAAP Financial Measures**

We use non-GAAP gross margin of product sales measure in the "Cost of Product Revenues" section and non-GAAP effective tax rate measures in the "Income Tax Provision" section. These are non-GAAP financial measures. The most directly comparable GAAP financial measures of each non-GAAP financial measure as well as the reconciliation between each non-GAAP financial measure and the GAAP financial measure are presented in the discussions of the non-GAAP financial measures. We believe that the non-GAAP financial measures provide useful information to investors. In particular, we believe that the non-GAAP financial measures allow investors to monitor and evaluate our ongoing operating results and trends and gain a better understanding of our past performance as well as period-to-period performance.

# **Contractual Obligations and Off-Balance Sheet Arrangements**

The following summarizes our contractual obligations (excluding contingent milestone payments totaling \$332.5 million under our collaboration and license agreements, and construction commitments disclosed



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separately under "Financial Condition") at December 31, 2004, and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period									
			Less than 1 Year	1-3 Years (In thousands)		rs Years		_	After 5 Years	
Non-cancelable operating leases	\$	133,626	\$	28,112	\$	40,123	\$	27,814	\$	37,577
Other long-term obligations		46,862		25,696		16,462		4,704		_
Total contractual cash obligations	\$	180,488	\$	53,808	\$	56,585	\$	32,518	\$	37,577

All material intercompany balances and transactions have been eliminated. We do not have any other relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

#### **Collaboration and License Agreements**

In connection with our research and development efforts, we have entered into various collaboration arrangements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by the parties. Terms of the various license agreements may require us to make milestone payments upon the achievement of certain product development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration.

In October 2004, we entered into a development and license agreement with ImmunoGen, Inc., or ImmunoGen, for a worldwide, exclusive license to develop and commercialize anticancer therapeutics that comprise an antibody that we have developed to an undisclosed tumor cell target and ImmunoGen's proprietary Tumor-Activated Prodrug (TAP) technology. As part of the agreement, we paid ImmunoGen an upfront fee of \$1.0 million, which was recorded as a research and development expense. Upon the achievement of certain predetermined milestones, we would be required to pay ImmunoGen up to a total of \$42.0 million plus royalties over the life of the agreement. ImmunoGen will also receive compensation from us for product development research done on its behalf, as well as for the production of preclinical and initial clinical materials.

In August 2004, we entered into a collaborative agreement with Sunesis Pharmaceuticals, Inc., or Sunesis, to discover and develop small molecule cancer therapeutics targeting primarily kinases. Under the agreement, we acquired exclusive licenses to develop and commercialize certain compounds resulting from the collaboration. Upon signing the agreement, we paid Sunesis a non-refundable upfront license fee of \$7.0 million, which was recorded in research and development expenses in the third quarter of 2004. Under the terms of this agreement, we purchased approximately 2.9 million shares of preferred stock of Sunesis for \$14.0 million, the fair value of the shares. In December 2002, Biogen, Inc. entered into a collaboration agreement with Sunesis related to the discovery and development of oral therapeutics for the treatment of inflammatory and autoimmune diseases. Under the terms of this agreement, we purchased 1.25 million shares of preferred stock of Sunesis for \$6.0 million, the fair value of the shares. We acquired certain exclusive licenses to develop and commercialize certain compounds resulting from the collaboration. Our investments in Sunesis are included in investments and other assets. We account for our investments in Sunesis using the cost method of accounting, subject to periodic review of impairment. Under the terms of the December 2002 agreement, we will pay Sunesis a quarterly license maintenance fee of \$357,500 during the period January 1, 2005 through July 1, 2005. Additionally, we have a Credit Facility Agreement with Sunesis under which we are obligated to loan Sunesis up to \$4.0 million. At December 31, 2004, there is \$3.2 million of borrowings outstanding. We have committed to paying Sunesis additional amounts upon the completion of certain future research milestones and first and second indication development milestones. If all the milestones were to be achieved in both agreements, we would be required to pay up to an additional \$121.0 million over the life of the agreements, excluding roy



In July 2004, we and Elan entered into a patent license agreement with Genentech for a non-exclusive license to certain Genentech patents related to the manufacture of licensed products, including TYSABRI. As a part of the agreement, we and Elan paid a \$1.0 million license grant fee upon execution of the agreement, which was charged to research and development expenses, and will pay an additional \$1.0 million on the first anniversary of the agreement. In addition, we and Elan each have to pay a development milestone fee of \$2.5 million related to the approval of TYSABRI by the FDA in November 2004, half of which was paid in 2004 upon approval of TYSABRI and half of which is payable on the anniversary of such approval. At December 31, 2004, our \$2.5 million total milestone fee is included in intangible assets, net on the consolidated balance sheets and is being amortized to cost of product revenues over the life of the patent. The agreement also requires that we or Elan pay royalties on net sales of TYSABRI and other licensed products.

In June 2004, we entered into a collaborative research and development agreement with Vernalis plc, or Vernalis, aimed at advancing research into Vernalis' adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders. Under the agreement, we receive exclusive worldwide rights to develop and commercialize Vernalis' lead compound, V2006. We paid Vernalis an initial license fee of \$10.0 million in July 2004, which was recorded in research and development expenses in the second quarter of 2004. Terms of the collaborative agreement may require us to make milestone payments upon the achievement of certain program objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. We made an immediate investment of \$5.5 million through subscription for approximately 6.2 million new Vernalis common shares, representing 4.19 percent of Vernalis' post-financing issued share capital, and committed to purchase an additional \$4.0 million in the event of future Vernalis financing. Our investment in Vernalis is included in investments and other assets. We account for our investment in Vernalis using the cost method of accounting, subject to periodic review of impairment. Excluding royalties, total potential payments to Vernalis could exceed \$100.0 million.

In June 2004, we entered into a license agreement with BioWa, Inc., or BioWa, for a worldwide, non-exclusive license for research purposes and a worldwide, exclusive license for development and commercialization purposes to certain BioWa intellectual property rights related to monoclonal antibodies. As part of the agreement, we have committed to paying BioWa certain amounts upon the achievement of certain research and clinical milestones. If all the milestones were to be achieved, we would be required to pay BioWa a total of \$18.8 million plus royalties over the life of the agreement.

In May 2004, we entered into a limited partnership agreement as a limited partner with MPM Bioventures III GP, LP, to create MPM Bioventures Strategic Fund, LP, or the Strategic Fund. The purpose of the Strategic Fund is to make, manage, and supervise investments in biotechnology companies with novel products or technologies that fit strategically with Biogen Idec. The Strategic Fund takes only minority positions in the equity of its investments, and does not seek to engage in day-to-day management of the entities. We have committed \$65.0 million to the Strategic Fund over a three-year period. During 2004, we contributed \$5.5 million to the Strategic Fund.

In April 2004, we became a limited partner in MPM Bioventures III-QP, LP, or the LP, a limited partnership that invests in entities that are engaged in the research, development, manufacture, marketing and/or sale of novel biological products or technologies. We have committed to contribute \$4.0 million to the limited partnership. Through December 31, 2004, we have contributed \$1.8 million into the LP, which is included in investments and other assets in our consolidated balance sheets.

In September 2003, Biogen, Inc. entered into a license agreement with Fumapharm AG, or Fumapharm, under which Biogen, Inc. obtained exclusive rights to develop and market a second-generation fumarate derivative with an immunomodulatory mechanism of action, which is currently in clinical trials in Europe. Under the terms of this agreement, we have an exclusive worldwide marketing and distribution license for psoriasis, and a production and exclusive marketing and distribution license for the entire world for MS. During 2004, we made payments totaling \$4.2 million to Fumapharm for the achievement of certain milestones, which were expensed to research and development expense. We have committed to paying Fumapharm additional amounts upon the completion of certain future research milestones and first and

second indication development milestones. If all the milestones were to be achieved, we would be required to pay up to an additional 20.0 million Swiss francs plus royalties over the remaining life of the agreement.

In August 2003, Biogen, Inc. entered into a collaboration agreement with Vetter Pharma-Fertigung GmbH & Co. KG, or Vetter, for the fill-finish of our products. Under the terms of this agreement, we made a partial advance payment to Vetter of 35.0 million Euros in return for reserving certain capacity at Vetter's fill-finish facility. As of December 31, 2004, we have made payments totaling \$22.7 million to Vetter for the achievement of certain milestones achieved under the terms of our supply agreement for reserving certain capacity at Vetter's fill-finish facility. These payments are recorded in investments and other assets on our consolidated balance sheets. The asset will be amortized to cost of product revenues over the units produced upon delivery to Biogen Idec. We have total potential milestone payments of approximately 16.0 million euros remaining as part of the agreement.

In September 2001, we entered into a collaborative development agreement with Mitsubishi Pharma to support clinical development of anti-CD80 (anti-B7.1) antibody products developed using our Primatized® antibody technology. Under the terms of an existing license agreement with Mitsubishi Pharma, entered into in November 1993, Mitsubishi Pharma had an exclusive license in Asia to develop and commercialize anti-CD80 (anti-B7.1) antibody products. These agreements were terminated in December 2003. As a result of the termination of these agreements, we have no continuing financial obligations under these agreements. During 2003 and 2002, we recognized revenues from these agreements of \$1.5 million and \$1.4 million, respectively, which are included in corporate partner revenues. Under these agreements, amounts earned by us and recognized as revenue for contract research and development approximated the research and development expenses incurred under the related agreement.

In August 2000, Biogen, Inc. entered into a development and marketing collaboration agreement with Elan to collaborate in the development, manufacture and commercialization of TYSABRI. In November 2004, we received approval by the FDA to market TYSABRI as a treatment for relapsing forms of MS to reduce frequency of clinical relapses. We are also developing TYSABRI as a potential treatment for Crohn's disease and RA. In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI and suspended dosing in clinical trials of TYSABRI. See "Overview" for a description of the suspension and related events. Under the terms of this agreement, we share costs with Elan for on-going development activities. As of December 31, 2004, Elan owed us \$34.4 million, representing commercialization and development expenses that we incurred, which is included in other current assets on our consolidated balance sheets. We received the entire \$34.4 million from Elan in the first quarter of 2005 related to the receivable.

In June 1999, we entered into a collaboration and license agreement with Schering AG, or Schering, aimed at the development and commercialization of ZEVALIN. Under the terms of the agreement, we may receive milestone and research and development support payments totaling up to \$47.5 million, subject to the attainment of product development objectives. Schering received exclusive marketing and distribution rights to ZEVALIN outside the U.S., and we will receive royalties on product sales by Schering. Under the terms of a separate supply agreement, we are obligated to meet Schering's clinical and commercial requirements for ZEVALIN. Schering may terminate these agreements for any reason. During 2004, 2003 and 2002, we recognized revenues from our agreements with Schering of \$10.0 million, \$0.2 million and \$0.3 million, respectively, which are included in corporate partner revenues. In the first quarter of 2004, we received a \$10.0 million payment from Schering for the EMEA grant of marketing approval of ZEVALIN in the EU. The payment represented, in part, a milestone payment to compensate us for preparing, generating, and collecting data that was critical to the EMEA marketing approval process, and to which we have no continuing involvement. Under the above agreement, amounts earned by us and recognized as revenue for contract research and development approximate the research and development expenses incurred under the related agreement.

In December 1994, we entered into a collaborative development agreement and a license agreement with Seikagaku, aimed at the development and commercialization of an anti-CD23 antibody using Primatized antibody technology. During 2003 and 2002, we recognized revenues from our agreement with Seikagaku of

\$0.6 million and \$1.6 million, respectively, which are included in corporate partner revenues. Although this agreement was terminated effective January 17, 2004, we have certain continuing obligations under the agreement that we expect to fulfill in the first half of 2005 and for which we would receive revenue from Seikagaku. Under the above agreement, amounts earned by us and recognized as revenue for contract research and development approximate the research and development expenses incurred under the related agreement.

As part of previous agreements that Biogen, Inc. had with Targeted Genetics Corporation, or Targeted, for gene therapy research and development, we own approximately 12.1 million shares of Targeted's common stock with a fair value of \$18.8 million, which is included in investments and other assets in our consolidated balance sheets. In the third quarter of 2004, we recognized a \$12.7 million charge for the impairment of our Targeted investment that was determined to be other than temporary. We have no remaining commitments or obligations with Targeted.

#### Legal Matters

On March 2, 2005, we, along with William H. Rastetter, our Executive Chairman, and James C. Mullen, our Chief Executive Officer, were named as defendants in a purported class action lawsuit, captioned Brown v. Biogen Idec Inc., et al., filed in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. The plaintiff alleges that the defendants made materially false and misleading statements regarding potentially serious side effects of TYSABRI in order to gain accelerated approval from the FDA for the product's distribution and sale. The plaintiff alleges that these materially false and misleading statements harmed the purported class by artificially inflating our stock price during the purported class period and that company insiders benefited personally from the inflated price by selling our stock. The plaintiff seeks unspecified damages, as well as interest, cost and attorneys' fees. A substantially similar action, captioned Grill v. Biogen Idec Inc., et al., was filed on March 10, 2005 in the same court by another purported class representative. We believe that the actions are without merit and intend to contest them vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss.

On March 4, 2005, a purported shareholder derivative action, captioned Halpern v. Rastetter, et al., was filed in the Court of Chancery for the State of Delaware, in New Castle County, on our behalf of Biogen Idec Inc., against us as nominal defendant, our Board of Directors and our former general counsel. The plaintiff derivatively claims breaches of fiduciary duty by the Board of Directors for inadequate oversight of our policies, practices, controls and assets, and for recklessly awarding executive bonuses despite alleged awareness of potentially serious side effects of TYSABRI and the potential for related harm to our financial position. The plaintiff also derivatively claims that our Executive Chairman, former general counsel and a director misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI, and alleges that our Board of Directors did not ensure that appropriate policies were in place regarding the control of confidential information and personal trading in our securities by officers and directors. The plaintiff seeks unspecified damages, profits, the return of all bonuses paid by us, costs and attorneys' fees. A substantially similar action, captioned Golaine v. Rastetter, et al., was filed on March 14, 2005 in the same court. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. As required by applicable law, we and our Board of Directors are considering the derivative claims in the complaints and will respond in a time and manner consistent with applicable Delaware statutory and common law. The purported derivative actions do not seek affirmative relief from the company.

On March 9, 2005, two additional purported shareholder derivative actions, captioned Carmona v. Mullen, et al. and Fink v. Mullen, et al., were brought in the Superior Court of the State of California, County of San Diego, on our behalf, against us as nominal defendant, our Board of Directors and our chief financial officer. The plaintiffs derivatively claim breach of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment against all defendants. The plaintiffs also derivatively claim insider selling in violation of California Corporations Code § 25402 and breach of fiduciary duty and

misappropriation of information against certain defendants who sold our securities during the period of February 18, 2004 to the date of the complaints. The plaintiffs allege that the defendants caused and/or allowed us to issue, and conspired, aided and abetted and acted in concert in concealing that we were issuing, false and misleading press releases about the safety of TYSABRI and its financial prospects which resulted in legal claims being asserted against us, irreparable harm to our corporate image, depression of our stock price and impairment of our ability to raise capital. The plaintiffs also allege that certain defendants sold personally owned shares of our stock while in possession of material, undisclosed, adverse information. The plaintiffs seek unspecified damages, treble damages for the purported insider trading in violation of California Corporate Code § 25402, equitable relief including restriction of the defendants' trading proceeds or other assets, restitution, disgorgement and costs, including attorneys' fees and expenses. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. As required by applicable law, we and our Board of Directors are considering the derivative claims in the complaints and will respond in a time and manner consistent with applicable statutory and common law. The purported derivative actions do not seek affirmative relief from the company.

Our Board of Directors has received letters, dated March 1 and 15, 2005, respectively, on behalf of purported owners of our securities purportedly constituting demands under Delaware law. A supplement to the March 1 letter was received on March 2, 2005. The letters generally allege that certain of our officers and directors breached their fiduciary duty to us by selling personally held shares our securities while in possession of material, non-public information about potential serious side effects of TYSABRI. The letters generally request that our Board of Directors take action on our behalf to recover compensation and profits from the officers and directors, consider enhanced corporate governance controls related to the sales of securities by insiders, and pursue other such equitable relief, damages, and other remedies as may be appropriate. As required by applicable law, our Board of Directors is currently considering the letters and will respond in a time and manner consistent with Delaware law.

We are providing information to the SEC regarding the SEC's informal inquiry into the suspension of marketing and commercial distribution of TYSABRI and trading in our securities by certain of our directors, officers and employees.

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York, or Columbia, in the U.S. District Court for the District of Massachusetts, contending that we no longer have any obligation to pay royalties to Columbia on sales of our products under a 1993 license agreement between us and Columbia related to U.S. Patent Nos. 4,399,216, 4,634,665, and 5,179,017, also referred to as the Original Patents, or under a newly issued patent, U.S. Patent No. 6,455,275, also referred to as the '275 patent (the 2003 action). Based, in part, on the court's subsequent finding that we had made a strong showing that we might prevail in proving the '275 patent is invalid under the doctrine of non-statutory double patenting, Columbia has since covenanted not to sue Biogen Idec MA, Inc. on any claim of the '275 patent and any claim that is the same or substantially the same as the claims of the '275 patent if such claim(s) emerge from the reexamination or reissue proceedings currently pending before the U.S. Patent and Trademark Office, or USPTO, with respect to the '275 patent. As a result of Columbia's covenant not to sue, and Columbia's assertion that Biogen Idec MA, Inc. is a licensee in good standing, the court issued an order on November 5, 2004, in which it dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction. At this time, we are unable to predict whether any claims will issue from the USPTO on the reexamination or reissue proceedings concerning the '275 patent, or whether, if any claims do issue, such claims will pose a risk of infringement with respect to our activities.

On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation, filed suit against Columbia in the U.S. District Court for the District of Massachusetts (the 2004 action). In the 2004 action we reasserted some of the contentions made in our complaint in the action filed in 2003 action. For example, that we are seeking a declaratory judgment that we have no obligation to pay any further royalties under the license agreement because the Original Patents have expired and the '275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based on the '275 patent or on any pending continuations, continuations-in-part, or divisional applications of

the Original Patents. We have also asserted claims for relief based on abuse of process, breach of contract, violation of Massachusetts laws concerning unfair and deceptive trade practices, prosecution laches and inequitable conduct. To date, Columbia has refused to extend its covenant not to sue on the '275 patent to Biogen Idec Inc. In the event that we are unsuccessful in the present litigation and Columbia asserts a claim for infringement against Biogen Idec Inc., we may be liable for damages suffered by Columbia with respect to unpaid royalties and such other relief as Columbia may seek and be granted by the Court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, GlaxoSmithKline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of infringement claims are based on allegations that we "provided instructions and/or recommendations on a proper immunization schedule for vaccines" to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. Under our 1988 license agreement with GlaxoSmithKline, GlaxoSmithKline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that GlaxoSmithKline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in certain cases, Biogen Idec Inc., was named as a defendant in lawsuits filed by the County of Suffolk, New York, the County of Westchester, New York, the County of Rockland, New York, the County of Nassau, New York, the County of Chenango, New York, the County of Erie, New York, the City of New York, and the County of Chautauqua, New York. All of the cases are pending in the U.S. District Court for the District of Massachusetts, with the exception of the Onondaga, Chenango and Chautauqua lawsuits, which are expected to be transferred to the U.S. District Court for the District of Massachusetts, and the Erie lawsuit, which is pending in the Supreme Court of the State of New York for the County of Erie. The complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs; marketed and promoted the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs,; and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaints allege violations of New York state law and advance common law claims for unfair trade practices, fraud, and unjust enrichment. In addition, all of the complaints, with the exception of the County of Erie, allege that the defendants failed to accurately report the "best price" on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services, and excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the "best price." The Suffolk, Westchester, Rockland, and Nassau County complaints also claim that Biogen violated the Racketeering Influence and Corrupt Organizations Act (RICO) 18 U.S.C. § 1962(c). In September 2003, Biogen joined other named defendants in filing a motion to dismiss the Suffolk County complaint. Biogen also separately filed a motion on its own behalf arguing that the plaintiffs made no specific factual allegations against Biogen to connect it with the alleged scheme. In September 2004, the court, in ruling on defendants' joint motion to dismiss, allowed the motion, in part, and dismissed the RICO claim, the Medicaid best price claim, the breach of contract claim, and the common law fraud claim. The court did not dismiss the claims brought under the New York State Medicaid and Social Services statutes, the unfair trade practices claim, or the claim for unjust enrichment. In October 2004, the court issued a partial decision on Biogen's individual motion to dismiss. The court dismissed all of the state law claims against Biogen based on the alleged failure to report best price, but deferred ruling on the fraud-based claims and ordered Suffolk County to produce all documents in support of its fraud-based claims. Suffolk County subsequently produced

documents in response to the court's request and Biogen renewed its motion to dismiss. Neither Biogen nor the other defendants have answered or responded to the other complaints, as all of the plaintiffs except Erie County have agreed to stay the time to respond until the resolution of the pending motion to dismiss the Suffolk County complaints. Biogen Idec intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

#### **Critical Accounting Estimates**

The preparation of consolidated financial statements requires us to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and related allowances, marketable securities, derivative and hedging activities, inventories, patents, income taxes including the valuation allowance for deferred tax assets, impairment for intangible assets and goodwill, valuation of long-lived assets and investments, research and development, loans, pensions, retiree medical plan, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

#### **Revenue Recognition and Accounts Receivable**

SEC Staff Accounting Bulletin No. 101, or SAB 101, superceded in part by SAB 104, provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB 104 establishes the SEC's view that it is not appropriate to recognize revenue until all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured. SAB 104 also requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. We believe that our revenue recognition policies are in compliance with SAB 104.

Product revenue consists of sales from our four products: AVONEX, AMEVIVE, ZEVALIN, and TYSABRI. The timing of distributor orders and shipments can cause variability in earnings. Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer, typically upon delivery. Revenues are recorded net of applicable allowances for returns, patient assistance, trade term discounts, Medicaid rebates, Veteran's Administration rebates, and managed care discounts and other applicable allowances. Included in our consolidated balance sheets at December 31, 2004 and 2003, are allowances for returns, rebates, discounts and other allowances which totaled \$33.8 million and \$20.8 million, respectively. At December 31, 2004, our allowance for product returns was \$5.2 million. At December 31, 2004, total discounts and allowances were approximately 1.8% of total current assets and less than 1% of total assets. We prepare our estimates for sales returns and allowances, discounts and rebates quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate. If actual future results vary, we may need to adjust our estimates, which could have an impact on earnings in the period of adjustment. In the past, our estimates based on historical experience have not materially differed from actual results.

We closely monitor levels of inventory in the distribution channel. At December 31, 2004, we had approximately, on average, 1 to 3 weeks of inventory in the distribution channel. The shelf life associated with

our products is long (15 to 30 months, depending on the product); therefore obsolescence due to dating expiration has not been a historical concern, given the rapidity in which our products move through the channel. Changes due to our competitors' price movements have not adversely affected us. We do not provide incentives to our distributors to assume additional inventory levels beyond what is customary in their ordinary course of business.

For the years ended December 31, 2004, 2003, and 2002, we recorded \$169.3 million, \$13.9 million and \$0.7 million, respectively, in our consolidated statements of income related to sales returns and allowances, discounts, and rebates. Our sales returns and allowances, discounts, and rebates related to AVONEX and AMEVIVE were included in our results of operations for all of 2004 as opposed to 2003, when sales returns and allowances, discounts, and rebates related to AVONEX and AMEVIVE were included in our results of operations only for the period from November 13, 2003 through December 31, 2003. In 2004, the amount of product returns was approximately 1% of product revenue for all our products. Product returns were \$17.4 million, \$3.7 million and \$0.5 million for 2004, 2003 and 2002, respectively. Product returns in 2004 included \$3.2 million related to product sales made prior to 2004. During 2004, we had encountered problems in manufacturing our pre-filled syringe formulation of AVONEX. As a result, we had an increase in our expected level of returns related to batches that failed to meet specifications.

In November 2004, we received regulatory approval in the U.S. of TYSABRI for the treatment of MS and paid a \$7.0 million approval-based milestone to Elan. Upon approval, we also became obligated to provide Elan with \$5.3 million in credits for payments on certain purchases of TYSABRI and for reimbursement of commercialization costs. Elan can apply \$1.5 million of the credits per year. The approval and credit milestones were capitalized upon approval in investments and other assets and are being amortized over the remaining patent life of 15.7 years. The amortization of the approval and credit milestones is being recorded as a reduction of revenue. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification.

Under our agreement with Elan, we manufacture TYSABRI and, in the U.S. prior to the suspension, sold TYSABRI to Elan who then distributed TYSABRI to third party distributors. In the U.S., we record revenue when TYSABRI is shipped from Elan to third party distributors. In December 2004, we recorded \$3.1 million of product revenues related to sales of TYSABRI to Elan. Additionally, as of December 31, 2004, we deferred \$1.9 million in revenue related to sales of TYSABRI, which had not yet been shipped by Elan. As of December 31, 2004, Elan owed us \$34.4 million, representing commercialization and development expenses incurred by us to be reimbursed by Elan, which we received from Elan in the first quarter of 2005.

Revenues from unconsolidated joint business consist of our share of the RITUXAN pretax copromotion profits generated from our copromotion arrangement with Genentech, reimbursement from Genentech of our RITUXAN-related sales force and development expenses and royalties from Genentech for sales of RITUXAN outside the U.S. by Roche and Zenyaku. Under the copromotion arrangement, all U.S. sales of RITUXAN and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our amended and restated collaboration agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking U.S. net sales of RITUXAN to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. In June 2003, we amended and restated our collaboration agreement with Genentech to include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to RITUXAN, for a broad range of indications. Upon approval of the first new anti-CD20 product, the pretax copromotion profit-sharing formula for RITUXAN and other anti-CD20 products will change over a period of time to a fixed annual profit-sharing percentage at the lower tier. Currently, we record our share of expenses incurred for the development of new anti-CD20 products in research and development expense until such time as a new product is approved,

at which time we will record our share of pretax copromotion profits related to the new product in revenues from unconsolidated joint business. We record our royalty revenues on sales of RITUXAN outside the U.S. on a cash basis. Under the amended and restated collaboration agreement, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products and only for the first eleven years from the date of first commercial sale of such new anti-CD20 products.

In February 2002, the FASB Emerging Issues Task Force, or EITF, released EITF Issue No. 01-09 or EITF 01-09, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)." EITF 01-09 states that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement, rather than a sales and marketing expense. We have various contracts with distributors that provide for discounts and rebates. These contracts are classified as a reduction of revenue. We also maintain select customer service contracts with distributors and other customers in the distribution channel. In accordance with EITF 01-09, we have established the fair value of these contracts and, as provided by EITF 01-09, classified these customer service contracts as sales and marketing expense. If we had concluded that sufficient evidence of the fair value did not exist for these contracts, we would have been required to classify these costs as a reduction of revenue.

We receive royalty revenues under license agreements with a number of third parties that sell products based on technology developed by us or to which the we have rights. The license agreements provide for the payment of royalties to us based on sales of the licensed product. We record these revenues based on estimates of the sales that occurred during the relevant period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties paid to us (adjusted for any changes in facts and circumstances, as appropriate). We maintain regular communication with our licensees in order to gauge the reasonableness of our estimates. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period which they become known, typically the following quarter. Historically, adjustments have not been material based on actual amounts paid by licensees. There are no future performance obligations on our part under these license agreements. Under this policy, revenue can vary due to factors such as resolution of royalty disputes and arbitration.

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which could affect future earnings.

#### **Biogen, Inc. Purchase Price Allocation**

The purchase price related to the Merger was allocated to tangible and identifiable intangible assets acquired and liabilities assumed based on the estimated fair market values as of the acquisition date. An independent third party valuation firm was engaged to assist in determining the fair values of inprocess research and development, identifiable intangible assets, inventory and certain property, plant and equipment, and in determining the useful lives of such tangible and identifiable intangible assets acquired. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete the in-process projects, determining the product life and term of estimated future cash flows, and developing appropriate costs, expenses, depreciation and amortization assumptions, tax rates, discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. These assumptions are based on the best available information that we had at the time. Additionally, certain estimates for the purchase price allocation related to income taxes may change as subsequent information becomes available.

### **Marketable Securities**

We invest our excess cash balances in short-term and long-term marketable securities, principally corporate notes and government securities. At December 31, 2004, substantially all of our securities were

classified as "available-for-sale". All available-for-sale securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive (loss) income in shareholders' equity, net of related tax effects. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are reported in other expense. In 2004, we recognized a charge of approximately \$5.7 million for certain unrealized losses on available-for-sale securities that were determined to be other-than-temporary, because we believe the securities will be sold prior to a potential recovery of their decline in value. Any future determinations that unrealized losses are other than temporary could have an impact on earnings. The cost of available-for-sale securities sold is based on the specific identification method. We have established guidelines that maintain safety and provide adequate liquidity in our available-for-sale portfolio. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

As part of our strategic product development efforts, we invest in equity securities of certain biotechnology companies with which we have collaborative agreements. Statement of Financial Accounting Standards No. 115, or SFAS 115, "Accounting for Certain Investments in Debt and Equity Securities," addresses the accounting for investment in marketable equity securities. As a matter of policy, we determine on a quarterly basis whether any decline in the fair value of a marketable security is temporary or other than temporary. Unrealized gains and losses on marketable security below our cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value with a charge to current earnings. The factors that we consider in our assessments include the fair market value of the security, the duration of the security's decline, and prospects for the company, including favorable clinical trial results, new product initiatives and new collaborative agreements. In 2004, we recognized a \$12.7 million charge for the impairment of an investment that was determined to be other than temporary. Any future determinations that unrealized losses are other than temporary could have an impact on earnings. At December 31, 2004, we had no unrealized losses related to these marketable securities. The fair market value of these marketable securities are other than temporary could have an impact on earnings. At December 31, 2004.

We also invest in equity securities of certain companies whose securities are not publicly traded and fair value is not readily available. These investments are recorded using the cost method of accounting and, as a matter of policy, we monitor these investments in private securities on a quarterly basis, and determine whether any impairment in their value would require a charge to current earnings, based on the implied value from any recent rounds of financing completed by the investee, market prices of comparable public companies, and general market conditions. At December 31, 2004, we included approximately \$33.9 million of investments in private securities in investments and other assets. There were no significant charges to current earnings in 2004, 2003 or 2002 for impairments of these investments. Recognition of impairments for these securities may cause variability in earnings.

#### Inventory

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out ("FIFO") method. Included in inventory are raw materials used in the production of pre-clinical and clinical products, which are expensed as research and development costs when consumed.

Our policy is to capitalize inventory costs associated with our products prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Our accounting policy addresses the attributes that should be considered in evaluating whether the costs to manufacture a product have met the definition of an asset as stipulated in FASB Concepts Statement No. 6. We assess the regulatory approval process and where the particular product stands in relation to that approval process including any known constraints and impediments to approval, including safety, efficacy and potential labeling restrictions. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication in which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could possibly hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or cause

delay in commercialization. We are sensitive to the significant commitment of capital to scale up production and to launch commercialization strategies. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize.

There is a risk inherent in these judgments, which is the reason we disclose the risk and the potential for a change in judgment. At December 31, 2004, all products included in inventory have been approved for sale by either the EMEA or FDA.

In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of two serious adverse events that occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases, of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine future commercial availability. We cannot predict the outcome of these evaluations. An unfavorable or inconclusive outcome could result in the permanent withdrawal of TYSABRI from the market and termination of clinical studies of TYSABRI, or the re-introduction of TYSABRI to the market with significant restrictions on its permissible uses, blackbox or other significant safety warnings in its label and such other restrictions, requirements and limitations as the FDA may require. While we presently believe that we will be able to find a path forward for TYSABRI, there are no assurances as to the likelihood of success. In light of our inability to predict to the required degree of certainty that our TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we have written down all of the \$19.1 million of TYSABRI inventory that had been included on the balance sheet as of December 31, 2004, which was charged to cost of product revenues. We are continuing to manufacture TYSABRI. Because of the uncertainty described above, in the first quarter of 2005, we also expect to expense between \$22 million and \$25 million of TYSABRI that was manufactured in the first quarter of 2005. In subsequent periods, we will continue to assess TYSABRI to determine if it needs to be expensed in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards. See "Forward Looking Information and Risk Factors That May Affect Futures Results — Safety Issues with TYSABRI Could Significantly Affect Our Growth."

We periodically review our inventories for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-offs may be required. This periodic review led to the write-downs of TYSABRI inventory as of December 31, 2004 and the expensing of TYSABRI expected to occur in the first quarter of 2005, as described above, and may lead us to expense TYSABRI in subsequent periods. Also included in product cost of revenues were write-downs of commercial inventory that did not meet quality specifications or became obsolete due to dating expiration, in all cases this product inventory was written-down to its net realizable value. We wrote-down \$46.7 million of unmarketable inventory during 2004, which was charged to cost of product revenues and consisted of \$16.2 million related to AVONEX, \$9.7 million related to ZEVALIN, \$1.7 million related to AMEVIVE and \$19.1 million to TYSABRI. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory did not meet quality specifications. The ZEVALIN inventory was written-down to net realizable value when it was determined that the inventory did not meet quality specifications as well as a determination that certain of the inventory will not be marketable based on estimates of demand.

#### **Income Taxes**

Income tax expense includes a provision for income tax contingencies, which we believe is adequate and appropriate.

In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and the effects of viable tax planning strategies. Our estimates of future taxable income include, among other items, our estimates of future income tax deductions related to the exercise of stock options. In the event that actual results differ from our estimates or we adjust our estimates in future periods, we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

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

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, facilities costs, overhead costs, clinical trial and related clinical manufacturing costs, contract services and other outside costs. Research and development costs, including upfront fees and milestones paid to collaborators, are expensed as incurred. The timing of upfront fees and milestone payments in the future may cause variability in future research and development expense. Clinical trial costs include costs associated with contract research organizations, or CROs. The invoicing from CROs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO activities based on our estimate of management fees, site management and site monitoring costs, and data management costs. We maintain regular communication with our CRO vendors to gauge the reasonableness of our estimates. Differences between actual clinical trial costs and estimated clinical trial costs have not been material and are adjusted for in the period which they become known. Under this policy, research and development expense can vary due to accrual adjustments related to clinical trials.

#### **Derivatives and Hedging Activities**

We have operations in Europe, Japan, Australia and Canada in connection with the sale of AVONEX. We also receive royalty revenues based on worldwide product sales by our licensees. As a result, our financial position, results of operations and cash flows can be affected by fluctuations in foreign currency exchange rates (primarily Euro, Swedish krona, British pound, Japanese yen, Swiss Franc and Canadian dollar).

We use foreign currency forward contracts to manage foreign currency risk and do not engage in currency speculation. We use these forward contracts to hedge certain forecasted transactions denominated in foreign currencies. SFAS 133, "Accounting for Derivative Instruments and Hedging Activities", or SFAS 133, requires that all derivatives be recognized on the balance sheet at their fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether a derivative is designated as part of a hedge transaction and, if it is, the type of hedge transaction. We assess, both at their inception and on an on-going basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings to the extent significant. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings. Under this policy, and in accordance

with SFAS 133, earnings may vary if the forecasted transaction does not occur, or if there is material hedge ineffectiveness or if the hedge ceases to be highly effective.

### **Impairment of Long-Lived Assets**

Long-lived assets to be held and used, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

In the third quarter of 2004, management determined that certain clinical trials would be discontinued or would not be initiated which indicated that the carrying value of certain core technology intangible assets might not be recoverable. As a result, in the third quarter of 2004, we recorded a charge of approximately \$27.8 million to amortization of intangible assets, which reflects the adjustment to the valuation of certain core technology intangible assets related to AMEVIVE to its net realizable value. If future events or circumstances indicate that the carrying value of certain of these remaining assets may not be recoverable, we may be required to record additional charges to our results of operations.

In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. In light of the two reports of PML, the companies initiated a systemic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability. We cannot predict the outcome of these evaluations. An unfavorable or inconclusive outcome could result in the permanent withdrawal of TYSABRI from the market and termination of clinical studies of TYSABRI, or the re-introduction of TYSABRI to the market with significant restrictions on its permissible uses, blackbox or other significant safety warnings in its label and such other restrictions, requirements and limitations as the FDA may require. As a result of these events, we have assessed our long-lived assets related to TYSABRI, which include intangible assets and facilities, and have determined that there are no impairments related to these assets as a result of the suspension of the marketing of TYSABRI. However, should new information arise, we may be required to take impairment charges related to certain of our long-lived assets. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth."

#### Goodwill

Goodwill associated with the Merger represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for by the purchase method of accounting. Goodwill is not amortized, but rather subject to periodic review for impairment. Goodwill is reviewed annually and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. In the fourth quarter of 2004, we performed an assessment of our goodwill, and concluded that goodwill was not impaired at October 31, 2004.

As a result of the voluntary suspension of TYSABRI in February 2005, we have performed an interim review for impairment. We believe that the fair value of our legacy Biogen, Inc. reporting unit exceeds its carrying value and therefore, we believe goodwill is properly valued as of the date of the filing of our 2004 Form 10-K. However, should new information arise, we may need to reassess goodwill for impairment in light of the new information and we may be required to take impairment charges related to goodwill. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth."

#### **Notes Payable**

In connection with our senior and subordinated notes payable, we capitalized certain issuance costs, which are being amortized to interest expense over the estimated outstanding term of the notes, according to EITF 86-15, "Increasing-Rate Debt." We currently expect that holders of the senior notes due in 2032 will require us to purchase all or a portion of the senior notes on April 29, 2005. As a result, we have reassessed the estimated term of this debt, and recorded additional interest expense of approximately \$7.1 million in the fourth quarter of 2004. We have also classified our senior notes as current liabilities on the consolidated balance sheet as of December 31, 2004. The remaining unamortized issuance costs of approximately \$9.7 million will be amortized through April 29, 2005.

#### **Contingencies and Litigation**

There has been, and we expect there may be significant litigation in the industry regarding commercial practices, regulatory issues, pricing, and patents and other intellectual property rights. Certain adverse unfavorable rulings or decisions in the future, including in the litigation described under "Legal Matters," could create variability or have a material adverse effect on our future results of operations and financial position.

#### New Accounting Standards

EITF 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," was issued in February 2004. EITF 03-01 stipulates disclosure requirements for investments with unrealized losses that have not been recognized as other-than-temporary impairments. We have complied with the disclosure provisions of EITF 03-01. In September 2004, the FASB staff issued two proposed FASB Staff Positions: Proposed FSP EITF Issue 03-01-a, which provides guidance for the application of paragraph 16 of EITF Issue 03-01 to debt securities that are impaired because of interest rate and/or sector spread increases, and Proposed FSP EITF Issue 03-01-b, which delays the effective date of Issue 03-01 for debt securities that are impaired because of interests rate and/or sector spread increases. We are currently monitoring these developments and assessing the impact these will have on our results of operations.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123(R), "Share-Based Payments," which replaces SFAS No. 123, "Accounting for Stock-Based Compensation," and supercedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123(R) will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. SFAS 123(R) will be effective for public companies for fiscal periods beginning after June 15, 2005 and offers alternative methods for determining the fair value. We expect that SFAS 123(R) will have a significant impact on our financial statements. At the present time, we have not yet determined which valuation method we will use.

The FASB has proposed amending SFAS 128, "Earnings per Share," to make it consistent with International Accounting Standard 33, "Earnings per Share", and make earnings per share, or EPS, computations comparable on a global basis. Under the proposed amendment, the year-to-date EPS computation would be performed independently from the quarterly computations. Additionally, for all contracts that may be settled in either cash or shares of stock, companies must assume that settlement will occur by the issuance of shares for purposes of computing diluted EPS, even if they intend to settle by paying cash or have a history of cash-only settlements, regardless of who controls the means of settlement. Lastly,

under the proposed amendment, shares that will be issued upon conversion of a mandatory convertible security must be included in the weighted-average number of shares outstanding used in computing basic EPS from the date that conversion becomes mandatory, using the if-converted method, regardless of whether the result is anti-dilutive. The proposed amended standard is expected to be issued during the first quarter of 2005. Retrospective application in all periods presented would be required, and could require the conformance of previously reported EPS. We do not expect the provisions of the amended SFAS 128 will have a significant impact on our results of operations.

In November 2004, the FASB issued SFAS 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4," which amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement amends ARB 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not expect the provisions of SFAS 151 will have a significant impact on our results of operations.

In December 2004, the FASB issued SFAS 153, "Exchanges of Non-Monetary Assets, an amendment of APB Opinion No. 29," which eliminates the exception from fair value measurement for nonmonetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29, "Accounting for Nonmonetary Transactions," and replaces it with an exception for exchanges that do not have commercial substance. This Statement specifies that a nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this Statement shall be effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. We do not expect the provisions of SFAS 153 will have a significant impact on our results of operations.

In December 2004, the FASB reached consensus on EITF Issue No. 02-14, "Whether an Investor Should Apply the Equity Method of Accounting to Investments Other Than Common Stock," which requires an investor that has the ability to exercise significant influence over the operating and financial policies of the investee to apply the equity method of accounting only when it has an investment(s) in common stock and/or an investment that is in-substance common stock. The Task Force also reached a consensus on the definition of in-substance common stock and related guidance. The provisions of EITF 02-14 are effective for reporting periods beginning after September 15, 2004, and have not had any impact on our accounting for investments as of December 31, 2004.

Under EITF No. 04-01, "Accounting for Preexisting Relationships between the Parties to a Business Combination," the EITF reached a consensus that the consummation of a business combination between parties with a preexisting relationship should be evaluated to determine if a settlement of a preexisting relationship exists, thus requiring accounting separate from the business combination. Under EITF 04-01, the acquisition of a right that the acquiring entity had previously granted to the acquired entity to use the acquirer's recognized or unrecognized intangible assets (for example, rights to the acquirer's trade name under a franchise agreement or rights to the acquirer's technology under a technology licensing agreement) should be included as part of the business combination and recorded by the acquiring entity as an intangible asset at fair value. If the contract giving rise to the reacquired right includes terms that are favorable or unfavorable when compared to pricing (for example, royalty rates) for current market transactions for the same or similar items, an entity should measure a settlement gain or loss as the lesser of (a) the amount by which the contract is favorable or unfavorable to market terms from the perspective of the acquirer or (b) the stated settlement provisions of the contract available to the counterparty to which the contract is unfavorable. EITF 04-01 is effective for all business combinations consummated and goodwill impairment tests (i.e., in step 2 of the impairment test) performed in reporting periods beginning after October 13, 2004. The provisions of EITF 04-01 have not had any significant impact on our results of operations in 2004.

## Disclosure Controls and Procedures and Internal Control over Financial Reporting

## Controls and Procedures

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act), as of December 31, 2004. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of that period, our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

### Changes in Internal Control over Financial Reporting

We evaluate the effectiveness of our internal control over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning in 2004, and to include a management report assessing the effectiveness of our internal control over financial reporting in all annual reports beginning with this Annual Report on Form 10-K. In evaluating our internal control over financial reporting, we have identified a number of changes that need to be made to our internal controls, primarily related to better documentation of internal controls, and related changes to information systems used in financial reporting. We continued to make these changes during the fourth quarter of 2004. The changes during the fourth quarter of 2004 did not, individually or in the aggregate, have a material effect on our internal control over financial reporting.

#### Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that

controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2004, our internal control over financial reporting is effective based on those criteria. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page F-51 of this Annual Report on Form 10-K.

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

See the sections from "Item 1 — Business — Forward Looking Information and Risk Factors that May Affect Future Results" entitled "We are Subject to Market Risk," "Our Financial Position, Results of Operations and Cash Flows can be Affected by Fluctuations in Foreign Currency Exchange Rates," and "We are Exposed to Risk of Interest Rate Fluctuations."

#### Item 8. Consolidated Financial Statements and Supplementary Data.

The information required by this Item 8 is contained on pages F-1 through F-53 of this Annual Report on Form 10-K.

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

Not applicable.

#### Item 9A. Controls and Procedures

The information required by this Item is contained in the section "Disclosure Controls and Procedures and Internal Control over Financial Reporting" beginning on page 75 of this Annual Report on Form 10-K.

#### Item 9B. Other Information

Not applicable.

## PART III

#### Item 10. Directors and Executive Officers of the Registrant

The information concerning our executive officers is set forth in Part I of this Form 10-K. The text of our code of business conduct, which includes the code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions, is posted on our website, www.biogenidec.com, under the "Corporate Governance" subsection of the "Company" section of the site. Disclosure regarding any amendments to, or waivers from, provisions of our code of business conduct, if required, will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting of such amendments or waivers is permitted by the rules of The Nasdaq Stock Market, Inc. Our corporate governance principles (also posted on <u>www.biogenidec.com</u>) prohibit our Board of Directors from granting any waiver of the code of ethics for any of our directors or executive officers. We include our website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website.

The response to the remainder of this item is incorporated by reference from the discussion responsive thereto in the sections labeled "Proposal 1 — Election of Directors — Information about our Directors" and

"Stock Ownership — Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement for our 2005 Annual Meeting of Stockholders.

## Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto in the section labeled "Executive Compensation and Related Information" contained in the Proxy Statement for our 2005 Annual Meeting of Stockholders.

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The response to this item is incorporated by reference from the discussion responsive thereto in the sections labeled "Stock Ownership" and "Disclosure with Respect to our Equity Compensation Plans" contained in the Proxy Statement for our 2005 Annual Meeting of Stockholders.

## Item 13. Certain Relationships and Related Transactions.

The response to this item is incorporated by reference from the discussion responsive thereto in the sections labeled "Proposal 1 — Election of Directors — Information about our Board of Directors and its Committees," "Executive Compensation and Related Information — Employment Agreements and Change of Control Arrangements," and "Certain Relationships and Related Party Transactions" contained in the Proxy Statement for our 2005 Annual Meeting of Stockholders.

### Item 14. Principal Accountant Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto in the sections labeled "Proposal 2 — Ratification of the Selection of our Independent Registered Public Accounting Firm" contained in the Proxy Statement for our 2005 Annual Meeting of Stockholders.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

### a. (1) Consolidated Financial Statements and Schedule:

The Financial Statements required to be filed by Item 8 of this Annual Report on Form 10-K, and filed in this Item 15, are as follows:

	Page Number in This
Financial Statements	Form 10-K
Consolidated Statements of Income	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Cash Flows	F-4
Consolidated Statements of Shareholders' Equity	F-5
Notes to Consolidated Financial Statements	F-6
Reports of Independent Registered Public Accounting Firms	F-51

## (2) Financial Statement Schedules

The following financial statement schedule is included in the Annual Report on Form 10-K:

	Page Number in This
Financial Statement Schedule[s]	Form 10-K
Schedule II — Valuation and Qualifying Accounts and Reserves	F-50

## (3) Exhibits:

The following exhibits are referenced or included in this Form 10-K.

Exhibit Number 2.1(12		Description Agreement and Plan of Merger, dated as of June 20, 2003, by and among us, Bridges Merger Corporation and Biogen,
2.1(1.	2)	Inc.
3.1(24	4)	Amended and Restated Certificate of Incorporation
3.2(24	4)	Certificate of Amendment of Amended and Restated Certificate of Incorporation, dated as of May 21, 2001
3.3(24	4)	Certificate Increasing the Number of Authorized Shares of Series X Junior Participating Preferred Stock, dated as of July 26, 2001
3.4(24	4)	Certificate of Amendment of Amended and Restated Certificate of Incorporation, dated as of November 12, 2003
3.5(24	4)	Bylaws
3.6(24	4)	Amendment to Bylaws, dated as of December 21, 2001
3.7(24	4)	Amendment to Bylaws, dated as of November 12, 2003
4.1		Reference is made to Exhibit 3.1 for a description of the rights, preferences and privileges of our Series A Preferred Stock and Series X Junior Participating Preferred Stock
4.2(24	4)	Specimen Common Stock Certificate
4.3(6)	)	Indenture dated as of February 16, 1999 between us and Chase Manhattan Bank and Trust Company, National Association, as Trustee
4.4(4)	)	Form of Registered Liquid Yield Option™ Note due 2019
4.5(9)	)	Amended and Restated Rights Agreement dated as of July 26, 2001 between us and Mellon Investor Services LLC
4.6(12	2)	Amendment No. 1 to Amended and Restated Rights Agreement dated as of June 23, 2003 between us and Mellon Investor Services LLC
4.7(1)	1)	Indenture dated as of April 29, 2002 between us and JP Morgan Trust Company, N.A., as Trustee
4.8(1)	1)	Registration Rights Agreement, dated as of April 29, 2002, between us and Merrill Lynch, Pierce, Fenner & Smith Incorporated
4.9(1)	1)	Form of Liquid Yield Option™ Note dated April 29, 2002
10.1(13	3)*	IDEC Pharmaceuticals Corporation 1988 Stock Option Plan, as amended and restated through February 19, 2003
10.2(5)	)	Letter Agreement between the Registrant and Genentech, Inc., dated May 21, 1996
10.3(2)	)†	License Agreement between us and Coulter Immunology (now Corixa Corporation), dated May 16, 1991
10.5(13	3)	1993 Non-Employee Directors Stock Option Plan, as amended and restated through February 19, 2003
10.6(3)	)†	Expression Technology Agreement between us and Genentech. Inc., dated March 16, 1995
10.8(1)	)*	Form of Indemnification Agreement for certain directors and executive officers
10.9(6)	)	Indenture dated as of February 16, 1999 between us and Chase Manhattan Bank and Trust Company, National Association, as Trustee
10.10(	11)	Indenture dated as of April 29, 2002 between us and JP Morgan Trust Company, N.A., as Trustee
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xhibit Number	Description
10.11(7)†	Collaboration & License Agreement between us and Schering Aktiengesellschaft, dated June 9, 1999
10.12(8)†	Isotope Agreement between us and MDS Nordion Inc. as amended by a first amendment on January 21, 2000 and a second amendment on March 16, 2001
10.13(24)*	Voluntary Executive Supplemental Savings Plan (as amended and restated; effective January 1, 2004)
10.14(10)†	Third Amendment to Agreement between MDS Canada Inc., MDS Nordion division, successor to MDS Nordion Inc. and us dated November 12, 2001
10.15(14)†	Commercial Supply Agreement between us and Baxter Pharmaceutical Solutions LLC dated June 1, 2002
10.16(15)*	2003 Omnibus Equity Plan
10.17(15)*	2003 Performance Based Management Incentive Plan
10.18(21)*	Form of Indemnification Agreement between Biogen, Inc. and certain directors and executive officers
10.19(18)	Cambridge Center Lease dated October 4, 1982 between Mortimer Zuckerman, Edward H. Linde and David Barrett, a Trustees of Fourteen Cambridge Center Trust, and B. Leasing, Inc.
10.20(19)	First Amendment to Lease dated January 19, 1989, amending Cambridge Center Lease dated October 4, 1982
10.21(19)	Second Amendment to Lease dated March 8, 1990, amending Cambridge Center Lease dated October 4, 1982
10.22(19)	Third Amendment to Lease dated September 25, 1991, amending Cambridge Center Lease dated October 4, 1982
10.23(20)	Fourth Amendment to Lease dated October 6, 1993, amending Cambridge Center Lease dated October 4, 1982
10.24(20)	Fifth Amendment to Lease dated October 9, 1997, amending Cambridge Center Lease dated October 4, 1982
10.25	Lease dated April 1, 1990 between Biogen, Inc. and Steven D. Rosenberg as Trustee of the Fifth Realty Trust of 300 Bent Street
10.26(22)*	Biogen, Inc. 1985 Non-Qualified Stock Option Plan (as amended and restated through February 7, 2003)
10.27(22)*	Biogen, Inc. 1987 Scientific Board Stock Option Plan (as amended and restated through February 7, 2003)
10.28(24)*	Voluntary Board of Directors Savings Plan (as amended and restated; effective January 1, 2004)
10.29(24)*	Executive Severance Policy — Senior/ Executive Vice Presidents
10.30(22)†	ANTEGREN (now TYSABRI) Development and Marketing Collaboration Agreement between us and Elan Pharma International Limited, dated August 15, 2000
10.31(16)*	Employment Agreement between us and James C Mullen, dated June 20, 2003
10.32(16)*	Employment Agreement between us and William R. Rastetter, Ph.D., dated June 20, 2003.
10.33(17)†	Amended and Restated Collaboration Agreement between us and Genentech, Inc., dated June 19, 2003
10.34(24)	Fourth Amendment to Agreement between us, MDS (Canada) Inc., MDS Nordion division, successor to MDS Nordic Inc., dated June 10, 2003
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Exhibit Number	Description
10.35(24)†	Fifth Amendment to Agreement between us, MDS (Canada) Inc., MDS Nordion division, successor to MDS Nordion Inc., dated December 17, 2003
10.36(24)*	Form of letter agreement regarding employment arrangement between us and our Executive Vice Presidents
10.37(23)*	Letter agreement regarding employment arrangement of Peter N. Kellogg, dated June 21, 2000
10.38(25)	Lease agreement between Biogen Idec BV, a wholly-owned subsidiary of the registrant, and TUG Vastgoed B.V., dated as of September 24, 2004
10.39(26)*	Amendment to the IDEC Pharmaceuticals Corporation 1988 Stock Option Plan, as amended and restated through February 19, 2003
10.40(26)*	Amendment to Biogen Idec Inc. Executive Severance Policy — Senior/ Executive Vice Presidents
10.41(27)*	Letter agreement regarding use of company-owned condominium of William H. Rastetter, Ph.D., dated January 5, 2005
10.42*	Board of Directors — Annual Retainer Summary Sheet
12.1	Computation of Ratio of Earnings to Fixed Charges
21.1	Subsidiaries
23.1	Consent of PricewaterhouseCoopers LLP — an Independent Registered Public Accounting Firm
23.2	Consent of KPMG LLP — an Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes- Oxley Act of 2002

Reference to "our" in these cross-references mean filings made by Biogen Idec and filings made by IDEC Pharmaceuticals Corporation prior to the merger with Biogen, Inc.

- \* Management contract or compensatory plan or arrangement.
- † Confidential Treatment has been granted with respect to portions of this agreement.
- TM Trademark of Merrill Lynch & Co., Inc.
- (1) Incorporated by reference from an exhibit filed with our Registration Statement on Form 8-B filed on June 2, 1997.
- (2) Incorporated by reference from an exhibit filed with our Registration Statement on Form S-1, File No. 33-40756.
- (3) Incorporated by reference from an exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 1995.
- (4) Incorporated by reference from an exhibit filed with our Registration Statement on Form S-3/ A, File No. 333-85339, filed on November 10, 1999.
- (5) Incorporated by reference from an exhibit filed with our Current Report on Form 8-K, filed on June 6, 1996.
- (6) Incorporated by reference from an exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 1998.

- (7) Incorporated by reference from an exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.
- (8) Incorporated by reference from an exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
- (9) Incorporated by reference from an exhibit filed with our Registration Statement on Form 8-A, File No. 333-37128, dated July 27, 2001.
- (10) Incorporated by reference from an exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
- (11) Incorporated by reference from an exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
- (12) Incorporated by reference from an exhibit filed with our Current Report on Form 8-K filed on June 23, 2003.
- (13) Incorporated by reference from an appendix filed with our Definitive Proxy Statement on Schedule 14A filed on April 11, 2003.
- (14) Incorporated by reference from an exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 2002.
- (15) Incorporated by reference from an exhibit filed with our Current Report on Form 8-K filed on November 12, 2003.
- (16) Incorporated by reference from an exhibit filed with our Registration Statement on Form S-4, File No. 333-107098, filed with the SEC on July 16, 2003.
- (17) Incorporated by reference from an exhibit filed with our Current Report on Form 8-K filed on July 31, 2003.
- (18) Incorporated by reference from an exhibit filed with Biogen, Inc.'s Registration Statement on Form S-1, File No. 2-81689
- (19) Incorporated by reference from an exhibit filed with Biogen, Inc.'s Annual Report on Form 10-K for the year ended December 31, 1992, File No. 0-12042
- (20) Incorporated by reference from an exhibit filed with Biogen, Inc.'s Annual Report on Form 10-K for the year ended December 31, 1997, File No. 0-12042
- (21) Incorporated by reference from an exhibit filed with Biogen, Inc.'s Annual Report on Form 10-K for the year ended December 31, 1988, File No. 0-12042
- (22) Incorporated by reference from an exhibit filed with Biogen, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2002, File No. 0-12042.
- (23) Incorporated by reference from an exhibit filed with Biogen, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2001, File No. 0-12042.
- (24) Incorporated by reference from an exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 2003.
- (25) Incorporated by reference from an exhibit filed with our Current Report on Form 8-K filed on September 29, 2004.
- (26) Incorporated by reference from an exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
- (27) Incorporated by reference from an exhibit filed with our Current Report on Form 8-K filed on January 6, 2005.

## 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.

## BIOGEN IDEC INC.

James C. Mullen

By:

/s/ James C. Mullen

Date: March 31, 2005

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

Chief Executive Officer and President

Name	Capacity	Date
/s/ William H. Rastetter, Ph.D.	Director, Executive Chairman	March 31, 2005
William H. Rastetter, Ph.D.		
/s/ James C. Mullen	Director, Chief Executive Officer and President (principal	March 31, 2005
James C. Mullen	executive officer)	
/s/ Peter N. Kellogg	Executive Vice President, Finance and Chief Financial Officer	March 31, 2005
Peter N. Kellogg	(principal financial and accounting officer)	
/s/ Alan Belzer	Director	March 31, 2005
Alan Belzer		
/s/ Lawrence C. Best	Director	March 31, 2005
Lawrence C. Best		
/s/ Alan B. Glassberg, M.D.	Director	March 31, 2005
Alan B. Glassberg, M.D.		
/s/ Mary L. Good, Ph.D.	Director	March 31, 2005
Mary L. Good, Ph.D.		
/s/ Thomas F. Keller, Ph.D.	Director	March 31, 2005
Thomas F. Keller, Ph.D.		
/s/ Robert W. Pangia	Director	March 31, 2005
Robert W. Pangia		
/s/ Bruce R. Ross	Director	March 31, 2005
Bruce R. Ross		
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Name	Capacity	Date
/s/ Lynn Schenk	Director	March 31, 2005
Lynn Schenk		
/s/ Phillip A. Sharp, Ph.D.	Director	March 31, 2005
Phillip A. Sharp, Ph.D.		
/s/ William D. Young	Director	March 31, 2005
William D. Young		

## CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE

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## CONSOLIDATED STATEMENTS OF INCOME

	For the Years Ended December 31,					
		2004 2003				
Revenues:		(In th	ousands, exc	ept per share amoun	its)	
Product	\$	1,486,344	\$	171,561	\$	13,711
Revenue from unconsolidated joint business	φ	615,743	Ф	493,049	Ъ	385,809
Royalties		98,945		12,010		303,009
Corporate partner		10,530		2,563		4,702
Total revenues		2,211,562		679,183		
		2,211,302		0/9,105		404,222
Costs and expenses:		F 40 700		202.012		1 457
Cost of product revenues		548,702 5,617		283,813 926		1,457
Cost of royalty revenues Research and development		687,663		233,337		100,868
Selling, general and administrative		578,487		174,596		88,021
Acquisition of in-process research and development		570,407		823,000		00,021
Amortization of acquired intangible assets		347,677		33,180		
Total costs and expenses		2,168,146		1,548,852		190,346
-				<u> </u>		
Income (loss) from operations		43,416 20,677		(869,669)		213,876
Other income (expense), net		,		(10,955)		17,646
Income (loss) before income taxes (benefit)		64,093		(880,624)		231,522
Income taxes (benefit)	<u></u>	39,007	<u>+</u>	(5,527)	-	83,432
Net Income (Loss)	\$	25,086	\$	(875,097)	\$	148,090
Basic earnings (loss) per share	\$	0.07	\$	(4.92)	\$	0.95
Diluted earnings (loss) per share	\$	0.07	\$	(4.92)	\$	0.85
Shares used in calculating:						
Basic earnings (loss) per share		334,996		177,982		153,086
Diluted earnings (loss) per share		343,475		177,982		176,805

See accompanying notes to consolidated financial statements.

## CONSOLIDATED BALANCE SHEETS

	As of December 31,					
			ds, except per amounts)			
ASSETS		Shure	iniounits)			
Current assets						
Cash and cash equivalents	\$	209,447	\$	314,850		
Marketable securities available-for-sale		848,495		521,109		
Accounts receivable, less allowances of \$35,882 and \$22,830 at December 31, 2004 and						
2003, respectively		278,637		198,524		
Due from unconsolidated joint business		137,451		117,342		
Deferred tax assets		86,880		123,945		
Inventory		251,016		496,349		
Other current assets		119,118		66,545		
Total current assets		1,931,044		1,838,664		
Marketable securities available-for-sale		1,109,624		1,502,327		
Property and equipment, net		1,525,225		1,252,783		
ntangible assets, net		3,292,827		3,638,812		
Goodwill		1,151,105		1,151,066		
nvestments and other assets		155,933		120,293		
	\$	9,165,758	\$	9,503,945		
LIABILITIES AND SHAREHOLDERS' E	OUITY					
Current liabilities	<b>2</b> 011 1					
Accounts payable	\$	121,471	\$	63,364		
Deferred revenue		13,695		7,155		
Current taxes payable		129,350		94,176		
Notes payable		748,430				
Accrued expenses and other		247,802		240,130		
Total current liabilities		1,260,748		404,825		
Notes payable		101,879		887,270		
Long-term deferred tax liability		921,771		1,108,318		
Other long-term liabilities		54,959		50,204		
Commitments and contingencies						
Shareholders' equity						
Convertible preferred stock, par value \$0.001 per share (8 shares authorized, issued and outstanding at December 31, 2004 and 2003; \$551 liquidation value at December 31, 2004 and 2003)		_		_		
Common stock, par value \$0.0005 per share (1,000,000 shares authorized; 336,700 shares						
and 330,410 shares issued and outstanding at December 31, 2004 and 2003, respectively)		173		166		
Additional paid-in capital		8,184,979		7,801,170		
Accumulated other comprehensive (loss) income		(6,767)		1,054		
Deferred stock-based compensation		(36,280)		(2,141)		
Accumulated deficit		(801,094)		(611,921)		
		7,341,011		7,188,328		
Less treasury stock, at cost; 8,766 and 2,209 shares at December 31, 2004 and 2003,						
respectively		514,610		135,000		
respectively						
Total shareholders' equity		6,826,401		7,053,328		

See accompanying notes to consolidated financial statements.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

		For the Years Ended December 31						
		2004	2003 (In thousands)			2002		
Cash Flows from Operating Activities			(In	thousands)				
Net Income (Loss)	\$	25,086	\$	(875,097)	\$	148,090		
Adjustments to reconcile net income (loss) to net cash flows from operating activities		-,		() )		-,		
Write-off of acquired in-process research and development		_		823,000				
Depreciation and amortization		439,435		61,308		10,156		
Stock based compensation		16,795						
Non-cash interest expense		55,002		41,226		26,905		
Deferred income taxes		(135,553)		(27,267)		(39,922)		
Tax benefit from stock options		144,550		23,373		114,337		
Realized loss (gain) on sale of marketable securities available-for-sale		4,090		(2,153)		(2,779)		
Write-down of inventory to net realizable value		43,358		173,896		_		
Impact of inventory step-up		289,505		79,097				
Impairment of investments		18,482		_		_		
Loss on disposition of assets		2,577		_				
Other		830		2,643		1,665		
Changes in, net of assets and liabilities acquired:								
Accounts receivable		(76,529)		22,618		(3,927)		
Due from unconsolidated joint business		(20,109)		(17,054)		(32,637)		
Inventory		(90,804)		(8,720)		(33,141)		
Other current and other assets		(63,894)		(35,076)		(27,434)		
Accrued expenses and other current liabilities		63,870		(66,775)		24,648		
Deferred revenue		6,540		2,700		(1,575)		
Other long-term liabilities		4,755		(27,752)		12,333		
Net cash flows from operating activities		727,986		169,967		196,719		
Cash Flows from Investing Activities		<u> </u>						
Cash received from acquisition of Biogen, Inc., net of cash paid		_		136,793				
Purchases of marketable securities available-for-sale		(3,187,717)		(1,233,251)		(1,501,404)		
Proceeds from sales and maturities of marketable securities available-for-sale		3,200,386		1,118,775		841,225		
Acquisitions of property, plant and equipment, net		(361,013)		(301,248)		(165,904)		
Restricted cash		_		22,500		(17,498)		
Acquisitions of intangible assets		(8,750)		_		_		
Increase in investments and other assets		(25,334)		_		(13,071)		
Net cash flows from investing activities		(382,428)		(256,431)		(856,652)		
Cash Flows from Financing Activities		(001,110)		(100,101)		(000,002)		
Proceeds from issuance of notes payable, net						696,004		
Purchases of treasury stock		(734,427)		_		(135,000)		
Issuance of common stock for option exercises and employee stock purchase plan		132,977		24.439		23,059		
Issuance of treasury stock for option exercises and employee stock purchase plan		140,558		24,455		23,035		
Change in cash overdraft		9,931		26,746				
Net cash flows from financing activities		(450,961)		51,185		584,063		
		<u> </u>						
Net decrease in cash and cash equivalents		(105,403)		(35,279)		(75,870)		
Cash and cash equivalents, beginning of the year	-	314,850		350,129		425,999		
Cash and cash equivalents, end of the year	\$	209,447	\$	314,850	\$	350,129		
Supplemental Cash Flow Data								
Cash paid during the year for:								
Interest	\$	_	\$	_	\$			
interest	φ							

For information associated with assets and liabilities assumed in the Merger with Biogen, Inc., see Note 2.

See accompanying notes to consolidated financial statements.

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

Balance, December 31, 2001 Comprehensive income: Net income			Shares	Amount	Paid-In Capital	(Loss) Income	Stock-Based Compensation		Deficit) Retained Earnings	Treasury Stock	Total Shareholders' Equity
Comprehensive income:	48	\$ —	152,775	\$ 76	(In t \$ 840,232	housands) \$ 1,085	\$ —	\$	115,086	\$ —	\$ 956,4
	40	ф —	132,773	\$ 70	\$ 040,232	\$ 1,005	\$	φ		ф —	
Unrealized gains (losses) on securities available for sale, net of tax of \$1,945 Total comprehensive						2,679			148,090		2,6
income Issuance of common stock under stock											150,7
option and stock purchase plans, net Issuance of common stock from conversion of series A-2			3,112	2	23,057						23,0
convertible preferred stock	(12)		708								
Issuance of common stock from conversion of notes payable due 2019			5		46						
Repurchase of common stock for treasury, at cost			(2,209)							(135,000)	(135,0
Tax benefit from stock option and stock purchase plan					114,337						114,3
Balance, December 31, 2002 Comprehensive income:	36		154,391	78	977,672	3,764			263,176	(135,000)	1,109,6
Net loss Unrealized gains (losses) on securities									(875,097)		(875,0
available for sale, net of tax of \$1,408 Unrealized losses on foreign currency						(1,262)					(1,2
forward contracts, net of tax of \$1,862 Translation adjustment,						(3,268)					(3,2
net of tax of \$823 Total comprehensive income						1,820					1,8
Issuance of common stock under stock											(877,8
option and stock purchase plans, net Issuance of common stock and assumption of stock options related			2,401	1	24,438						24,4
to merger with Biogen, Inc Issuance of common			171,938	86	6,775,652						6,775,7
stock from conversion of series A-2 and A-3 convertible preferred	(20)		1.000	1	(1)						
stock Deferred stock-based compensation related to unvested Biogen, Inc. options assumed in the merger, net of	(28)		1,680	1	(1)						
amortization of \$120 Compensation expense					26		(2,141)				(2,1
related to stock options Tax benefit from stock option and stock purchase plan					36 23,373						23,3
Balance, December 31, 2003	8		330,410	166	7,801,170	1,054	(2,141)		(611,921)	(135,000)	7,053,3
Comprehensive income: Net income									25,086		25,0
Unrealized gains (losses) on securities available for sale, net of tax of \$1,851						(3,256)					(3,2
Unrealized losses on foreign currency forward contracts, net of tax of \$4,817						(8,105)					(8,1
Translation adjustment, net of tax of \$2,324 Total comprehensive						3,540					3,5
Issuance of common stock under stock											17,2
option and stock purchase plans, net Issuance of common stock under restricted			6,604 1,266	3 1	132,974 55,491		(55,491)				132,9

stock purchase plan, net

net												
Issuance of common stock from conversion of notes payable due 2019			5,078	3	55,351							55,354
Forfeiture of common stock under restricted stock purchase plan, net			(102)		(4,557)				4,557			_
Issuance of common			(102)		(4,007)				4,007			
stock from treasury, at cost			6,048							(214,259)	354,817	140,558
Repurchase of common stock for treasury, at			(10.00.0)									(70.4.407)
cost			(12,604)								(734,427)	(734,427)
Amortization of deferred stock compensation									16,795			16,795
Tax benefit from stock option and stock purchase plan					144,550	_		_				144,550
Balance, December 31, 2004	8	<u>\$                                    </u>	336,700	<u>\$ 173</u>	\$ 8,184,979	\$	(6,767)	\$	(36,280)	\$ (801,094)	<u>\$ (514,610</u> )	\$ 6,826,401

See accompanying notes to consolidated financial statements.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 1. Summary of Significant Accounting Policies

#### Overview

Biogen Idec creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. We currently have five products:

- AVONEX® (interferon beta-1a) for the treatment of relapsing forms of multiple sclerosis, or MS.
- RITUXAN® (rituximab) and ZEVALIN® (ibritumomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs. We collaborate with Genentech Inc., or Genentech, on the development and commercialization of RITUXAN. RITUXAN is the trade name in the United States, or U.S., Canada and Japan for the compound Rituximab. MabThera is the tradename for rituximab in the European Union, or EU. In these financial statements, we refer to rituximab, RITUXAN and MabThera collectively as RITUXAN, except where we have otherwise indicated.
- TYSABRI® (natalizumab), formerly known as ANTEGREN®, which was approved by the U.S. Food and Drug Administration, or FDA, in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan Corporation plc, or Elan, voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and rheumatoid arthritis, or RA. These decisions were based on reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of progressive multifocal leukoencephalopathy, or PML, a rare and frequently fatal, demyelinating disease of the central nervous system. Both patients received more than two years of TYSABRI in combination with AVONEX. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability.
- AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

We also receive royalty revenues on sales by our licensees of a number of products covered under patents that we control, including on sales by Schering AG of ZEVALIN in EU. In addition, we have a number of ongoing research and development programs in our core therapeutic areas and in other areas of interest.

## Merger

On November 12, 2003, IDEC Pharmaceuticals Corporation and Biogen, Inc. completed a merger transaction, or the Merger, resulting in Biogen, Inc. becoming a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. The Merger was treated as an acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation for accounting purposes. In connection with the Merger, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### **Principles of Consolidation**

The consolidated financial statements include our financial statements and those of our wholly owned subsidiaries. We also consolidate a limited partnership investment, in which we are the majority investor. All material intercompany balances and transactions have been eliminated. On November 12, 2003, we completed the Merger and changed our name to Biogen Idec Inc. (see Note 2, Merger of IDEC Pharmaceuticals Corporation and Biogen, Inc.). Our results of operations for the year ended December 31, 2003 include the results of operations of Biogen, Inc. from November 13, 2003 through December 31, 2003.

#### Use of Estimates

The preparation of consolidated financial statements requires our management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and related allowances, marketable securities, derivatives and hedging activities, inventories, patents, impairment of intangible assets and goodwill, income taxes including the valuation allowance for deferred tax assets, valuation of long-lived assets and investments, research and development, loans, pensions, retiree medical plan, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

#### **Translation of Foreign Currencies**

The functional currency for most of our foreign subsidiaries is the local currency. Assets and liabilities are translated at current rates of exchange. Income and expense items are translated at the average exchange rates for the year. Adjustments resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are accumulated in a separate component of shareholders' equity. The U.S. dollar is the functional currency for certain foreign subsidiaries. Our subsidiaries that have the U.S. dollar as the functional currency are remeasured into U.S. dollars using current rates of exchange for monetary assets and liabilities and historical rates of exchange for nonmonetary assets. Foreign exchange transaction gains and losses are included in the results of operations in other income (expense), net. We had foreign exchange gains totaling \$5.4 million and \$1.3 million for the years ended December 31, 2004 and 2003, respectively.

#### Cash and Cash Equivalents

We consider only those investments which are highly liquid, readily convertible to cash and which mature within three months from date of purchase to be cash equivalents.

### Fair Value of Financial Instruments

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, due from unconsolidated joint business, other current assets, accounts payable, and accrued expenses and other, approximate fair value due to their short-term maturities. Our marketable securities available-for-sale are carried at fair value based on quoted market prices. The fair values of our foreign currency forward contracts are based on quoted market prices or pricing models using current market rates. At December 31, 2004, the fair value of our senior and subordinated notes were \$778.7 million and \$591.0 million, respectively.

## 

#### Inventories

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out ("FIFO") method. Included in inventory are raw materials used in the production of pre-clinical and clinical products, which are expensed as research and development costs when consumed.

The components of inventories for the periods ending December 31 are as follows:

	2004	2003
	(In t	housands)
Raw materials	\$ 48,465	\$ 36,247
Work in process	157,947	443,666
Finished goods	44,604	16,436
	\$ 251,016	\$ 496,349

Our policy is to capitalize inventory costs associated with our products prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Our accounting policy addresses the attributes that should be considered in evaluating whether the costs to manufacture a product have met the definition of an asset as stipulated in FASB Concepts Statement No. 6. We assess the regulatory approval process and where the particular product stands in relation to that approval process including any known constraints and impediments to approval, including safety, efficacy and potential labeling restrictions. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication in which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could possibly hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or cause delay in commercialization. We are sensitive to the significant commitment of capital to scale up production and to launch commercialization strategies. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize.

There is a risk inherent in these judgments, and we would be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by necessary regulatory bodies.

In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of two serious adverse events that occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases, of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine future commercial availability. We cannot predict the outcome of these evaluations. An unfavorable or inconclusive outcome could result in the permanent withdrawal of TYSABRI from the market and termination of clinical studies of TYSABRI, or the re-introduction of TYSABRI to the market with significant restrictions on its permissible uses, blackbox or other significant safety warnings in its label and

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

such other restrictions, requirements and limitations as the FDA may require. While we presently believe that we will be able to find a path forward for TYSABRI, there are no assurances as to the likelihood of success. In light of our inability to predict to the required degree of certainty that our TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we have written down all of the \$19.1 million of TYSABRI inventory that had been included on the balance sheet as of December 31, 2004, which was charged to cost of product revenues. We are continuing to manufacture TYSABRI. Because of the uncertainty described above, in the first quarter of 2005, we also expect to expense between \$22 million (unaudited) and \$25 million (unaudited) of TYSABRI that was manufactured in the first quarter of 2005. In subsequent periods, we will continue to assess TYSABRI to determine if it needs to be expensed in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards. See "Forward Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect Our Growth."

We had no unapproved products capitalized to inventory as of December 31, 2004 or 2003. At December 31, 2004 and 2003, all products that we capitalize to inventory have been approved for sale by either the European Medicines Agency, the regulatory authority in the EU, or EMEA, or FDA.

We periodically review our inventories for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realized value. If the actual realizable value is less than that estimated by us, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-offs may be required. This periodic review led to the write-down of TYSABRI inventory as of December 31, 2004 and the expensing of TYSABRI expected to occur in the first quarter of 2005, as described above, and may lead us to expense TYSABRI in subsequent periods. Also included in product cost of revenues were write-downs of commercial inventory that did not meet quality specifications or become obsolete due to dating expiration, in all cases this product inventory was written-down to its net realizable value. We wrote-down \$46.7 million of unmarketable inventory during 2004, which was charged to cost of product revenues and consisted of \$16.2 million related to AVONEX, \$9.7 million related to ZEVALIN, \$1.7 million related to AMEVIVE and \$19.1 million related to TYSABRI. The AVONEX and AMEVIVE inventory was written-down when it was determined that the inventory did not meet quality specifications. The ZEVALIN inventory was written-down when it was determined that the inventory did not meet quality specifications.

We wrote-down \$173.9 million of unmarketable inventory during 2003, which was charged to cost of product revenues and consisted of \$160.8 million related to AVONEX, \$1.0 million related to AMEVIVE and \$12.1 million related to ZEVALIN. Of the \$160.8 million write-down related to AVONEX, \$149.6 million represented the increase to fair market value in connection with the Merger and \$11.2 million represented the historical manufacturing costs. ZEVALIN was written-down to net realizable value due to product expiration.

The AVONEX inventory that was written-down had been assessed as commercially viable and saleable and there were no known contingent issues at the acquisition date. This inventory was recorded at the estimated selling price less the costs to complete, costs of disposal and a reasonable distribution profit allowance. Our products are required to meet numerous stringent quality specifications that are agreed upon with the FDA at various times prior to and after approval. Based on quality testing performed subsequent to the Merger date, we became aware of certain lots of our pre-filled syringe formulation of AVONEX that previously had been approved for sale, but after additional testing no longer met the established quality specifications. Substantially all of the AVONEX inventory write-down was related to our pre-filled syringe formulation of AVONEX, in which certain lots had aggregate levels that exceeded the approved specifications. As a result of extensive discussions with the FDA, a new set of testing protocols were agreed to and certain lots were deemed unmarketable. Upon management's determination that the inventory was unmarketable, we wrote off the carrying value of the inventory to earnings in the fourth quarter of 2003 because the cost



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

of the inventory would not be recoverable. In 2004, we developed a new pre-filled syringe formulation of AVONEX, which was approved by the EMEA in November 2004 and the FDA in March 2005. We do not expect to experience interruption in the supply of AVONEX. However, we expect to write-down between \$6 million and \$8 million of the remaining supplies of the older formulation in the first quarter of 2005, related to the FDA approval.

#### Marketable Securities

We invest our excess cash balances in short-term and long-term marketable securities, principally corporate notes and government securities. At December 31, 2004, substantially all of our securities were classified as "available-for-sale". All available-for-sale securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive (loss) income in shareholders' equity, net of related tax effects. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are reported in other expense. The cost of available-for-sale securities sold is based on the specific identification method. We have established guidelines that maintain safety and provide adequate liquidity in our available-for-sale portfolio. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. In 2004, we recognized a charge of approximately \$5.7 million for certain unrealized losses on available-for-sale securities that were determined to be other than temporary, because we believe the securities will be sold prior to a potential recovery of their decline in value.

As part of our strategic product development efforts, we invest in equity securities of certain biotechnology companies with which we have collaborative agreements. As a matter of policy, we determine on a quarterly basis whether any decline in the fair value of a marketable security is temporary or other than temporary. Unrealized gains and losses on marketable securities are included in other comprehensive (loss) income in shareholders' equity, net of related tax effects. If a decline in the fair value of a marketable security below our cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value with a charge to current earnings. The factors that we consider in our assessments include the fair market value of the common stock, the duration of the stock's decline, prospects for favorable clinical trial results, new product initiatives and new collaborative agreements.

We also invest in equity securities of certain companies whose securities are not publicly traded and fair value is not readily available. These investments are recorded using the cost method of accounting and are adjusted only for other-than-temporary declines in fair value, distributions of earnings and additional investments. As a matter of policy, we monitor these investments in private securities on a quarterly basis and determine whether any impairment in their value would require a charge to current earnings, based on the implied value from any recent rounds of financing completed by the investee, and general market conditions.

## **Property and Equipment**

Property and equipment are carried at cost, subject to review of impairment for significant assets whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Depreciation is calculated on the straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the useful life or the term of the respective lease. Maintenance costs are expensed as incurred. Buildings and building components are depreciated over estimated useful lives ranging from 15 to 45 years, machinery and equipment from 5 to 15 years, and furniture and fixtures 7 years. We capitalize certain incremental costs associated with the validation effort required for licensing by the FDA of manufacturing equipment for the production of a commercially approved drug. These costs include primarily direct labor and material and are incurred in preparing the equipment for its intended use. The validation costs are amortized over the life of the related equipment.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

The timing of the anticipated licensing and use of the Oceanside facility and the Hillerod facility is dependent upon the commercial availability and potential market acceptance of TYSABRI. If TYSABRI is permanently withdrawn from the market, we would need to evaluate our long-term plans for these facilities. If we are able to reintroduce TYSABRI to the market, we would need to evaluate our requirements for existing inventory and additional manufacturing capacity in light of the approved label and our judgment of the potential U.S. market acceptance of TYSABRI in MS, the probability of obtaining marketing approval of TYSABRI in MS in the EU and other jurisdictions, and the probability of obtaining marketing approval of TYSABRI in additional.

## Intangible Assets and Goodwill

In connection with the Merger (see Note 2), we recorded intangible assets related to patents, trademarks, and core technology as part of the purchase price. These intangible assets were recorded at fair value and at December 31, 2004 net of accumulated amortization and impairments. Intangible assets related to out-licensed patents and core technology are amortized over their remaining estimated useful lives, ranging from 11 to 19 years, based on the greater of the straight-line method or economic consumption each period. These amortization costs are included in "Amortization of acquired intangible assets" in the accompanying consolidated statements of income. Intangible assets related to trademarks have indefinite lives, and as a result are not amortized, but are subject to review for impairment. We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In the third quarter of 2004, management determined that certain clinical trials would not continue which indicated that the carrying value of certain core technology intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AMEVIVE.

Goodwill associated with the Merger represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for by the purchase method of accounting. Goodwill is not amortized, but rather subject to periodic review for impairment. Goodwill is reviewed annually and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. In the fourth quarter of 2004, we performed an assessment of our goodwill, and concluded that goodwill was not impaired as of October 31, 2004. As a result of the voluntary suspension of TYSABRI in February 2005, we have performed an interim review for impairment. We believe that the fair value of our legacy Biogen reporting unit exceeds its carrying value and therefore, we believe goodwill is properly valued. However, should new information arise, we may need to reassess goodwill for impairment in light of the new information and we may be required to take impairment charges related to goodwill.

As of December 31, 2004 and 2003, intangible assets and goodwill, net of accumulated amortization and impairment charges, are as follows (amounts in thousands):

December 31, 2004:	Estimated Life	Fai	r Value	rumulated ortization	 Net
Out-licensed patents	12 years	\$	578,000	\$ 54,589	\$ 523,411
Core/developed technology	15-20 years	-	2,993,000	297,269	2,695,731
Trademarks & tradenames	Indefinite		64,000		64,000
In-licensed patents	7-14 years		12,482	2,797	9,685
Total		\$ 3	3,647,482	\$ 354,655	\$ 3,292,827
Goodwill	Indefinite	\$	1,151,105	\$ 	\$ 1,151,105

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

December 31, 2003:	Estimated Life	]	Fair Value	umulated ortization	_	Net
Out-licensed patents	12 years	\$	578,000	\$ 6,422	\$	571,578
Core/developed technology	15-21 years		3,022,000	26,758		2,995,242
Trademarks & tradenames	Indefinite		64,000			64,000
In-licensed patents	7-12 years		9,482	 1,490		7,992
Total		\$	3,673,482	\$ 34,670	\$	3,638,812
Goodwill	Indefinite	\$	1,151,066	\$ 	\$	1,151,066

Amortization on intangible assets is expected to be in the range of approximately \$276 million to \$323 million for each of the next five years.

#### Impairment of Long-Lived Assets

Long-lived assets to be held and used, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX in MS clinical studies. These events involved two cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system. In light of the two reports of PML, the companies initiated a systematic review of the TYSABRI safety database. On March 30, 2005, we and Elan announced that the review of the safety database led a serious adverse event previously reported by a clinical investigator in a clinical study of TYSABRI in Crohn's disease to be reassessed as PML. The case was originally reported by the investigator as malignant astrocytoma in July 2003. The patient died in December 2003. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and are consulting with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical studies and future commercial availability.

We cannot predict the outcome of these evaluations. An unfavorable or inconclusive outcome could result in the permanent withdrawal of TYSABRI from the market and termination of clinical studies of TYSABRI, or the re-introduction of TYSABRI to the market with significant restrictions on its permissible uses, blackbox or other significant safety warnings in its label and such other restrictions, requirements and limitations as the FDA may require. We have reassessed our long-lived assets related to TYSABRI, such as intangibles and manufacturing facilities, and have determined that there are no impairments related to these assets as a result of the suspension of the marketing of TYSABRI. However, should new information arise, we may be required to take impairment charges related to certain of our long-lived assets.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

#### Loans Receivable

In connection with certain of our research collaborations, we have extended loans or made loan commitments to collaborators. On a quarterly basis, the loans are monitored for potential impairment, based on the probability of the collection of the full amount due under the loan according to each loan's terms. If it is determined that it is not probable that we will be able to collect all interest and principal due, we will recognize a corresponding impairment charge to current earnings.

### **Notes Payable**

In connection with our senior and subordinated notes payable, we capitalized certain issuance costs which are being amortized to interest expenses over the estimated outstanding term of the notes, according to EITF 86-15, "Increasing-Rate Debt." We currently expect that holders of the senior notes due in 2032 will require us to purchase all or a portion of the senior notes on April 29, 2005. As a result, we have reassessed the estimated term of this debt, and recorded additional interest expense of approximately \$7.1 million in the fourth quarter of 2004. We have also classified our senior notes as current liabilities on the consolidated balance sheet as of December 31, 2004. The remaining unamortized issuance costs of approximately \$9.7 million will be amortized through April 29, 2005.

#### **Derivatives and Hedging Activities**

Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities", ("SFAS 133") requires that all derivatives be recognized on the balance sheet at their fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive (loss) income, depending on whether a derivative is designated as part of a hedge transaction and, if it is, the type of hedge transaction. We assess, both at its inception and on an on-going basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows of hedge items. We also assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings to the extent significant. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

#### **Comprehensive Income**

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income", ("SFAS 130"), requires us to display comprehensive income and its components as part of our full set of financial statements. Comprehensive income is comprised of net income (loss) and other comprehensive (loss) income. Other comprehensive (loss) income includes certain changes in equity that are excluded from net income (loss), such as translation adjustments and unrealized holding gains and losses on available-for-sale marketable securities and certain derivative instruments, net of tax.

#### Segment Information

Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information", ("SFAS 131") establishes standards for reporting information on operating segments in interim and annual financial statements. We operate in one segment, which is the business of development, manufacturing and commercialization of novel therapeutics for human health care. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### **Revenue Recognition and Accounts Receivable**

SEC Staff Accounting Bulletin No. 101 ("SAB 101"), superceded in part by SAB 104, provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB 101 establishes the SEC's view that it is not appropriate to recognize revenue until all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured. SAB 104 also requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. We believe that our revenue recognition policies are in compliance with SAB 104.

Product revenue consists of sales from our four products: AVONEX, AMEVIVE, ZEVALIN, and TYSABRI. The timing of distributor orders and shipments can cause variability in earnings. Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer, typically upon delivery. Revenues are recorded net of applicable allowances for returns, patient assistance, trade term discounts, Medicaid rebates, Veteran's Administration rebates, and managed care discounts and other applicable allowances. Included in our consolidated balance sheets at December 31, 2004 and 2003, are allowances for returns, rebates, discounts and other allowances which totaled \$33.8 million and \$20.8 million, respectively. At December 31, 2004, our allowance for product revenues was \$5.2 million. In 2004, total discounts and allowances were approximately 1.8% of total current assets and less than 1% of total assets. We prepare our estimates for sales returns and allowances, discounts and rebates quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate.

For the years ended December 31, 2004, 2003, and 2002, we recorded \$169.3 million, \$13.9 million and \$0.7 million, respectively, in our consolidated statements of income related to sales returns and allowances, discounts, and rebates. In 2004, the amount of product returns was approximately 1% of product revenue for all our products. Product returns were \$17.4 million, \$3.7 million and \$0.5 million for 2004, 2003 and 2002, respectively. Product returns in 2004 included \$3.2 million related to product sales made prior to 2004. During 2004, we had encountered problems in manufacturing our pre-filled syringe formulation of AVONEX. As a result, we had an increase in our expected level of returns related to batches that failed to meet specifications.

In November 2004, we received regulatory approval in the U.S. of TYSABRI for the treatment of MS and paid a \$7.0 million approval-based milestone to Elan. Upon approval, we also became obligated to provide Elan with \$5.3 million in credits for payments on certain purchases of TYSABRI and for reimbursement of commercialization costs. Elan can apply \$1.5 million of the credits per year. The approval and credit milestones were capitalized upon approval in investments and other assets and are being amortized over the remaining patent life of 15.7 years. The amortization of the approval and credit milestones is being recorded as a reduction of revenue. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification.

Under our agreement with Elan, we manufacture TYSABRI and, in the U.S. prior to the suspension, sold TYSABRI to Elan who then distributed TYSABRI to third party distributors. In the U.S., we record revenue when TYSABRI is shipped from Elan to third party distributors. In December 2004, we recorded \$3.1 million of product revenues related to sales of TYSABRI to Elan. Additionally, as of December 31, 2004, we deferred \$1.9 million in revenue related to sales of TYSABRI which had not yet been shipped by Elan. As of December 31, 2004, Elan owed us \$34.4 million, representing commercialization and development expenses incurred by us, which is included in other current assets on our consolidated balance sheets. We received the entire \$34.4 million from Elan in the first quarter of 2005 related to the receivable.

Revenues from unconsolidated joint business consist of our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech, reimbursement from Genentech of our

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

RITUXAN-related sales force and development expenses and royalties from Genentech for sales of RITUXAN outside the U.S. by Roche and Zenyaku. Under the copromotion arrangement, all U.S. sales of RITUXAN and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our amended and restated collaboration agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking U.S. net sales of RITUXAN to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. In June 2003, we amended and restated our collaboration agreement with Genentech to include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to RITUXAN, for a broad range of indications. Upon approval of the first new anti-CD20 product, the pretax copromotion profit-sharing formula for RITUXAN and other anti-CD20 products will change over a period of time to a fixed annual profit-sharing percentage at the lower tier. Currently, we record our share of expenses incurred for the development of new anti-CD20 products in research and development expense until such time as a new product is approved, at which time we will record our share of pretax copromotion profits related to the new product in revenues from unconsolidated joint business. We record our royalty revenue on sales of RITUXAN outside the U.S. on a cash basis. Under the amended and restated collaboration agreement, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20

In February 2002, the FASB Emerging Issues Task Force, or EITF, released EITF Issue No. 01-09 ("EITF 01-09"), "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)". EITF 01-09 states that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement, rather than a sales and marketing expense. We have various contracts with distributors that provide for discounts and rebates. These contracts are classified as a reduction of revenue. We also maintain select customer service contracts with distributors and other customers in the distribution channel. In accordance with EITF 01-09, we have established the fair value of these contracts and, as provided by EITF 01-09, classified these customer service contracts as sales and marketing expense. If we had concluded that sufficient evidence of the fair value did not exist for these contracts, we would have been required to classify these costs as a reduction of revenue.

We receive royalty revenues under license agreements with a number of third parties that sell products based on technology we have developed or to which we have rights. The license agreements provide for the payment of royalties to us based on sales of the licensed product. We record these revenues based on estimates of the sales that occurred during the relevant period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties we have been paid (adjusted for any changes in facts and circumstances, as appropriate). We maintain regular communication with our licensees in order to gauge the reasonableness of our estimates. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period which they become known, typically the following quarter. Historically, adjustments have not been material based on actual amounts paid by licensees. There are no future performance obligations on our part under these license agreements. To the extent we do not have sufficient ability to accurately estimate revenue, we record it on a cash basis.

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

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, facilities costs, overhead costs, clinical trial and related

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

clinical manufacturing costs, contract services and other outside costs. Research and development costs, including upfront fees and milestones paid to collaborators, are expensed as incurred. We have entered into certain research agreements in which we share costs with our collaborator. We have entered into other collaborations where we are reimbursed for work performed by our collaborative partners. We record these costs as research and development expenses. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments by the collaborator for their share of the development effort as a reduction of research and development expense. If the arrangement is a reimbursement of research and development costs, we record the reimbursement as corporate partner revenue.

#### Reclassification

Certain reclassifications of prior years amounts have been made to conform to current year presentation.

#### Earnings per Share

We calculate earnings (loss) per share in accordance with Statement of Financial Accounting Standards No. 128, "Earnings per Share," or SFAS 128, and EITF 03-06, "Participating Securities and the Two-Class Method Under SFAS 128." SFAS 128 and EITF 03-06 together require the presentation of "basic" earnings (loss) per share and "diluted" earnings (loss) per share. Basic earnings (loss) per share is computed using the two-class method. Under the two-class method, undistributed net income is allocated to common stock and participating securities based on their respective rights to share in dividends. We have determined that our preferred shares meet the definition of participating securities, and have allocated a portion of net income to our preferred shares on a pro rata basis. Net income allocated to preferred shares is excluded from the calculation of basic earnings (loss) per share. For basic earnings (loss) per share, net income (loss) available to holders of common stock is divided by the weighted average number of shares of common stock outstanding. For purposes of calculating diluted earnings (loss) per share, net income (loss) is adjusted for the after-tax amount of interest associated with convertible debt and net income allocable to preferred shares, and the denominator includes both the weighted average number of shares of common stock outstanding and the number of dilutive common stock equivalents such as stock options, unvested restricted stock awards and other convertible securities, to the extent they are dilutive.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

Basic and diluted earnings (loss) per share for the periods ending December 31 are calculated as follows (table in thousands):

	2004 2003		2003		2004 2003		2004 2003		 2002
Numerator:									
Net income (loss)	\$	25,086	\$	(875,097)	\$ 148,090				
Adjustment for net income allocable to preferred stock		37		—	2,687				
Net income (loss) used in calculating basic earnings (loss) per share	\$	25,049	\$	(875,097)	\$ 145,403				
Adjustment for interest, net of interest capitalized and tax				—	4,926				
Net income (loss) used in calculating diluted earnings (loss) per share	\$	25,049	\$	(875,097)	\$ 150,329				
Denominator:									
Weighted average number of common shares outstanding		334,996		177,982	153,086				
Effect of dilutive securities:									
Stock options		7,600			9,783				
Restricted stock awards		879			—				
Convertible promissory notes due 2019	_	_			 13,936				
Dilutive potential common shares		8,479			23,719				
Shares used in calculating diluted earnings (loss) per share		343,475		177,982	 176,805				

The following amounts were not included in the calculation of net income (loss) per share because their effects were anti-dilutive for the periods ending December 31 (table in thousands):

	2004	2003	2002
Numerator:			
Net income allocable to preferred shares	\$ 37	\$ —	\$ 2,687
Adjustment for interest, net of tax	3,762	9,378	5,605
Total	\$ 3,799	\$ 9,378	\$ 8,292
Denominator:			
Stock options	5,080	7,103	—
Convertible preferred stock	247	2,173	2,829
Convertible promissory notes due 2019	4,563	13,935	
Convertible promissory notes due 2032	2,165	8,661	5,917
Total	12,055	31,872	8,746

## Accounting for Stock Based Compensation

We have several stock-based compensation plans which are described more fully in Note 12. We apply APB Opinion No. 25 "Accounting for Stock Issued to Employees" in accounting for our plans and apply Statement of Financial Accounting Standards No. 123 "Accounting for Stock Issued to Employees," or SFAS 123, as amended by Statement of Financial Accounting Standards No. 148 "Accounting for Stock-Based Compensation — Transition and Disclosure", or SFAS 148, for disclosure purposes only. The SFAS 123 disclosures include pro forma net income and earnings per share as if the fair value-based method



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

of accounting had been used. Stock-based compensation issued to non-employees is accounted for in accordance with SFAS 123 and related interpretations.

If compensation cost for awards issued in 2004, 2003 and 2002 under the stock-based compensation plans, including costs related to prior years' awards, had been determined based on SFAS 123, as amended by SFAS 148, our pro forma net income (loss), and pro forma earnings (loss) per share for the years ending December 31, would have been as follows:

	 2004 2003 (In thousands, except			lata)	2002
Reported net income (loss)	\$ 25,086	\$	(875,097)	\$	148,090
Stock based compensation included in net income (loss)	16,795		—		
Pro forma stock compensation expense, net of tax	(76,421)		(51,850)		(54,662)
Pro forma net income (loss)	\$ (34,540)	\$	(926,947)	\$	93,428
Reported basic earnings (loss) per share	\$ 0.07	\$	(4.92)	\$	0.95
Pro forma basic earnings (loss) per share	\$ (0.10)	\$	(5.21)	\$	0.60
Reported diluted earnings (loss) per share	\$ 0.07	\$	(4.92)	\$	0.85
Pro forma diluted earnings (loss) per share	\$ (0.10)	\$	(5.21)	\$	0.53

The fair value of each option granted under our stock-based compensation plans and each purchase right granted under our employee stock purchase plan is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	 Option Grants				
	 2004		2003		2002
Expected dividend yield	0%		0%		0%
Expected stock price volatility	42%		41%		48%
Risk-free interest rate	3.4%		2.8%		2.7%
Expected option life in years	5.4		5.8		5.8
Per share grant date fair value	\$ 19.93	\$	16.41	\$	28.90

		Purch	ase Rights	
	2004		2003	 2002
Expected dividend yield	0%		0%	0%
Expected stock price volatility	41%		48%	48%
Risk-free interest rate	1.4%		1.3%	1.0%
Expected option term in years	0.24 - 1.5		0.13 - 2.0	0.3 - 2.0
Per share grant date fair value	\$ 11.34	\$	21.46	\$ 19.73

The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. SFAS 123 did not apply to awards prior to 1995, and additional awards in future years are anticipated. Additionally, in December 2004, new accounting guidance was issued which will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of income based on their fair values, effective June 15, 2005. See "Note 17 — New Accounting Pronouncements" for a more complete description of this new accounting guidance and the potential impact it will have on our financial statements.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

#### 2. Merger of IDEC Pharmaceuticals Corporation and Biogen, Inc.

On November 12, 2003, IDEC Pharmaceuticals Corporation and Biogen, Inc. entered into the Merger. The Merger was treated as an acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation for accounting purposes. In connection with the Merger, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc.

As a result of the Merger, Biogen, Inc. stockholders received 1.15 shares of Biogen Idec common stock for each share of Biogen, Inc. common stock. As a result, Biogen Idec issued approximately 171.9 million shares of common stock at a fair value of approximately \$6.48 billion. In addition, options to purchase Biogen, Inc. common stock outstanding at November 12, 2003 were assumed by Biogen Idec and converted into options to purchase approximately 20.7 million shares of Biogen Idec common stock at a fair value of approximately \$295 million. We paid approximately \$19.9 million in fees for banking, legal, accounting and tax related services related to the Merger. Merger related fees paid by Biogen, Inc. prior to completion of the Merger are not included in this amount as they were expensed as incurred. The total Merger purchase price was approximately \$6.8 billion. The Merger qualifies as a tax-free reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

### Purchase price

The purchase price is as follows (table in thousands):

Fair value of Biogen Idec common stock	\$ 6,480,339	
Fair value of replacement stock options	295,399	
Cash paid for fractional shares	27	
Acquisition related costs	19,872	
Total purchase price	\$ 6,795,637	
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The fair value of Biogen Idec's shares used in determining the purchase price was \$37.69 per share based on the average of the closing price of IDEC Pharmaceuticals Corporation's common stock for the period two days before through two days after the announcement of the Merger on June 23, 2003. The fair value of assumed stock options was determined using the Black-Scholes option pricing model with the following assumptions: stock price of \$37.69, which is the value ascribed to IDEC Pharmaceutical Corporation's common stock in determining the purchase price; volatility of 40%; risk-free interest rate of 1.8%; and an expected life of 4.0 years.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

#### Purchase price allocation

The purchase price has been allocated to the acquired tangible and intangible assets and liabilities based on their fair values as of November 12, 2003, the date that the Merger was consummated (table in thousands):

Inventory	\$ 706,957
Accounts receivable	216,221
Property, plant and equipment	713,719
Acquired identifiable intangible assets	3,664,000
Goodwill	1,151,105
In-process research and development	823,000
Deferred stock-based compensation	2,261
Other current and long-term assets	1,106,112
Assumed liabilities	(424,648)
Increase benefit plan liability to fair value	(26,650)
Deferred tax liabilities arising from fair value adjustments	(1,136,440)
Total purchase price	\$ 6,795,637

The allocation of the purchase price was based, in part, on a third-party valuation of the fair value of in-process research and development, identifiable intangible assets, and certain property, plant and equipment. The excess of the purchase price over the fair value of assets and liabilities acquired is allocated to goodwill. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. These assumptions are based on the best available information that we had at the time.

### Identifiable intangible assets

The amount allocated to acquired identifiable intangible assets has been attributed to the following categories (table in thousands):

Patents	\$ 578,000
Trademarks	64,000
Core Technology	3,022,000
	\$ 3,664,000

The estimated fair value attributed to core technology, which relates to Biogen, Inc.'s existing FDA-approved products, was determined based on a discounted forecast of the estimated net future cash flows to be generated from the technology. The estimated fair value attributed to core technology will be amortized over 15 to 20 years, which is the estimated period over which cash flows will be generated from the technology.

The estimated fair value attributed to patents represents only those patents from which Biogen, Inc. derives cash flows through contractual third-party outlicensing activity and not patents related to Biogen, Inc.'s current product portfolio or in-process research projects. The estimated fair value was determined based on a discounted forecast of the estimated net future cash flows to be generated from the patents. The estimated fair value attributed to patents is being amortized over 12 years, which is the estimated period over which cash flows will be generated from the patents.

The amount allocated to in-process research and development, or IPR&D, represents an estimate of the fair value of purchased in-process technology for research projects that, as of the date of the Merger, had not



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

reached technological feasibility and have no alternative future use. Only those research projects that had advanced to a stage of development where management believed reasonable net future cash flow forecasts could be prepared and a reasonable likelihood of technical success existed were included in the estimated fair value. As of the date of the Merger, the IPR&D primarily represented the estimated fair value of TYSABRI, which is currently in Phase III development for Crohn's disease, and was approved by the FDA in November 2004 for MS. In February 2005, we suspended the marketing and commercial distribution of TYSABRI, and suspended dosing of TYSABRI in clinical trials. See "Note 1 — Summary of Significant Accounting Policies — Overview" for a discussion on the TYSABRI suspension. The estimated fair value of the IPR&D was determined based on a discounted forecast of the estimated net future cash flows for each project, adjusted for the estimated probability of technical success and FDA approval for each research project. IPR&D was expensed immediately following consummation of the Merger.

### Pro forma results of operations (unaudited)

The following unaudited pro forma information presents a summary of the historical consolidated statements of income of IDEC Pharmaceuticals Corporation and Biogen, Inc. for the years ended December 31, 2003 and 2002, giving effect to the merger as if it occurred on January 1, 2002 and 2003 (in thousands, except per share amounts):

	 Year Ended December 31,			
	2003		2002	
Product sales	\$ 1,228,493	\$	1,048,068	
Total revenue	1,853,233		1,552,586	
Net loss	(243,929)		(168,476)	
Pro forma earnings (loss) per share:				
Basic	(0.75)		(0.52)	
Diluted	(0.75)		(0.52)	

The pro forma net income (loss) and income (loss) per share for the periods presented exclude the acquired IPR&D charge of \$823.0 million. Amortization of the acquired intangibles is included on a straight-line basis. This unaudited pro forma information does not purport to indicate the results that would have actually been obtained had the Merger been completed on the assumed date or for the period presented, or which may be realized in the future. To produce the pro forma financial information, Biogen Idec allocated the purchase price using its best estimates of fair value. These estimates are based on the information that was available at the purchase date.

#### 3. Financial Instruments

Financial instruments that potentially subject us to concentrations of credit risk are accounts receivable and marketable securities. Wholesale distributors and large pharmaceutical companies account for the majority of our accounts receivable and collateral is generally not required. We also sell ZEVALIN to radiopharmacies throughout the U.S., and collateral is generally not required. To mitigate the risk, we monitor the financial performance and credit worthiness of our customers. We invest our excess cash balances in marketable debt securities, primarily U.S. government securities and corporate bonds and notes, with strong credit ratings. We limit the amount of investment exposure as to institution, maturity and investment type.

The average maturity of our marketable securities as of December 31, 2004 and 2003 was 20 months and 16 months, respectively. Proceeds from maturities and other sales of marketable securities, which were primarily reinvested, for the years ended December 31, 2004, 2003, and 2002 were approximately \$3.2 billion, \$1.1 billion, and \$841.0 million, respectively. Realized losses on these sales for the years ended December 31, 2004, 2003, and 2002 were \$4.1 million, \$2.1 million, and \$2.8 million, respectively.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following is a summary of marketable securities:

	 Fair Value	Un	Gross realized <u>Gains</u> (In tho	Ur	Gross irealized Losses	 Amortized Cost
December 31, 2004:						
Corporate debt securities						
Current	\$ 436,719	\$	2	\$	(405)	\$ 437,122
Noncurrent	619,454		90		(3,793)	623,157
U.S. Government securities						
Current	411,776		8		(203)	411,971
Noncurrent	490,170		333		(4,657)	494,494
Total securities available-for-sale	\$ 1,958,119	\$	433	\$	(9,058)	\$ 1,966,744
Other marketable securities, noncurrent	\$ 29,434	\$	7,369	\$		\$ 22,065

	]	Fair Value	Un	Gross realized Gains	Ur	Gross rrealized Losses		Amortized Cost
December 21, 2002			(In thousands)					
December 31, 2003:								
Foreign debt								
Current	\$	10,102	\$	30	\$	—	\$	10,072
Corporate debt securities								
Current		347,865		883		(9)		346,991
Noncurrent		768,840		3,280		(520)		766,080
U.S. Government securities								
Current		163,142		733		(4)		162,413
Noncurrent		733,487		2,680		(511)		731,318
Total securities available-for-sale	\$	2,023,436	\$	7,606	\$	(1,044)	\$	2,016,874
Other marketable securities, noncurrent	\$	27,115	\$	138	\$	(2,789)	\$	29,766

The amortized cost and estimated fair value of securities available-for-sale at December 31, 2004 by contractual maturity are as follows:

5	0.40.000	-	
P	849,093	\$	848,495
	1,117,651		1,109,624
5	1,966,744	\$	1,958,119
\$		1,966,744	1,966,744 \$

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Unrealized losses for which other-than-temporary losses have not been recognized at December 31, 2004 consist of the following (in thousands):

		Less than	12 Month	IS	 12 Months	s or Grea	ter	 Total		
		Fair Value		realized Losses	Fair Value		realized Losses	 Fair Value		nrealized Losses
Corporate debt securities	\$	865,097	\$	(3,796)	\$ 57,097	\$	(402)	\$ 922,194	\$	(4,198)
U.S. Government securities		672,839		(4,393)	 111,560		(467)	 784,399		(4,860)
	<b>\$</b> 1	1,537,936	\$	(8,189)	\$ 168,657	\$	(869)	\$ 1,706,593	\$	(9,058)

Unrealized losses relate to various debt securities, including U.S. government issues, corporate bonds and asset-backed securities. The unrealized losses on these securities were primarily caused by higher interest rates, and represent less than 1% of the total fair value of the portfolio. We believe these unrealized losses are not other-than-temporary, and have the intent and ability to hold these securities with unrealized losses to maturity or to recovery. In 2004, we recognized a charge of approximately \$5.7 million for certain unrealized losses on available-for-sale securities that were determined to be other-than-temporary, because we believe the securities will be sold prior to a potential recovery of their decline in value.

We have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies. All foreign currency forward contracts have durations of ninety days to 12 months. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in other comprehensive income. Realized gains and losses for the effective portion are recognized with the underlying hedge transaction. We assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings to the extent significant. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument and any related unrealized gain or loss on the contract is recognized in current earnings. The notional settlement amount of the foreign currency forward contracts outstanding at December 31, 2004 was approximately \$164.3 million. These contracts had a fair value of \$18.1 million, representing an unrealized loss, and were included in other current liabilities at December 31, 2004. The notional settlement amount of the foreign currency forward contracts outstanding at December 31, 2003 was approximately \$109.4 million. These contracts had a fair value of \$5.9 million, representing an unrealized loss, and were included in other current liabilities at December 31, 2003.

In 2004, approximately \$0.9 million of losses were recognized in earnings due to hedge ineffectiveness. We recognized \$5.5 million of losses in product revenue and \$0.5 million of losses in royalty revenue for the settlement of certain effective cash flow hedge instruments at December 31, 2004. These settlements were recorded in the same period as the related forecasted transactions affecting earnings. We expect approximately \$18.1 million of unrealized losses at December 31, 2004 to affect earnings in 2005 related to our foreign currency forward contracts.

In 2003, there were no losses recognized in earnings due to hedge ineffectiveness or as a result of the discontinuance of cash flow hedges upon determining that it was no longer probable that the original forecasted transaction would occur. We recognized \$1.3 million of losses in product revenue and \$0.5 million of losses in royalty revenue for the settlement of certain effective cash flow hedge instruments at December 31, 2003. These settlements were recorded in the same period as the related forecasted transactions affecting earnings.

We had no forward currency forward contracts during 2002.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 4. Notes Payable

In April and May 2002, we issued 30-year senior convertible promissory notes, or senior notes, for gross proceeds of approximately \$714.4 million, or \$696.0 million net of underwriting commissions and expenses of \$18.4 million. Simultaneously with the issuance of the senior notes, we used a portion of the proceeds to fund the repurchase of \$135 million of our outstanding common stock. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. We will pay contingent cash interest to the holders of these senior notes during any nine-month period commencing on or after April 30, 2007 if the average market price of the senior notes for a five-trading-day measurement period preceding such nine-month period equals 120% or more of the sum of the issue price and accrued original issue discount for such senior note. The contingent interest payable per senior note with respect to any quarterly period within such nine-month period where contingent interest is determined to be payable will equal the greater of (1) the amount of regular cash dividends paid by us per share on our common stock during that quarterly period multiplied by the then applicable conversion rate or (2) 0.0625% of the average market price of a senior note for the five-trading-day measurement period, provided that if we do not pay regular cash dividends during a semiannual period, we will pay contingent interest semiannually at a rate of 0.125% of the average market price of a senior note for the five-trading-day measurement period.

Upon maturity, the senior notes will have an aggregate principal face value of \$1.2 billion. Each \$1,000 aggregate principal face value senior note is convertible at the holder's option at any time through maturity into 7.1881 shares of our common stock at an initial conversion price of \$82.49, resulting in total potential common shares to be issued upon conversion of 8.7 million shares. In addition, holders of the senior notes may require us to purchase all or a portion of the senior notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable in cash. We expect that on April 29, 2005, holders of the senior notes will require us to purchase all or a portion of the senior notes of approximately \$809 million. This outflow includes payments of the aggregate purchase price of the notes of approximately \$753 million plus the payment of tax for which deferred tax liabilities have been previously established related to additional deductible interest expense. As a result, these senior notes are included in notes payable under current liabilities in our consolidated balance sheets. In addition, if a change in control in our company occurs on or before April 29, 2007, holders may require us to purchase all or a portion of the issue price plus the accrued original issue discount to the date of redemption, all or a portion of the senior notes for cash at any time on or after April 29, 2007.

In February 1999, we raised through the issuance of our subordinated notes, approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The subordinated notes were priced with a yield to maturity of 5.5% annually. Upon maturity, the subordinated notes issued in February 1999 had an aggregate principal face value of \$345.0 million. As of December 31, 2004, our remaining indebtedness under the subordinated notes was approximately \$219.2 million at maturity, due to conversion of subordinated notes into common stock.

Each \$1,000 aggregate principal face value subordinated note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36 per share. Additionally, the holders of the subordinated notes may require us to purchase the subordinated notes on February 16, 2009 or 2014 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, with us having the option to repay the subordinated notes plus accrued original issue discount in cash, common stock or a combination of cash and stock. We have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the subordinated notes for cash at any time. During 2004, holders of subordinated notes with a face value of approximately \$125.7 million elected to convert their subordinated notes to approximately 5.1 million shares

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of our common stock. To date, in the first quarter of 2005, holders of subordinated notes with a face value of approximately \$18.1 million elected to convert their subordinated notes to approximately 0.7 million shares of our common stock.

Notes payable at December 31, consists of the following:

	 2004		2003	
	(In thousands)			
Current liabilities:				
30-year senior convertible promissory notes, due 2032 at 1.75%	\$ 748,430	\$	_	
	\$ 748,430	\$	_	
Long-term liabilities:				
20-year subordinated convertible promissory notes, due 2019 at 5.5%	\$ 101,879	\$	151,772	
30-year senior convertible promissory notes, due 2032 at 1.75%	 		735,498	
	\$ 101,879	\$	887,270	

## 5. Consolidated Balance Sheets Details

### **Property and equipment:**

		December 31,			
	2004 2003			2003	
		(In thou	sands)		
Land	\$	127,411	\$	90,282	
Buildings		476,615		305,326	
Leasehold improvements		58,945		57,907	
Furniture and fixtures		36,348		15,808	
Machinery and equipment		546,101		401,642	
Construction in progress		436,750		450,122	
Total cost		1,682,170		1,321,087	
Less accumulated depreciation		156,945		68,304	
	\$	1,525,225	\$	1,252,783	

Depreciation expense was \$92.0 million, \$26.7 million and \$10.2 million for 2004, 2003 and 2002, respectively.

During 2004 and 2003, we capitalized to construction in progress approximately \$8.8 million and \$6.8 million, respectively, of interest costs primarily related to the development of our West Coast headquarters and research and development campus in San Diego, California and our large-scale manufacturing facility in Oceanside, California.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Accrued expenses and other:

	 December 31,			
	2004 200			
	(In thousands)			
Employee compensation and benefits	\$ 68,002	\$	55,277	
Royalties and licensing fees	45,201		42,074	
Clinical development expenses	20,564		19,303	
Construction costs			21,888	
Legal settlement costs			20,000	
Unrealized losses on foreign currency contracts	18,051		5,926	
Other	95,984		75,662	
	\$ 247,802	\$	240,130	

### 6. Employee Benefit Plans

#### 401(k) Employee Savings Plan

We maintain a 401(k) Savings Plan, or 401(k) Plan, an employee savings plan, available to substantially all U.S. regular employees over the age of 21. Participants may make voluntary contributions. We make matching contributions according to the 401(k) Plan's matching formula. The matching contributions vest over four years of service by the employee. The Plan also provides for certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. Employer contributions for the years ended December 31, 2004, 2003 and 2002 totaled \$11.4 million, \$2.4 million and \$1.8 million, respectively.

#### **Deferred Compensation Plan**

We maintain the Voluntary Executive Supplemental Savings Plan, a non-qualified deferred compensation plan that allows a select group of management and highly compensated U.S. employees to defer a portion of their compensation and that provides for certain company credits to participants' accounts. The deferred compensation amounts are accrued when earned but are unfunded. Such deferred compensation is distributable in cash in accordance with the Plan. Deferred compensation amounts under such plan at December 31, 2004 and 2003, totaled approximately \$33.4 million and \$17.6 million, respectively, and is included in other long-term liabilities in the accompanying consolidated balance sheets. Participant contributions are immediately 100% vested. Certain employer credits to participants' accounts are subject to vesting schedules. Distributions to participants can be either in a one lump sum payment or annual installments as elected by the participants.

### **Retiree Medical Plan**

We have had a program since 2003, prior to the Merger, in which we provide medical plan benefits to former IDEC retirees under 65. In 2004, former Biogen retirees began participation in this plan. Our obligation is funded on a pay-as-you-go basis and there are no plan assets. Our liability at December 31, 2004 related to this program was approximately \$2.4 million.

#### Pension

In connection with the Merger, we assumed Biogen, Inc.'s Retirement Plan, a tax-qualified defined benefit pension plan. Prior to November 13, 2003, we did not have a pension plan. Prior to the Merger, the



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

Retirement Plan covered substantially all of Biogen, Inc.'s regular U.S. employees and provided compensation credits and interest credits to participants' Retirement Plan accounts using a cash balance method.

We also assumed Biogen, Inc.'s unfunded Supplemental Executive Retirement Plan, or SERP, which covered a select group of highly compensated U.S. employees. The plans are noncontributory. The Retirement Plan's benefit formula was based on employee earnings and age. The SERP provided benefits for covered executives in excess of those permitted under the tax-qualified Retirement Plan. Biogen, Inc.'s funding policy for the plans has been to contribute amounts deductible for federal income tax purposes. Funds contributed to the plans have been invested in fixed income and equity securities. At October 31, 2003, Biogen, Inc. ceased allowing new participants into the plans. Effective December 31, 2003, we amended the Plan so that no further benefits would accrue to participants.

We credited participants' cash balance accounts under the Retirement Plan for compensation and interest earned through December 31, 2003. After that date, no further compensation credits will be made, but interest credits will be made until Retirement Plan benefits have been distributed to participants.

We credited participants' accounts under the SERP for compensation and interest earned through December 31, 2003. No further compensation credits will be made, but interest credits will be made until SERP is terminated.

In connection with the termination of the Retirement Plan, we requested an Internal Revenue Service, or IRS, ruling that the Plans' terminations did not adversely affect its tax-qualified status. During 2004, our management decided to accelerate the payment and to pay out participants' benefits as soon as administratively possible. In December 2004, we began distributing to employees their respective Retirement Plan benefits. Participants had the following options with respect to the value of their Plan distribution: (a) to receive an immediate lump sum payment which may be rolled over into the 401(k) Plan or other designated qualified plan or individual retirement account, or (b) to receive an annuity that would begin either immediately or at a deferred date.

During 2004, we incurred charges of approximately \$2.1 million related to transition benefits associated with the plan termination, and plan curtailment costs and additional premium costs related to the annuity transfer of approximately \$3.0 million, which are included in our results of operations for 2004. At December 31, 2004 we had a liability of \$14.1 million related to these plans, including \$7.7 million for related to transition benefits associated with the Retirement Plan terminations.

The components of net periodic pension cost for the years ended December 31, 2004 and 2003 are summarized below (table in thousands):

		Pension Benefit
	2004	2003
Service cost	\$	— \$ 511
Interest cost	2,	479 332
Expected return on plan assets	(1,	955) (149)
Amortization of prior service cost		
Amortization of net actuarial loss		(40) —
Net pension cost	\$	484 \$ 694

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Reconciliations of projected benefit obligations, fair value of plan assets and the funded status of the plans as of December 31, are presented below (table in thousands):

		Pension Benefits		 Other Benef			
		2004		2003	 2004		2003
Change in projected benefit obligation							
Net projected benefit obligation at December 31 and November 13,							
2003	\$	(52,444)	\$	(51,964)	\$ —	\$	—
Service cost		—		(511)	(2,430)		—
Interest cost		(2,478)		(332)	—		—
Actuarial gain (loss)		(2,212)		353	—		—
Transfers		12,408			—		—
Gross benefits paid	_	37,212		10	 22		
Net projected benefit obligation at the end of the year		(7,514)		(52,444)	 (2,408)		
Change in plan assets							
Fair value of plan assets at the beginning of the year		38,431		28,639	—		
Actual return on plan assets		433		(202)	_		
Employer contributions		11,032		10,004	—		—
Transfers		(12,408)			—		
Gross benefits paid		(37,212)		(10)	 		_
Fair value of plan assets at the end of the year		276		38,431	 		_
Reconciliation of funded status							
Funded status at the end of the year		(7,239)		(14,013)	(12,676)		
Unrecognized net actuarial gain		796		(2)	2,689		
Unrecognized prior service cost		—			7,579		
Net amount recognized at the end of the year	\$	(6,443)	\$	(14,015)	\$ (2,408)	\$	
Weighted average assumptions at the end of the year							
Discount rate		5.56%		5.68%	4.75%		6.25%
Expected return on plan assets		5.12%		5.63%			
Rates of compensation increase		—					—

As of December 31, 2004, the unfunded supplemental retirement plan has a projected benefit of \$4.8 million. At December 31, 2003, the unfunded supplemental retirement plan had a projected benefit of \$6.6 million.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

Amounts recognized in the statements of financial position consist of (in thousands):

	Pensio	n Benefits	Other Be	Benefits	
	2004	2003	2004	2003	
Prepaid Benefit Cost	\$ —	\$ —	\$ —	\$ —	
Accrued Benefit Cost	(7,239)	(14,015)	(2,408)	—	
Intangible Assets	—	—	—		
Accumulated other comprehensive income	796	—		_	
Net Amount Recognized	\$ (6,443)	\$ (14,015)	\$ (2,408)	\$ —	

The accumulated benefit obligation for all defined benefit pension plans was \$7.5 million at December 31, 2004. The accumulated benefit obligation for all defined benefit pension plans was \$52.4 million at December 31, 2003.

#### Assumptions

The weighted-average assumptions used to determine net periodic benefit cost for 2004 and the period November 12, 2003 through December 31, 2003 were:

	2004	2003
Discount Rate	5.69%	5.63%
Expected long-term return on plan assets	5.12%	5.00%
Rate of compensation increase	N/A	N/A

The expected return on assets was determined based on the average rate of earnings expected to be earned reflecting the plan's current allocation.

Weighted-average assumptions used to determine pension benefit obligations were:

	December 31, 2004	December 31, 2003
Discount Rate	5.56%	5.69%
Rate of compensation increase	N/A	N/A

Weighted-average assumptions used to determine postretirement benefit obligation for the medical plan were:

	December 31, 2004	December 31, 2003
Discount Rate	4.75%	6.25%
Health Care Trend	9.00%	10.00%
Years to Ultimate Trend Rate	4.0	5.0

The discount rates used for the retiree medical plan were based on an average yield of bonds between the 10<sup>th</sup> to 90<sup>th</sup> percentile in the six to eight year maturity group. A 1% decrease in the assumed health care trend rate would have the effect of approximately \$1.7 million on the postretirement benefit obligation, and approximately \$0.2 million on the total service cost and interest.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### Plan Assets

The Biogen Retirement Plan weighted-average asset allocations by asset category are as follows:

	December 31, 2004	December 31, 2003
Equity securities	—	—
Debt securities	—	11.9%
Real estate	—	—
Cash and cash equivalents	100.0%	88.1%
Total	100.0%	100.0%

## Contributions

In January 2005, we made a contribution of \$1.2 million to the Biogen Retirement Plan to cover the remaining lump sum benefit payments. We do not expect to make any additional contributions to the Plan in 2005.

### **Expected Benefit Payments**

Benefit payments of approximately \$1.8 million are expected to be paid out from the Retirement Plan during 2005, which should complete the distribution of remaining benefit payments.

## 7. Other Income (Expense), Net

Total other income (expense), net consists of the following:

		De	cember 31,				
	 2004		2003				2002
		(In	thousands)				
Interest income	\$ 57,225	\$	33,610	\$	34,528		
Interest expense	(18,898)		(15,182)		(16,073)		
Other expense	(17,650)		(29,383)		(809)		
Total other income (expense), net	\$ 20,677	\$	(10,955)	\$	17,646		

Other expense included the following:

	December 31,						
		2004		2003		2002	
			(In the	ousands)			
Impairments of marketable securities	\$	(18,482)	\$	—	\$	—	
Foreign exchange remeasurement gains		5,353		1,319			
Loss on sale of marketable securities available-for-sale		(4,090)					
Gain on investments in executive deferred compensation plan		1,029				—	
Donation to Biogen Idec Foundation				(10,000)			
Settlement of patent disputes				(20,668)		—	
Miscellaneous		(1,460)		(34)		(809)	
Total other expense	\$	(17,650)	\$	(29,383)	\$	(809)	

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

In 2004, we recorded charges totaling \$18.5 million to other expense when it was determined that certain marketable securities were impaired on an otherthan-temporary basis.

In October 2002, Biogen, Inc. established The Biogen Foundation, a private, U.S. based, non-profit philanthropic organization. In December 2002, Biogen, Inc. made a charitable contribution of \$15.0 million to fund the Biogen Foundation. As a result of the Merger, we changed the name of the foundation to The Biogen Idec Foundation and, in December 2003 contributed an additional \$10.0 million. The foundation is to operate exclusively for the benefit of funding charitable, educational and scientific causes. Certain executive officers and other employees serve as directors and officers of the foundation. We classify charitable contributions to other income (expense).

In December 2003, we recorded charges of \$2.5 million and \$18.2 million to other expense related to the final settlement of patent infringement disputes with Apoxis S.A. and Corixa Corporation, respectively.

## 8. Income Taxes

The components of income (loss) before income taxes (benefit) and of income tax expense (benefit) for each of the three years ended December 31 are as follows:

	 2004		2003 nousands)	 2002
Income (loss) before income taxes (benefit):			,	
Domestic	\$ 108,298	\$	(846,711)	\$ 231,522
Foreign	(44,205)		(33,913)	
	\$ 64,093	\$	(880,624)	\$ 231,522
Income tax expense (benefit):				
Current				
Federal	\$ 151,552	\$	15,075	\$ 65,653
State	17,648		6,872	14,414
Foreign	5,360		192	 
	\$ 174,560	\$	22,139	\$ 80,067
Deferred	 			 
Federal	\$ (121,343)	\$	(31,988)	\$ 6,195
State	(14,210)		4,322	(2,830)
	(135,553)		(27,666)	3,365
Total income tax expense (benefit)	\$ 39,007	\$	(5,527)	\$ 83,432

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Deferred tax assets (liabilities) are comprised of the following at December 31:

	2004			2003	
	(In thousands)				
Tax credits	\$	103,651	\$	86,263	
Net operating loss carryforwards				1,439	
Inventory and other reserves		26,343		21,656	
Capitalized costs		42,774		49,013	
Intangibles, net		13,688		2,414	
Other		17,184		1,756	
Unrealized loss on investments and cumulative translation adjustment		6,101		—	
Deferred tax assets	\$	209,741	\$	162,541	
Fair value adjustment	\$	(867,907)	\$	(1,055,358)	
Interest expense on notes payable		(54,951)		(31,776)	
Depreciation, amortization and other		(121,774)		(45,844)	
Unrealized gain on investments and cumulative translation adjustment		_		(13,936)	
Deferred tax liabilities	\$	(1,044,632)	\$	(1,146,914)	

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the periods ending December 31 is as follows:

	2004	2003	2002
Statutory rate	35.00%	35.00%	35.00%
In process R&D	—	(32.71)	_
State taxes	2.75	(0.83)	3.20
Change in valuation allowance	—	—	(0.80)
Foreign taxes	(49.36)	1.28	—
Credits and net operating loss utilization	(8.98)	0.71	(1.60)
Fair value step-up	74.81	(2.74)	
Non-deductible items	4.54	—	—
Other	2.10	(0.08)	0.20
Effective tax rate	60.86%	0.63%	36.00%

At December 31, 2004, we had general business credit carryforwards for federal income tax purposes of approximately \$88 million, which expire from 2020 through 2024. Additionally, for state income tax purposes, we had research credit carryforwards of approximately \$23 million that have no prescribed expiration period.

In assessing the realizability of our deferred tax assets, we have considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial reporting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. Our estimates of future taxable income takes into consideration, among other items, our estimates of future income tax deductions related to the exercise of

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

stock options. Based upon the level of historical taxable income and income tax liability and projections for future taxable income over the periods in which the deferred tax assets are utilizable, we believe it is more likely than not that we will realize the benefits of our entire deferred tax assets. In the event that actual results differ from our estimates or we adjust our estimates in future periods, we may need to establish a valuation allowance which could materially impact our financial position and results of operations.

As of December 31, 2004, undistributed foreign earnings of non-U.S. subsidiaries included in consolidated retained earnings aggregated \$624.4 million, exclusive of earnings that would result in little or no net income tax expense under current U.S. tax law. We intend to reinvest these earnings indefinitely in operations outside the U.S. It is not practicable to estimate the amount of additional tax that might be payable if such earnings were remitted to the U.S.

On October 22, 2004, the American Jobs Creation Act of 2004, or the Act, was signed into law. The Act creates a temporary incentive for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate that could be as low as 5.25%. On December 21, 2004, the FASB issued FASB staff position 109-2, "Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004", or FSP 109-2. FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS 109's exception to recognizing deferred tax liabilities and require explanatory disclosures from those who need the additional time. Through December 31, 2004, we have not recognized deferred taxes on foreign earnings because such earnings were, and continue to be, indefinitely reinvested outside the U.S. Whether we will ultimately take advantage of the above temporary tax incentive depends on a number of factors including reviewing future Congressional or other Governmental guidance with respect to certain aspects of the new legislation that require clarification before an informed decision can be made. Until such clarification is received, we will continue our plan and intention to indefinitely reinvest accumulated earnings of its foreign subsidiaries. If we decide to avail ourselves of this temporary incentive, up to \$500 million could be repatriated under the Act, and we could incur a one-time tax charge to our consolidated results of operations of up to approximately \$32 million.

Another important provision of the Act relates to the deduction for domestic manufacturing. In principle, this should provide a favorable impact on future cash taxes and on our effective tax rate. Biogen Idec is still in the process of evaluating this provision and has not quantified the impact on its effective rate.

#### 9. Research Collaborations and Strategic Investments

In connection with our research and development efforts, we have entered into various collaboration arrangements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by the parties. Terms of the various license agreements may require us to make milestone payments upon the achievement of certain product development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration.

In October 2004, we entered into a development and license agreement with ImmunoGen, Inc., or ImmunoGen, for a worldwide, exclusive license to develop and commercialize anticancer therapeutics that comprise an antibody that we have developed to an undisclosed tumor cell target and ImmunoGen's proprietary Tumor-Activated Prodrug (TAP) technology. As part of the agreement, we paid ImmunoGen an upfront fee of \$1.0 million, which was recorded as a research and development expense. Upon the achievement of certain predetermined milestones, we would be required to pay ImmunoGen up to a total of \$42.0 million plus royalties over the life of the agreement. ImmunoGen will also receive compensation from us for product development research done on its behalf, as well as for the production of preclinical and initial clinical materials.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

In August 2004, we entered into a collaborative agreement with Sunesis Pharmaceuticals, Inc., or Sunesis, to discover and develop small molecule cancer therapeutics targeting primarily kinases. Under the agreement, we acquired exclusive licenses to develop and commercialize certain compounds resulting from the collaboration. Upon signing the agreement, we paid Sunesis a non-refundable upfront license fee of \$7.0 million, which was recorded in research and development expenses in the third quarter of 2004. Under the terms of this agreement, we purchased approximately 2.9 million shares of preferred stock of Sunesis for \$14.0 million, the fair value of the shares. In December 2002, Biogen, Inc. entered into a collaboration agreement with Sunesis related to the discovery and development of oral therapeutics for the treatment of inflammatory and autoimmune diseases. Under the terms of this agreement, we purchased 1.25 million shares of preferred stock of Sunesis for \$6.0 million, the fair value of the shares. We acquired certain exclusive licenses to develop and commercialize certain compounds resulting from the collaboration. Our investments in Sunesis are included in investments and other assets. We account for our investments in Sunesis using the cost method of accounting, subject to periodic review of impairment. Under the terms of the December 2002 agreement, we will pay Sunesis a quarterly license maintenance fee of \$357,500 during the period January 1, 2005 through July 1, 2005. Additionally, we have a Credit Facility Agreement with Sunesis under which we are obligated to loan Sunesis up to \$4.0 million. At December 31, 2004, there is \$3.2 million of borrowings outstanding. We have committed to paying Sunesis additional amounts upon the completion of certain future research milestones and first and second indication development milestones. If all the milestones were to be achieved in both agreements, we would be required to pay up to an additional \$121.0 million over the life of the agreements, excluding roy

In July 2004, we and Elan entered into a patent license agreement with Genentech for a non-exclusive license to certain Genentech patents related to the manufacture of licensed products, including TYSABRI. As a part of the agreement, we and Elan paid a \$1.0 million license grant fee upon execution of the agreement, which was charged to research and development expenses, and each will pay an additional \$1.0 million on the first anniversary of the agreement. In addition, we and Elan each have to pay a development milestone fee of \$2.5 million related to the approval of TYSABRI by the FDA in November 2004, half of which was paid in 2004 upon approval of TYSABRI and half of which is payable on the anniversary of such approval. At December 31, 2004, our \$2.5 million total milestone fee is included in intangible assets, net on the consolidated balance sheets, and is being amortized to cost of product revenues over the life of the patent. The agreement also requires that we or Elan pay royalties on net sales of TYSABRI and other licensed products.

In June 2004, we entered into a collaborative research and development agreement with Vernalis plc, or Vernalis, aimed at advancing research into Vernalis' adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders. Under the agreement, we receive exclusive worldwide rights to develop and commercialize Vernalis' lead compound, V2006. We paid Vernalis an initial license fee of \$10.0 million in July 2004, which was recorded in research and development expenses in the second quarter of 2004. Terms of the collaborative agreement may require us to make milestone payments upon the achievement of certain program objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. We made an immediate investment of \$5.5 million through subscription for approximately 6.2 million new Vernalis common shares, representing 4.19 percent of Vernalis' post-financing issued share capital, and committed to purchase an additional \$4.0 million in the event of future Vernalis financing. Our investment in Vernalis is included in investments and other assets. We account for our investment in Vernalis using the cost method of accounting, subject to periodic review of impairment. Excluding royalties, total potential payments to Vernalis could exceed \$100.0 million.

In June 2004, we entered into a license agreement with BioWa, Inc., or BioWa, for a worldwide, non-exclusive license for research purposes and a worldwide, exclusive license for development and commercialization purposes to certain BioWa intellectual property rights related to monoclonal antibodies. As part of the agreement, we have committed to paying BioWa certain amounts upon the achievement of certain research

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

and clinical milestones. If all the milestones were to be achieved, we would be required to pay BioWa a total of \$18.8 million plus royalties over the life of the agreement.

In May 2004, we entered into a limited partnership agreement as a limited partner with MPM Bioventures III GP, LP, to create MPM Bioventures Strategic Fund, LP, or the Strategic Fund. The purpose of the Strategic Fund is to make, manage, and supervise investments in biotechnology companies with novel products or technologies that fit strategically with Biogen Idec. The Strategic Fund takes only minority positions in the equity of its investments, and does not seek to engage in day-to-day management of the entities. We have committed \$65.0 million to the Strategic Fund over a three-year period. During 2004, we contributed \$5.5 million to the Strategic Fund.

In April 2004, we became a limited partner in MPM Bioventures III-QP, LP, or the LP, a limited partnership that invests in entities that are engaged in the research, development, manufacture, marketing and/or sale of novel biological products or technologies. We have committed to contribute \$4.0 million to the limited partnership. Through December 31, 2004, we have contributed \$1.8 million into the LP, which is included in investments and other assets in our consolidated balance sheets.

In September 2003, Biogen, Inc. entered into a license agreement with Fumapharm AG, or Fumapharm, under which Biogen, Inc. obtained exclusive rights to develop and market a second-generation fumarate derivative with an immunomodulatory mechanism of action, currently in clinical trials in Europe. Under the terms of this agreement, we obtained an exclusive worldwide marketing and distribution license for psoriasis, and a production and exclusive marketing and distribution license for the entire world for MS. During 2004, we made payments totaling \$4.2 million to Fumapharm for the achievement of certain milestones, which were expensed to research and development expense. We have committed to paying Fumapharm additional amounts upon the completion of certain future research milestones and first and second indication development milestones. If all the milestones were to be achieved, we would be required to pay up to an additional 20 million Swiss francs plus royalties over the remaining life of the agreement.

In August 2003, Biogen, Inc. entered into a collaboration agreement with Vetter Pharma-Fertigung GmbH & Co. KG, or Vetter, for the fill-finish of Biogen Idec products. Under the terms of this agreement, Biogen, Inc. paid a partial advance payment to Vetter of 35 million Euros in return for reserving certain capacity at Vetter's fill-finish facility. As of December 31, 2004, we have made payments totaling \$22.7 million to Vetter for the achievement of certain milestones achieved under the terms of our supply agreement for reserving certain capacity at Vetter's fill-finish facility. These payments are recorded in investments and other assets on our consolidated balance sheets. The asset will be amortized to cost of product revenues over the units produced upon delivery to Biogen Idec. We have total potential milestone payments of approximately 16.0 million euros remaining as part of the agreement.

In September 2001, we entered into a collaborative development agreement with Mitsubishi Pharma to support clinical development of anti-CD80 (anti-B7.1) antibody products developed using our Primatized® antibody technology. Under the terms of an existing license agreement with Mitsubishi Pharma, entered into in November 1993, Mitsubishi Pharma had an exclusive license in Asia to develop and commercialize anti-CD80 (anti-B7.1) antibody products. These agreements were terminated in December 2003. As a result of the termination of these agreements, we have no continuing financial obligations under these agreements. During 2003 and 2002, we recognized revenues from these agreements of \$1.5 million and \$1.4 million, respectively, which are included in corporate partner revenues. Under these agreements, amounts earned by us and recognized as revenue for contract research and development approximated the research and development expenses incurred under the related agreement.

In August 2000, Biogen, Inc. entered into a development and marketing collaboration agreement with Elan to collaborate in the development, manufacture and commercialization of TYSABRI. In November 2004, we received approval by the FDA to market TYSABRI as a treatment for relapsing forms of MS to

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

reduce frequency of clinical relapses. We are also developing TYSABRI as a potential treatment for Crohn's disease and RA. In February 2005, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI and suspended dosing in clinical trials of TYSABRI. Under the terms of this agreement, we share costs with Elan for on-going development activities. As of December 31, 2004, Elan owed us \$34.4 million, representing commercialization and development expenses that we incurred, which is included in other current assets on the consolidated balance sheets. We received the entire \$34.4 million from Elan in the first quarter of 2005 related to the receivable.

In June 1999, we entered into a collaboration and license agreement with Schering AG, or Schering, aimed at the development and commercialization of ZEVALIN. Under the terms of the agreement, we may receive milestone and research and development support payments totaling up to \$47.5 million, subject to the attainment of product development objectives. Schering received exclusive marketing and distribution rights to ZEVALIN outside the U.S., and we will continue to receive royalties on product sales by Schering. Under the terms of a separate supply agreement, we are obligated to meet Schering's clinical and commercial requirements for ZEVALIN. Schering may terminate these agreements for any reason. During 2004, 2003 and 2002, we recognized revenues from our agreements with Schering of \$10.0 million, \$0.2 million and \$0.3 million, respectively, which are included in corporate partner revenues. In the first quarter of 2004, we received a \$10.0 million payment from Schering for the EMEA grant of marketing approval of ZEVALIN in the EU. The payment represented, in part, a milestone payment to compensate us for preparing, generating, and collecting data that was critical to the EMEA marketing approval process, to which we have no continuing involvement. Under the above agreement, amounts earned by us and recognized as revenue for contract research and development approximate the research and development expenses incurred under the related agreement.

In December 1994, we entered into a collaborative development agreement and a license agreement with Seikagaku Corporation, or Seikagaku, aimed at the development and commercialization of an anti-CD23 antibody using Primatized antibody technology. During 2003 and 2002, we recognized revenues from our agreement with Seikagaku of \$0.6 million and \$1.6 million, respectively, which are included in corporate partner revenues. Although this agreement was terminated effective January 17, 2004, we have certain continuing obligations under the agreement that we expect to fulfill in the first half of 2005 and for which we would receive revenue from Seikagaku. Under the above agreement, amounts earned by us and recognized as revenue for contract research and development approximate the research and development expenses incurred under the related agreement.

As part of previous agreements that Biogen, Inc. had with Targeted Genetics Corporation, or Targeted, for gene therapy research and development, we own approximately 12.1 million shares of Targeted common stock with a fair value of \$18.8 million, which is included in investments and other assets. In the third quarter of 2004, we recognized a \$12.7 million charge for the impairment of our Targeted investment that was determined to be other than temporary. We have no remaining commitments or obligations with Targeted.

### 10. Unconsolidated Joint Business Arrangement

In June 2003, we amended and restated our collaboration agreement with Genentech to include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to RITUXAN, for a broad range of indications. The original collaboration agreement was entered into in 1995 for the clinical development and commercialization of RITUXAN. Under the terms of the amended and restated agreement, we continue to receive a share of the pretax operating profits in the U.S. from RITUXAN and will share in the pretax operating profits or losses in the U.S. relating to any new products developed under the agreement. In connection with the agreement, in 2003, we paid Genentech \$20.0 million which we recorded as research and development expense.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

We copromote RITUXAN with Genentech, and share responsibility with Genentech for continued development of RITUXAN, in the U.S. Such continued development includes conducting supportive research and post-approval clinical studies and seeking potential approval for additional indications. Genentech provides the support functions for the commercialization of RITUXAN in the U.S., including marketing, customer service, order entry, distribution, shipping and billing, as well as fulfilling all worldwide manufacturing responsibilities. We share responsibility with Genentech for development in the U.S. of any new products developed under the agreement, and we will also copromote with Genentech any such new products in the U.S.

The amended and restated collaboration agreement provides that, upon the occurrence of a Biogen Idec change-in-control as described in the agreement, Genentech may present an offer to us to purchase our rights to RITUXAN. We must then accept Genentech's offer or purchase Genentech's rights to RITUXAN for an amount proportioned (using the profit sharing ratio between us) to Genentech's offer. If Genentech presents such an offer in such a situation, then Genentech will be deemed concurrently to have exercised a right, in exchange for a share in the operating profits or net sales in the U.S. of any new products developed under the agreement, to purchase our interest in each such product.

Concurrent with the original collaboration agreement, we also entered into an expression technology license agreement with Genentech (for a proprietary gene expression technology developed by us) and a preferred stock purchase agreement providing for certain equity investments in us by Genentech (see Note 12 — Shareholders' Equity).

Under the terms of separate agreements with Genentech, commercialization of RITUXAN outside the U.S. is the responsibility of Roche, except in Japan where it copromotes RITUXAN in collaboration with Zenyaku. We receive royalties from Genentech on sales by Roche and Zenyaku of RITUXAN outside the U.S., except in Canada. Royalties on sales of RITUXAN in Canada are received directly from Roche (and are included in revenues from unconsolidated joint business arrangement in the accompanying consolidated statements of income). Under our amended and restated collaborative agreement with Genentech, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products and only for the first eleven years from the date of first commercial sale of such new anti-CD20 products.

During 2003, we purchased certain clinical data from Roche related to RITUXAN supporting potential label expansion. Additionally, in 2003, Genentech and IDEC agreed that payments were owed to Columbia University for royalties related to past sales of RITUXAN in the U.S. As a result, we recognized \$2.6 million in royalty payments and \$0.5 million in interest charges related to these royalties.

Total revenues from unconsolidated joint business for the years ended December 31 consist of the following (in thousands):

	2004	2003	2002
Copromotion profits	\$ 457,025	\$ 419,197	\$ 324,498
Reimbursement of selling and development expenses	37,710	18,400	15,879
Royalty revenue on sales of RITUXAN outside the U.S.	121,008	67,869	45,432
RITUXAN clinical data purchased from Roche		(9,353)	_
Columbia patent royalty and interest payment		(3,064)	
	\$ 615,743	\$ 493,049	\$ 385,809

## 11. Commitments and Contingencies

We rent laboratory and office space and certain equipment under noncancellable operating leases. The rental expense under these leases, which terminate at various dates through 2015, amounted to \$35.4 million

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

in 2004, \$12.9 million in 2003, and \$9.8 million in 2002. The lease agreements contain various clauses for renewal at our option and, in certain cases, escalation clauses linked generally to rates of inflation.

At December 31, 2004, minimum annual rental commitments under noncancellable leases were as follows (in thousands):

Year	
2005	\$ 28,111
2006	20,931
2007	19,193
2008	15,366
2009	12,448
Thereafter	 37,577
Total minimum lease payments	\$ 133,626

In August 2004, we restarted construction of our large-scale biologic manufacturing facility in Hillerod, Denmark to be used to manufacture TYSABRI and other products in our pipeline. The cost of the project is estimated to be \$372.0 million. As of December 31, 2004, we had committed approximately \$129 million to the project, of which \$17.3 million has been paid. We expect this facility to be substantially complete in 2007 and available for commercial production in 2008. As of March 31, 2005, we determined that we would no longer proceed with the fill-finish component of our large-scale biologic manufacturing facility in Hillerod. As a result, we expect to write-off in the first quarter of 2005 to research and development expense approximately \$6.5 million of engineering costs which had previously been capitalized.

In June 2004, we commenced construction to add additional research facilities and administrative space to one of our existing buildings in Cambridge, Massachusetts. The cost of the project is estimated to be \$65.0 million. As of December 31, 2004, we had committed approximately \$29.0 million to the project, of which \$18.5 million had been paid. The project is expected to be substantially complete in late 2005.

In September 2001, we purchased approximately 42.6 acres of land in San Diego, California for approximately \$31.7 million in cash where we are building a consolidated research and development and administration campus. We have substantially completed construction and took occupancy in the building in the fourth quarter of 2004. The estimated total cost of the project is \$169.0 million. As of December 31, 2004, we have committed approximately \$168.0 million to the construction of these facilities, of which \$167.0 million has been paid.

In September 2000, we purchased a 60-acre site in Oceanside, California for approximately \$18.9 million in cash. In December 2002, we purchased an additional 27 acres of land at the Oceanside site for \$7.9 million. We are building a large-scale manufacturing facility at this location, which we anticipate using to manufacture TYSABRI and other commercial products. We have completed construction of this facility and obtained the certificate of occupancy in the fourth quarter of 2004. Commissioning and validation is expected to continue through 2005. We expect the facility to be licensed in 2006. Including start-up costs, total costs of this facility upon completion are estimated to be \$480.0 million. As of December 31, 2004, we have committed approximately \$413.0 million to the construction of this large-scale manufacturing facility, of which \$388.4 million has been paid.

In May 1999, we entered into an arrangement with MDS (Canada) Inc., MDS Nordion Division, successor to MDS Nordion Inc., or MDS (Canada), under which MDS (Canada) agreed to supply us yttrium-90, a radioisotope used in connection with administering ZEVALIN. MDS (Canada) initially supplied product for use in the ZEVALIN clinical trials. In anticipation of commercial launch of ZEVALIN, we subsequently determined that additional commercial production capacity for yttrium-90 would be

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

necessary. To obtain a commitment from MDS (Canada) that sufficient commercial supply would be available, we agreed to minimum purchase commitments of \$55.0 million, and to make periodic cash payments totaling \$25.0 million into an escrow account. The supply agreement was amended in November 2001 to give effect to these mutual commitments.

In December 2003, in light of the reduced expectations for ZEVALIN sales levels, we agreed to release the \$25.0 million of escrowed funds to MDS (Canada), and MDS (Canada) agreed to eliminate the minimum purchase commitments from the supply arrangement. MDS (Canada)'s obligation to supply yttrium-90 remains in effect. We are amortizing the prepayment over the economic life of the agreement.

On March 2, 2005, we, along with William H. Rastetter, our Executive Chairman, and James C. Mullen, our Chief Executive Officer, were named as defendants in a purported class action lawsuit, captioned Brown v. Biogen Idec Inc., et al., filed in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. The plaintiff alleges that the defendants made materially false and misleading statements regarding potentially serious side effects of TYSABRI in order to gain accelerated approval from the FDA for the product's distribution and sale. The plaintiff alleges that these materially false and misleading statements harmed the purported class by artificially inflating our stock price during the purported class period and that company insiders benefited personally from the inflated price by selling our stock. The plaintiff seeks unspecified damages, as well as interest, cost and attorneys' fees. A substantially similar action, captioned Grill v. Biogen Idec Inc., et al., was filed on March 10, 2005 in the same court by another purported class representative. We believe that the actions are without merit and intend to contest them vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss.

On March 4, 2005, a purported shareholder derivative action, captioned Halpern v. Rastetter, et al., was filed in the Court of Chancery for the State of Delaware, in New Castle County, on our behalf of Biogen Idec Inc., against us as nominal defendant, our Board of Directors and our former general counsel. The plaintiff derivatively claims breaches of fiduciary duty by the Board of Directors for inadequate oversight of our policies, practices, controls and assets, and for recklessly awarding executive bonuses despite alleged awareness of potentially serious side effects of TYSABRI and the potential for related harm to our financial position. The plaintiff also derivatively claims that our Executive Chairman, former general counsel and a director misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI, and alleges that our Board of Directors did not ensure that appropriate policies were in place regarding the control of confidential information and personal trading in our securities by officers and directors. The plaintiff seeks unspecified damages, profits, the return of all bonuses paid by us, costs and attorneys' fees. A substantially similar action, captioned Golaine v. Rastetter, et al., was filed on March 14, 2005 in the same court. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. As required by applicable law, we and our Board of Directors are considering the derivative claims in the complaints and will respond in a time and manner consistent with applicable Delaware statutory and common law. These purported derivative actions did not seek affirmative relief from the company.

On March 9, 2005, two additional purported shareholder derivative actions, captioned Carmona v. Mullen, et al. and Fink v. Mullen, et al., were brought in the Superior Court of the State of California, County of San Diego, on our behalf, against us as nominal defendant, our Board of Directors and our chief financial officer. The plaintiffs derivatively claim breach of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment against all defendants. The plaintiffs also derivatively claim insider selling in violation of California Corporations Code § 25402 and breach of fiduciary duty and misappropriation of information against certain defendants who sold our securities during the period of

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

February 18, 2004 to the date of the complaints. The plaintiffs allege that the defendants caused and/or allowed us to issue, and conspired, aided and abetted and acted in concert in concealing that we were issuing, false and misleading press releases about the safety of TYSABRI and its financial prospects which resulted in legal claims being asserted against us, irreparable harm to our corporate image, depression of our stock price and impairment of our ability to raise capital. The plaintiffs also allege that certain defendants sold personally owned shares of our stock while in possession of material, undisclosed, adverse information. The plaintiffs seek unspecified damages, treble damages for the purported insider trading in violation of California Corporate Code § 25402, equitable relief including restriction of the defendants' trading proceeds or other assets, restitution, disgorgement and costs, including attorneys' fees and expenses. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. As required by applicable law, we and our Board of Directors are considering the derivative claims in the complaints and will respond in a time and manner consistent with applicable statutory and common law. These purported derivative actions did not seek affirmative relief from the company.

Our Board of Directors has received letters, dated March 1 and 15, 2005, respectively, on behalf of purported owners of our securities purportedly constituting demands under Delaware law. A supplement to the March 1 letter was received on March 2, 2005. The letters generally allege that certain of our officers and directors breached their fiduciary duty to us by selling personally held shares our securities while in possession of material, non-public information about potential serious side effects of TYSABRI. The letters generally request that our Board of Directors take action on our behalf to recover compensation and profits from the officers and directors, consider enhanced corporate governance controls related to the sales of securities by insiders, and pursue other such equitable relief, damages, and other remedies as may be appropriate. As required by applicable law, our Board of Directors is currently considering the letters and will respond in a time and manner consistent with Delaware law.

We are providing information to the SEC regarding the SEC's informal inquiry into the suspension of marketing and commercial distribution of TYSABRI and trading in our securities by certain of our directors, officers and employees.

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York, or Columbia, in the U.S. District Court for the District of Massachusetts, contending that we no longer have any obligation to pay royalties to Columbia on sales of our products under a 1993 license agreement between us and Columbia related to U.S. Patent Nos. 4,399,216, 4,634,665, and 5,179,017, also referred to as the Original Patents, or under a newly issued patent, U.S. Patent No. 6,455,275, also referred to as the '275 patent (the 2003 action). Based, in part, on the court's subsequent finding that we had made a strong showing that we might prevail in proving the '275 patent is invalid under the doctrine of non-statutory double patenting, Columbia has since covenanted not to sue Biogen Idec MA, Inc. on any claim of the '275 patent and any claim that is the same or substantially the same as the claims of the '275 patent if such claim(s) emerge from the reexamination or reissue proceedings currently pending before the U.S. Patent and Trademark Office, or USPTO, with respect to the '275 patent. As a result of Columbia's covenant not to sue, and Columbia's assertion that Biogen Idec MA, Inc. is a licensee in good standing, the court issued an order on November 5, 2004, in which it dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction. At this time, we are unable to predict whether any claims will issue from the USPTO on the reexamination or reissue proceedings concerning the '275 patent, or whether, if any claims do issue, such claims will pose a risk of infringement with respect to our activities.

On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation, filed suit against Columbia in the U.S. District Court for the District of Massachusetts (the 2004 action). In the 2004 action we reasserted some of the contentions made in our complaint in the action filed in 2003 action. For example, that we are seeking a declaratory judgment that we have no obligation to pay any further royalties

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

under the license agreement because the Original Patents have expired and the '275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based on the '275 patent or on any pending continuations, continuations-in-part, or divisional applications of the Original Patents. We have also asserted claims for relief based on abuse of process, breach of contract, violation of Massachusetts laws concerning unfair and deceptive trade practices, prosecution laches and inequitable conduct. To date, Columbia has refused to extend its covenant not to sue on the '275 patent to Biogen Idec Inc. In the event that we are unsuccessful in the present litigation and Columbia asserts a claim for infringement against Biogen Idec Inc., we may be liable for damages suffered by Columbia with respect to unpaid royalties and such other relief as Columbia may seek and be granted by the Court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, GlaxoSmithKline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of infringement claims are based on allegations that we "provided instructions and/or recommendations on a proper immunization schedule for vaccines" to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. Under our 1988 license agreement with GlaxoSmithKline, GlaxoSmithKline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that GlaxoSmithKline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in certain cases, Biogen Idec Inc., was named as a defendant in lawsuits filed by the County of Suffolk, New York, the County of Westchester, New York, the County of Rockland, New York, the County of Nassau, New York, the County of Onondaga, New York, the County of Chenango, New York, the County of Erie, New York, the City of New York, and the County of Chautauqua, New York. All of the cases are pending in the U.S. District Court for the District of Massachusetts, with the exception of the Onondaga, Chenango and Chautauqua lawsuits, which are expected to be transferred to the U.S. District Court for the District of Massachusetts, and the Erie lawsuit, which is pending in the Supreme Court of the State of New York for the County of Erie. The complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs; marketed and promoted the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs; and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaints allege violations of New York state law and advance common law claims for unfair trade practices, fraud, and unjust enrichment. In addition, all of the complaints, with the exception of the County of Erie, allege that the defendants failed to accurately report the "best price" on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services, and excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the "best price." The Suffolk, Westchester, Rockland, and Nassau County complaints also claim that Biogen violated the Racketeering Influence and Corrupt Organizations Act (RICO) 18 U.S.C. § 1962(c). In September 2003, Biogen joined other named defendants in filing a motion to dismiss the Suffolk County complaint. Biogen also separately filed a motion on its own behalf arguing that the plaintiffs made no specific factual allegations against Biogen to connect it with the alleged scheme. In September 2004, the court, in ruling on

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

defendants' joint motion to dismiss, allowed the motion, in part, and dismissed the RICO claim, the Medicaid best price claim, the breach of contract claim, and the common law fraud claim. The court did not dismiss the claims brought under the New York State Medicaid and Social Services statutes, the unfair trade practices claim, or the claim for unjust enrichment. In October 2004, the court issued a partial decision on Biogen's individual motion to dismiss. The court dismissed all of the state law claims against Biogen based on the alleged failure to report best price, but deferred ruling on the fraud-based claims and ordered Suffolk County to produce all documents in support of its fraud-based claims. Suffolk County subsequently produced documents in response to the court's request and Biogen renewed its motion to dismiss. Neither Biogen nor the other defendants have answered or responded to the other complaints, as all of the plaintiffs except Erie County have agreed to stay the time to respond until the resolution of the pending motion to dismiss the Suffolk County complaints. Biogen Idec intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

#### 12. Shareholders' Equity

*Convertible Preferred Stock:* Our convertible preferred stock, which is held solely by Genentech, is convertible into shares of our common stock at anytime at the option of the holder. At December 31, 2003, Genentech converted 5,000 of the Series A-2 preferred shares and 22,993 of the Series A-3 preferred shares into approximately 1.7 million common shares.

The terms of our convertible preferred stock and the number of issued and outstanding shares at December 31, 2004 are as follows:

		Preferred			
Nonvoting		Shares	Lie	quidation	
Convertible		Issued and Preference Per			Common
Preferred Stock	Issue Date	Outstanding	Share		Conversion
Series A-2	August 1995	8,221	\$	67.00	60 shares

*Stockholder Rights Plan:* Effective July 26, 2001, our Board of Directors amended and restated the terms of our stockholder rights plan, originally adopted by the Board of Directors in 1997. Under the plan, we declared a dividend distribution of one "Right" for each outstanding share of our common stock to stockholders of record at the close of business on August 11, 1997. Since that time, we have issued one Right with each newly issued share of common stock. As amended, each Right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our Series X Junior Participating Preferred Stock at a purchase price of \$500.00. In general, under the amended and restated plan, if a person or affiliated group acquires beneficial ownership of 15% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The Board of Directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

substitute consideration. We may redeem the Rights at a price of \$0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on July 26, 2011.

Stock Option Plans: We currently have five stock option plans.

#### Directors Plan:

We maintain the 1993 Non-Employee Directors Stock Option Plan, or the Directors Plan. Options granted annually under the Directors Plan have a term of up to ten years and vest one year from the date of grant. Options granted to directors upon their appointment or election to the Board of Directors have a term of up to ten years and vests over four years from the date of grant. The options are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. As of December 31, 2004, the aggregate number of shares authorized for issuance under the Directors Plan was 3.1 million shares.

### **Omnibus** Plan:

We maintain the 2003 Omnibus Equity Plan, or the Omnibus Plan. Awards granted from the Omnibus Plan may include options, shares of restricted stock, shares of phantom stock, stock bonuses, stock appreciation rights and other awards in such amounts and with such terms and conditions subject to the provisions of the Plan. Options granted under the plan have a term of up to ten years and are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. At December 31, 2004, the maximum number of shares of Common Stock reserved for issuance under the Omnibus Plan was 17.4 million shares.

#### Other Plans:

We also maintain the 1988 Stock Option Plan, the Biogen, Inc. 1985 Non-Qualified Stock Option Plan and the Biogen, Inc. 1987 Scientific Board Stock Option Plan. We have not issued any shares from these plans since the Merger, and do not intend to issue any shares from these plans in the future. Under the 1998 Stock Option Plan, options for the purchase of our common stock were granted to key employees (including officers) and directors. Options were designated as incentive stock options or as nonqualified stock options and generally vest over four years, except under a provision of this plan which, under certain circumstances, allows accelerated vesting due to change in control events. Options under this plan, which have a term of up to ten years, are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. Options under the plans assumed from Biogen, Inc. were granted at no less than 100% of the fair market value on the date of grant. These options generally are exercisable over various periods, typically 4 to 7 years for employees and 3 years for directors and former scientific board members, and have a maximum term of 10 years.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of stock option activity is presented in the following table (shares are in thousands):

	All Option	Plans
	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2001	19,978	21.83
Granted	4,964	52.49
Exercised	(3,015)	6.58
Cancelled	(814)	44.02
Outstanding at December 31, 2002	21,113	\$ 30.36
Granted	4,872	34.29
Granted to Biogen, Inc employees (including 11.5 million vested options)	20,728	37.56
Exercised	(2,254)	9.04
Cancelled	(936)	46.08
Outstanding at December 31, 2003	43,523	\$ 35.01
Granted	7,054	46.27
Exercised	(12,263)	21.28
Cancelled	(3,191)	45.98
Outstanding at December 31, 2004	35,123	\$ 41.07

The following table summarizes combined information about options outstanding under all our stock option plans as of December 31, 2004 (shares are in thousands):

		Options Outstanding		Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Av Ex	eighted verage xercise Price
\$ 0.00 - \$10.00	2,183	3.19	\$ 6.51	2,183	\$	6.51
10.01 — 20.00	1,950	2.13	15.09	1,944		15.08
20.01 — 30.00	1,036	5.55	25.21	876		24.86
30.01 — 40.00	10,251	7.08	35.55	5,995		35.68
40.01 — 50.00	11,869	7.75	45.60	6,155		46.40
50.01 — 60.00	4,299	6.78	55.58	2,930		55.25
60.01 — 70.00	3,367	6.51	64.00	2,562		64.03
Over 70.00	168	4.80	74.74	160		74.71
Total	35,123	6.64	\$ 41.07	22,805	\$	39.58

At December 31, 2004, 2003, and 2002, options to purchase 22.8 million, 28.3 million, and 13.3 million shares, respectively, were exercisable at weighted average exercise prices of \$39.58, \$30.88, and \$19.26 per share, respectively.

*Employee Stock Purchase Plan:* We also maintain the 1995 Employee Stock Purchase Plan, or the Purchase Plan. As of December 31, 2004, a total of 0.5 million shares of our common stock were available for issuance. Under the terms of the Purchase Plan, employees can elect to have up to ten percent of their annual

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

compensation withheld to purchase shares of our common stock. The purchase price of the common stock is at 85 percent of the lower of the fair market value of the common stock at the enrollment or purchase date. During 2004, 2003 and 2002, 0.4 million, 0.2 million and 0.1 million shares, respectively, were issued under the Purchase Plan.

*Restricted Stock Awards:* In 2004, we granted a total of 1.3 million shares of restricted common stock to employees under our 2003 Omnibus Equity Plan. The restricted stock will vest 100% three years from the grant date, provided the employee remains continuously employed with us. During the vesting period, shareholders have full voting rights, even though the restricted stock remains subject to transfer restrictions and will generally be forfeited upon termination of employment prior to vesting. Approximately 0.1 million grants have been forfeited as of December 31, 2004 due to employee terminations. At December 31, 2004, deferred stock based compensation related to restricted stock was \$35.1 million and was included in shareholders' equity. For 2004, we recorded \$15.9 million of stock compensation charges related to the restricted stock.

#### Stock Repurchase Programs:

In February 2004, our Board of Directors authorized the repurchase of up to 12.0 million shares of our common stock. During 2004, we repurchased all 12.0 million shares at a cost of \$698.4 million, completing this program. The repurchased stock provided us with treasury shares to be used for general corporate purposes, such as common stock to be issued under employee equity and stock purchase plans

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program will expire no later than October 4, 2006. During the fourth quarter of 2004, we repurchased 0.6 million shares at a cost of \$36.0 million. Approximately 19.4 million shares remain authorized for repurchase under this program at December 31, 2004. In the first quarter of 2005, we repurchased approximately 3.5 million shares under this program, at a cost of \$168.5 million.

#### 13. Segment Information

We operate in one segment, which is the business of development, manufacturing and commercialization of novel therapeutics for human health care. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment. We currently have five commercial products: AVONEX and TYSABRI for the treatment of relapsing MS, RITUXAN and ZEVALIN, both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs, and AMEVIVE for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. We also receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control including sales of RITUXAN outside the U.S. Revenues are primarily attributed from external customers to individual countries where earned based on location of the customer or licensee.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Our geographic information is as follows (table in thousands):

December 31, 2004	US		 Europe	 Asia		Other		Total	
Product revenues from external customers	\$	986,050	\$ 406,898	\$ 	\$	93,396	\$	1,486,344	
Revenues from unconsolidated joint business	\$	494,735	\$ 121,008	\$ —	\$	_	\$	615,743	
Royalty revenues from external customers	\$	61,957	\$ 25,389	\$ 10,584	\$	1,015	\$	98,945	
Corporate partner revenues	\$	530	\$ 10,000	\$ —	\$	_	\$	10,530	
Long-lived assets	\$	6,645,692	\$ 433,895	\$ 1,569	\$	153,558	\$	7,234,714	

In 2004, we recorded revenue from one specialty distributor and three wholesale distributors accounting for a total of 17%, 17%, 16%, and 14% of total product revenue. Approximately 28%, 73%, and 95% of our total revenues in 2004, 2003, and 2002, respectively, are derived from our joint business arrangement with Genentech (see Note 10).

#### 14. Severance Obligations

In 2004 and 2003, we accrued \$2.3 million and \$10.2 million, respectively, of restructuring costs related to the relocation of our European headquarters, in selling, general and administrative expense. During 2004, we made payments of \$11.5 million related to this relocation obligation. At December 31, 2004, we had a remaining accrual of approximately \$1.1 million related to this relocation obligation.

In 2003, we accrued \$2.1 million of restructuring costs in selling, general and administrative expense related to severance obligations for certain employees affected by the Merger in our Cambridge facilities, and accrued an additional \$1.0 million of charges in 2004. During 2004, we made payments of \$2.9 million related to the Cambridge severance obligations and, at December 31, 2004, we had a remaining accrual of approximately \$0.2 million.

During 2004, we recorded charges of \$4.4 million in selling, general and administrative expense related to severance obligations for certain employees affected by the Merger in our San Diego facilities. During 2004, we made payments of \$4.0 million related to the San Diego restructuring obligations and, at December 31, 2004, we had a remaining accrual of approximately \$0.4 million.

#### 15. Guarantees

In November 2002, the FASB issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34", or FIN No. 45. FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. Since January 1, 2003, we have not issued or modified any guarantees as defined by FIN No. 45.

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2004.

### **16.** Quarterly Financial Data (Unaudited)

	_	First Quarter	 Second Quarter (In the		Third Quarter ousands, except per sha		Fourth Quarter are amounts)		Total Year	
2004			,		· · ·		,			
Total revenues	\$	541,742	\$ 538,763	\$	543,276	\$	587,781	\$	2,211,562	
Product revenue		372,537	363,186		359,692		390,929		1,486,344	
Royalties revenue		25,213	24,297		23,860		25,575		98,945	
Total expenses and taxes		594,666	544,349		504,935		563,203		2,207,153	
Other income (expense), net		11,726	6,413		(1,573)		4,111		20,677	
Net income (loss)		(41,198)	827		36,768		28,689		25,086	
Basic earnings (loss) per share		(0.12)	0.00		0.11		0.09		0.07	
Diluted earnings (loss) per share		(0.12)	0.00		0.10		0.08		0.07	
2003										
Total revenues	\$	117,246	\$ 123,562	\$	138,530	\$	299,845	\$	679,183	
Product revenue		5,663	4,980		4,427		156,491		171,561	
Royalties revenue		—	—		—		12,010		12,010	
Total expenses and taxes		79,356	98,049		95,016		1,270,904		1,543,325	
Other income (expense), net		3,310	3,253		1,986		(19,504)		(10,955)	
Net income (loss)		41,200	28,766		45,500		(990,563)		(875,097)	
Basic earnings (loss) per share		0.27	0.19		0.29		(4.03)		(4.92)	
Diluted earnings (loss) per share		0.24	0.17		0.26		(4.03)		(4.92)	

## 17. New Accounting Pronouncements

EITF 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," was issued in February 2004. EITF 03-01 stipulates disclosure requirements for investments with unrealized losses that have not been recognized as other-than-temporary impairments. We have complied with the disclosure provisions of EITF 03-01. In September 2004, the FASB staff issued two proposed FASB Staff Positions: Proposed FSP EITF Issue 03-01-a, which provides guidance for the application of paragraph 16 of EITF Issue 03-01 to debt securities that are impaired because of interest rate and/or sector spread increases, and Proposed FSP EITF Issue 03-01-b, which delays the effective date of Issue 03-01 for debt securities that are impaired because of interests rate and/or sector spread increases. We are currently monitoring these developments and assessing the impact these will have on our results of operations.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123(R), "Share-Based Payments," which replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123(R) will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. SFAS 123(R) will be effective for public companies for fiscal periods beginning after June 15, 2005, and offers alternative methods for determining the fair value. We

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

expect that SFAS 123(R) will have a significant impact on our financial statements. At the present time, we have not yet determined which valuation method we will use.

The FASB has proposed amending SFAS 128, "Earnings per Share," to make it consistent with International Accounting Standard 33, "Earnings per Share", and make earning per share, or EPS, computations comparable on a global basis. Under the proposed amendment, the year-to-date EPS computation would be performed independently from the quarterly computations. Additionally, for all contracts that may be settled in either cash or shares of stock, companies must assume that settlement will occur by the issuance of shares for purposes of computing diluted EPS, even if they intend to settle by paying cash or have a history of cash-only settlements, regardless of who controls the means of settlement. Lastly, under the proposed amendment, shares that will be issued upon conversion of a mandatory convertible security must be included in the weighted-average number of shares outstanding used in computing basic EPS from the date that conversion becomes mandatory, using the if-converted method, regardless of whether the result is anti-dilutive. The proposed amended standard is expected to be issued during the first quarter of 2005. Retrospective application in all periods presented would be required, and could require the restatement of previously reported EPS. We do not expect the provisions of the amended SFAS 128 will have a significant impact on our results of operations.

In November 2004, the FASB issued SFAS 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4," which amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement amends ARB 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not expect the provisions of SFAS 151 will have a significant impact on our results of operations.

In December 2004, the FASB issued SFAS 153, "Exchanges of Non-Monetary assets, an amendment of APB Opinion No. 29," which eliminates the exception from fair value measurement for nonmonetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29, "Accounting for Nonmonetary Transactions," and replaces it with an exception for exchanges that do not have commercial substance. This Statement specifies that a nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this Statement shall be effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. We do not expect the provisions of SFAS 153 will have a significant impact on our results of operations.

In December 2004, the FASB reached consensus on EITF Issue No. 02-14, "Whether an Investor Should Apply the Equity Method of Accounting to Investments Other Than Common Stock," which requires an investor that has the ability to exercise significant influence over the operating and financial policies of the investee to apply the equity method of accounting only when it has an investment(s) in common stock and/or an investment that is in-substance common stock. The Task Force also reached a consensus on the definition of in-substance common stock and related guidance. The provisions of EITF 02-14 are effective for reporting periods beginning after September 15, 2004, and have not had any impact on our accounting for investments as of December 31, 2004.

EITF No. 04-01, "Accounting for Preexisting Relationships between the Parties to a Business Combination," the EITF reached a consensus that the consummation of a business combination between parties with a preexisting relationship should be evaluated to determine if a settlement of a preexisting relationship exists, thus requiring accounting separate from the business combination. Under EITF 04-01, the acquisition of a right that the acquiring entity had previously granted to the acquired entity to use the acquirer's recognized or

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ---- (Continued)

unrecognized intangible assets (for example, rights to the acquirer's trade name under a franchise agreement or rights to the acquirer's technology under a technology licensing agreement) should be included as part of the business combination and recorded by the acquiring entity as an intangible asset at fair value. If the contract giving rise to the reacquired right includes terms that are favorable or unfavorable when compared to pricing (for example, royalty rates) for current market transactions for the same or similar items, an entity should measure a settlement gain or loss as the lesser of (a) the amount by which the contract is favorable to market terms from the perspective of the acquirer or (b) the stated settlement provisions of the contract available to the counterparty to which the contract is unfavorable. EITF 04-01 is effective for all business combinations consummated and goodwill impairment tests (i.e., in step 2 of the impairment test) performed in reporting periods beginning after October 13, 2004. The provisions of EITF 04-01 have not had any significant impact on our results of operations in 2004.

#### 18. Subsequent Event

In March 2005, we received FDA approval for a new pre-filled syringe formulation of AVONEX, which had previously received EMEA approval. As a result of the FDA approval, we expect to write-down between \$6 million and \$8 million of the remaining inventory of the older formulation, related to the FDA approval and which will no longer be available for commercial sale. This write-down will be recorded during the first quarter of 2005.

As of March 31, 2005, we determined that we would no longer proceed with the fill-finish component of our large-scale biologic manufacturing facility in Hillerod. As a result, we expect to write-off in the first quarter of 2005 to research and development expense approximately \$6.5 million of engineering costs which had previously been capitalized.

# **BIOGEN IDEC INC.**

## SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS AND RESERVES Years Ended December 31, 2004, 2003 and 2002

Description	Balance at Beginning of Year		A	Additions		Other <u>Additions(1)</u> (In thousands)		Deductions		Balance at End of Year	
Allowance for Doubtful accounts(2)											
Year Ended December 31, 2004	\$	2,074	\$	—	\$		\$		\$	2,074	
Year Ended December 31, 2003	\$	361	\$	2,277	\$		\$	565	\$	2,074	
Year Ended December 31, 2002	\$	_	\$	361	\$		\$		\$	361	
Sales Returns & Allowances, Discounts, and											
Rebates(3)											
Year Ended December 31, 2004	\$	20,756	\$	188,525	\$	_	\$	175,473	\$	33,808	
Year Ended December 31, 2003	\$	371	\$	14,729	\$	18,816	\$	13,161	\$	20,756	
Year Ended December 31, 2002	\$	99	\$	767	\$		\$	495	\$	371	

(1) As a result of the merger, we assumed sales returns and allowances, discounts and rebates of \$18.8 million from Biogen, Inc. as of the Merger date.

(2) Additions to allowance for doubtful accounts are recorded as an expense.

(3) Additions to sales returns and allowances, discounts, and rebates are recorded as a reduction of revenue.

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

To the Board of Directors and Shareholders of Biogen Idec Inc.:

We have completed an integrated audit of Biogen Idec Inc.'s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

#### **Consolidated financial statements and Financial Statement Schedule**

In our opinion, the consolidated financial statements listed in the index appearing under Item 15a.(1) present fairly, in all material respects, the financial position of Biogen Idec Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15a.(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

#### **Internal control over financial reporting**

Also, in our opinion, management's assessment, included in the accompanying "Management's Annual Report on Internal Control Over Financial Reporting," that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control over financial reporting as maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control over financial reporting as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of

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the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 31, 2005

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

The Board of Directors and Stockholders of Biogen Idec Inc.:

We have audited the accompanying consolidated statements of income, stockholders' equity, and cash flows for Biogen Idec, Inc. and subsidiaries (formerly known as IDEC Pharmaceuticals Corporation) for the year ended December 31, 2002. In connection with our audit of the consolidated financial statements, we have also audited the consolidated financial statement schedule for the year ended December 31, 2002, as listed in the accompanying index. These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of IDEC Pharmaceuticals Corporation and subsidiaries for the year ended December 31, 2002, in conformity with U.S generally accepted accounting principles. Also, in our opinion, the related consolidated financial statement schedule when considered in relation to the basic consolidated financial statements taken as a whole presents fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Diego, California January 29, 2003

1. PARTIES (fill in) Steven D. Rosenberg as Trustee of the Fifth Street Realty Trust of 300 Bent Street, Cambridge, MA 02141

LESSOR, which expression shall include his heirs, successors, and assigns where the context so admits, does hereby lease to Biogen, Inc., a corporation having its mailing address at 14 Cambridge Center, Cambridge, MA 02142

LESSEE, which expression shall include its successors, executors, administrators, and assigns where the context so admits, and the LESSEE hereby leases the following described premises:

2. PREMISES (fill in and include, if applicable, suite number, floor number, and square feet)
The land consisting of approximately 11,809 square feet as shown on the deed survey map attached hereto as Exhibit "A", together with the entire building thereon known and numbered as 190 Fifth Street, Cambridge, MA consisting of approximately 17,000 square feet as shown on the attached schematic maps attached hereto as Exhibit "B".

XXX

- 3. TERM The term of this lease shall be for Fourteen (14) (fill in) years and seven (7) months commencing on June 1, 1990 and ending on December 31, 2004, unless earlier terminated pursuant to paragraph 4A below.
- 4. RENT The LESSEE shall pay to the LESSOR rent [ILLEGIBLE] (fill in) as follows: [ILLEGIBLE]

THIS LEASE SHALL BE TREATED AS A SO-CALLED "TRIPLE NET LEASE"

#### SCHEDULE OF RENT

- a) Base rent of \$164,000.00 per year, payable in advance in monthly installments of \$13,666.66.
- b) Commencing as of June 1, 1992 and each June 1 thereafter, the base rent shall be increased by an amount equal to 5% of the prior year's base rent.
- c) The LESSEE shall pay to the LESSOR, within 30 days of invoice by the LESSOR together with a copy of the respective bills or invoices, the real estate taxes, premiums for insurance coverage and water and sewer charges incurred by the LESSOR for the premises during the term of this Lease. LESSOR shall send such bills to LESSEE at 14 Cambridge Center, Cambridge, MA 02142, Attention Accounts Payable. The LESSEE reserves the right to appeal real estate taxes and receive benefit of abatements if any. The LESSEE reserves the right to secure and pay for comparable insurance coverage itself.
- 4A. Premature Termination:
  - a) After the expiration of eight (8) years the LESSEE may prematurely terminate this Lease providing to the LESSOR a written notice sent not less than one (1) year in advance of the effective date together with the payment of a premature termination fee in an amount equal to six (6) months rent at the then current base rent rate.
  - b) After the expiration of nine (9) years the LESSEE may prematurely terminate this Lease by following the procedures set forth above except shall only pay an amount equal to three (3) months rent at the then current base rent rate.
  - c) After the expiration of ten (10) years the LESSEE may prematurely terminate this Lease by following the procedures set forth above, except LESSEE shall not pay any termination fee.

The LESSEE shall pay, as they become due, all bills 7. UTILITIES for electricity and other utilities (whether they delete "air are used for furnishing heat or other purposes) that conditioning" if not are furnished to the leased premises and presently applicable separately metered, and all bills for fuel furnished to a separate tank servicing the leased premises exclusively.

> LESSOR shall have no obligation to provide utilities or equipment other than the utilities and equipment within the premises as of the commencement date of this lease. In the event LESSEE requires additional utilities or equipment, the installation and maintenance thereof shall be the LESSEE's sole obligation, provided that such installation shall be subject to the written consent of the LESSOR, which shall not be unreasonably withheld.

- USE OF LEASED The LESSEE shall use the leased premises only for 8. PREMISES the purpose of any business use consistent with the (fill in) Cambridge Zoning Code and permitted within the specific district.
- COMPLIANCE The LESSEE acknowledges that no trade or occupation 9. WITH LAWS shall be conducted in the leased premises or use made thereof which will be unlawful, improper, noisy or offensive, or contrary to any law or any municipal by-law or ordinance in force in the city or town in which the premises are situated.
- 10. FIRE INSURANCE The LESSEE shall not permit any use of the leased premises which will make voidable any insurance on the property of which the leased premises are a part, or on the contents of said property or which shall be contrary to any law or regulation from time to time established by the New England Fire Insurance Rating Association, or any similar body succeeding to its powers.
- 11. MAINTENANCE The LESSEE agrees to maintain the leased premises in good condition, damage by fire and other casualty only excepted, and whenever necessary, to replace A. LESSEE'S plate glass and other glass therein, acknowledging OBLIGATIONS that the leased premises are now in good order and the glass whole\*. The LESSEE shall not permit the leased premises to be overloaded, damaged, stripped, or defaced, nor suffer any waste/LESSEE shall obtain written consent of LESSOR before erecting any sign on the premises. other than normal wear and tear.
  - \* provided LESSEE shall See Paragraph No. 24. have the right to have the premises inspected prior to the commencement date and any deficiencies corrected by LESSOR.

The LESSEE shall not make structural alterations or additions to the leased premises, but may make non-structural alterations provided the LESSOR consents thereto in writing, which consent shall not be unreasonably withheld or delayed. All such allowed alterations shall be at  $\ensuremath{\mathsf{LESSEE's}}$  expense and shall be in quality at least equal to the present construction. LESSEE shall not permit any mechanics' leins, or similar liens, to remain upon the leased premises for labor and material furnished to LESSEE or claimed to have been furnished to LESSEE in connection with work of any character performed or claimed to have been performed at the direction of LESSEE and shall cause any such lien to be released of record forthwith without cost to LESSOR. Any alterations or improvments made by the LESSEE shall become the property of the LESSOR at the termination of occupancy as provided herein. except for those which LESSEE elects to remove and repair any damage

12. ALTERATIONS-ADDITIONS

See also Paragraph 25

- B. LESSOR'S OBI TGATTONS

caused by removal and except for LESSEE'S trade fixtures and equipment.

13. ASSIGNMENT-SUBLEASING The LESSEE shall not assign or sublet the whole or any part of the leased premises without LESSOR's prior written consent Notwithstanding such consent, LESSEE shall remain liable to LESSOR for the payment of all rent and for the full performance of the covenants and conditions of this lease. See also paragraph 26 \* which shall not be unreasonably withheld.

- 14. SUBORDINATION
- This lease shall be subject and subordinate to any and all mortgages, deeds of trust and other instruments in the nature of a mortgage, now or at any time hereafter, a lien or liens on the property of which the leased premises are a part and the LESSEE shall, when requested, promptly execute and deliver such written instruments as shall be necessary to show the subordination of this lease to said mortgages, deeds of trust or other such instruments in the nature of a mortgage.
- 15. LESSOR'S The LESSOR or agents of the LESSOR may, at reasonable times, enter to view the leased premises ACCESS and may remove placards and signs not approved and affixed as herein provided, and make repairs and alterations as LESSOR should elect to do and may show the leased premises to others, and at any time within three (3) months before the expiration of the term, may affix to any suitable part of the leased premises a notice for letting or selling the leased premises or property of which the leased premises are a part and keep the same so affixed without hindrance or molestation.
- 16. INDEMNIFICATION The LESSEE shall save the LESSOR harmless from all loss and damage occasioned by the use or escape of AND LIABILITY water or by the bursting of pipes, as well as from (fill in) any claim or damage resulting from neglect in not removing snow and ice from the roof of the building or from the sidewalks bordering upon the premises so leased, or by any nuisance made or suffered on the leased premises, unless such loss is caused by the neglect of the LESSOR. The removal of snow and ice from the sidewalks bordering upon the leased premises shall be LESSOR'S responsibility.
- The LESSEE shall maintain with respect to the leased INSURANCE premises and the property of which the leased premises are a part comprehensive public liability (fill in) insurance in the amount of with property damage See also insurance in limits of in responsible companies qualified to do business in Massachusetts and in paragraph 23. good standing therein insuring the LESSOR as well as LESSEE against injury to persons or damage to property as provided. The LESSEE shall deposit with the LESSOR certificates for such insurance at or prior to the commencement of the term, and thereafter within thirty (30) days prior to the expiration of any such policies. All such insurance certificates shall provide that such policies shall not be cancelled without at least ten (10) days prior written notice to each assured named therein.
  - Should a substantial portion of the leased premises, or of the property of which they are a part, be substantially damaged by fire or other casualty, or be taken by eminent domain, the LESSOR may elect to terminate this lease. When such fire, casualty, or taking renders the leased premises substantially unsuitable for their intended use, a just and proportionate abatement of rent shall be made, and the LESSEE may elect to terminate this lease if:
    - (a) The LESSOR fails to give written notice within thirty (30) days of intention to restore leased premises, or
    - (b) The LESSOR fails to restore the leased premises to a condition substantially suitable for their intended use within ninety (90) days of said fire, casualty or taking.

The LESSOR reserves, and the LESSEE grants to the LESSOR, all rights which the LESSEE may have for damages or injury to the leased premises for any taking by eminent domain, except for damage to the LESSEE's fixtures, property, or equipment.

- LESSEE'S LIABILITY 17.

18. FIRE, CASUALTY EMINENT DOMAIN

19. DEFAULT AND BANKRUPTCY (fill in) In the event that:

- (a) The LESSEE shall default in the payment of any installment of rent or other sum herein specfied and such default shall continue for ten (10) days after written notice thereof; or
- (b) The LESSEE shall default in the observance or performance of any other of the LESSEE's covenants, agreements, or obligations hereunder and such default shall not be corrected within thirty (30) days after written notice thereof; or
- (c) The LESSEE shall be declared bankrupt or insolvent according to law, or, if any assignment shall be made of LESSEE's property for the benefit of creditors,

then the LESSOR shall have the right thereafter, while such default continues, to re-enter and take complete possession of the leased premises, to declare the term of this lease ended, and remove the LESSEE's effects, without prejudice to any remedies which might be otherwise used for arrears of rent or other default. The LESSEE shall indemnify the LESSOR against all loss of rent and other payments which the LESSOR may incur by reason of such termination during the residue of the term. If the LESSEE shall default, after reasonable notice thereof, in the observance or performance of any conditions or covenants on LESSEE's part to be observed or performed under or by virtue of any of the provisions in any article of this lease, the LESSOR, without being under any obligation to do so and without thereby waiving such default, may remedy such default for the account and at the expense of the LESSEE. If the LESSOR makes any expenditures or incurs any obligations for the payment of money in connection therewith, including but not limited to, reasonable attorney's fees in instituting, prosecuting or defending any action or proceeding, such sums paid or obligations insured, with interest at the rate of 10 per cent per annum and costs, shall be paid to the LESSOR by the LESSEE as additional rent.

#### \*Lessee at the address set forth above

- Any notice from the LESSOR to the LESSEE relating to the leased premises or to the occupancy thereof shall be deemed duly served, [ILLEGIBLE] or if mailed to the leased premises, registered or certified mail, return receipt requested, postage prepaid, addressed to the LESSEE. Any notices from the LESSEE to the LESSOR relating to the leased premises or to the occupancy thereof, shall be deemed duly served, if mailed to the LESSOR by registered or certified mail, return receipt requested, postage prepaid, addressed to the LESSOR at such address as the LESSOR may from time to time advise in writing. All rent notices shall be paid and sent to the LESSOR at 300 Bent Street, Cambridge, MA 02141
- 20. NOTICE (fill in)

21.	SURRENDER	The LESSEE shall at the expiration or other termination of this lease remove all LESSEE's goods and effects from the leased premises, (including, without hereby limiting the generality of the foregoing, all signs and lettering affixed or painted by the LESSEE, either inside or outside the leased premises). LESSEE shall deliver to the LESSOR the leased premises and all keys, locks thereto, and other fixtures connected therewith and all alterations and additions made to or upon the leased premises, in good condition, damage by fire or other casualty only excepted. In the event of the LESSEE's failure to remove any of LESSEE's property from the premises, LESSOR is hereby authorized, without liability to LESSEE for loss or damage thereto, and at the sole risk of LESSEE, to remove and store any of the property at LESSEE's expense, or to retain same under LESSOR's control or to sell at public or private sale, without notice any or all of the property not so removed and to apply the net proceeds of such sale to the payment of any sum due hereunder, or to destroy such property.			
22.	BROKERAGE (fill in or delete)	See Paragraph No. 27. **except Lessee's fixtures			
23.	OTHER PROVISIONS	It is also understood and agreed that the Addendum annexed hereto shall be and hereby is incorporated and made a part of the lease agreement.			
IN WITNESS WHEREOF, the said parties hereunto set their hands and seals this day of April, 1990.					

Biogen, Inc.

By: /s/ David W. Dennen

LESSEE Authorized Signatory David W. Dennen, Ph. D. Vice President of Operations Fifth Street Realty Trust

By: /s/ Steven D. Rosenberg LESSOR Steven D. Rosenberg, Trustee

#### Addendum to Lease By and Between Steven D. Rosenberg, as Trustee of Fifth Street Realty Trust (Lessor) and Biogen, Inc. (lessee) covering the Property at 190 Fifth Street, Cambridge, MA

23. The LESSEE shall provide and pay for fire insurance coverage of not less than \$1 Million with the Lessor named as an additional assured. A certificate covering the fire insurance coverage shall be delivered to the Lessor with the Lessor named thereon as an additional assured.

24. The LESSOR agrees to maintain only the exterior structure and the roof of the building of which the leased premises are a part in the same condition as it is at the commencement of the term or as it may be put in during the term of this lease by reasonable wear and tear or damage by fire or other casualty, unless such maintenance is required because of the LESSEE or those for whose conduct the LESSEE is legally responsible. The LESSOR also agrees to make all repairs to the building structure and systems such as, but not limited to, heating system, air conditioning system, electrical system, plumbing system, elevator, fire protection system, and structural elements whenever an individual repair exceeds \$5,000.00 and is not due to the LESSEE'S negligence.

25. The LESSOR shall not require the LESSEE to remove any agreed to alterations at the termination of the lease.

26. If the LESSEE elects to sublet all or any portion of the demised premises, then it shall notify the LESSOR who shall have the option of entering into a new Lease with the Sub-lessee covering said premises, thereby relieving LESSEE of all of its obligation under this Lease for such premises.

27. Brokerage - Both parties certify to the other that no broker was involved in this Lease or is entitled to any commission as a result of this Lease and each shall indemnify and save the other harmless from any such claims.

28. The LESSOR agrees to finance, at the LESSEE'S option, up to \$100,000.00 of improvements and rehabilitation, of the demised premises, initiated before December 31, 1990. Said amount shall be repaid together with interest on a monthly basis at the rate of 14.25% per annum under a Ten (10) year

amortization schedule of equal payments of interest and principal in arrears. These payments will commence January 1, 1991 and conclude on December 1, 2000 and will be added to the base rent. The escalation of base rate shall not apply to the funds loaned hereunder. In the event of premature termination the unpaid principal shall be paid in a lump sum (forthwith) with no prepayment penalty. LESSOR may prepay such amount at any time; the prepayment shall include unpaid interest accrued to the date of prepayment, but shall not be subject to any prepayment fee.

29. The LESSOR shall by July 1, 1990:

- a) secure and/or replace the broken windows;
- b) repair the flooring on the 1st floor near the street dock as well as other floor penetrations;
- c) clear out the parking area under the storage sheds;
- d) remove the spray booth and all duct work used for duct control;
- e) seal the subfloor vents against rodents and insects.

IN WITNESS WHEREOF, the said parties hereunto set their hands and seals this \_\_\_\_\_ day of April, 1990.

BIOGEN, INC.

FIFTH STREET REALTY TRUST

By: /s/ David W. Dennen

LESSEE Authorized Signatory David W. Dennen, Ph. D. Vice President of Operations By: /s/ Steven D. Rosenberg LESSOR Steven D. Rosenberg, Trustee [Location of Main Building in relation to cross streets, corner of Bent Street and Fifth Street] [Floor Plan of First Floor of Main Building 100 Fifth Street, Cambridge, MA.] [Floor Plan of Second Floor of Main Building 100 Fifth Street, Cambridge, MA.] [Floor Plan of Third Floor of Main Building 100 Fifth Street, Cambridge, MA.] First Trade Union Savings Bank F.S.B. 10 Drydock Avenue Boston, MA 02205

Re: Lease dated April, 1990 (the "Lease")
by and between Steven D. Rosenberg,
as Trustee of Fifth Street Realty Trust,
a Massachusetts Declaration of Trust ("Landlord")
and Biogen, Inc., a Massachusetts
corporation ("Tenant")

#### Dear Sir/Madam:

Reference is made to the above-described Lease in which the undersigned is the Tenant. We understand that First Trade Union Savings Bank, F.S.B. ("the Bank") is accepting an assignment of Landlord's rights under the Lease as security for an obligation in the amount of Eight Hundred Fifty Thousand Dollars (\$850,000.00) and we hereby, as a material inducement to you to loan said amount to Landlord, represent that:

1. The Lease is for a term of Fourteen (14) years and Seven (7) months commencing on June 1, 1990 or the date of the mortgage closing with the Bank, whichever is later, and ending December 31, 2004; and the Lease covers all of the real property known and numbered as 190 Fifth Street, Cambridge, Massachusetts (the "Property"). A true and correct copy of the Lease is attached hereto as Exhibit A and incorporated herein by reference thereto.

2. There are no modifications, amendments, supplements, arrangements, side letters or understandings, oral or written, of any sort, modifying, amending, altering, supplementing or changing the terms of the Lease.

3. The Lease is in full force and effect, and the Lease has been duly executed and delivered by, and is a binding obligation of, the Tenant as set forth therein.

4. There are no security deposits held by Landlord, and there are no other payments on account previously made by Tenant to the Landlord.

5. The undersigned acknowledges a) that the Lease is a Triple Net Lease with the base rent until December 31, 1991 in an amount of \$164,000.00 per annum or \$13,666.66 per month payable in advance on a monthly basis, and b) that no rent yet been paid under the Lease and no rent shall be paid in the future for a period in excess of one (1) month in advance.

6. TO THE BEST OF THE TENANT'S KNOWLEDGE, The improvements on the Premises are free from defects in design, materials and workmanship; and the improvements meet all governmental requirements, including, but not limited to, zoning and environmental requirements.

7. Neither the Landlord nor the Tenant are in default under the Lease and Landlord has peformed the obligations required to be performed by Landlord under the terms thereof through the date hereof.

8. The Lease shall be subordinate to a Mortgage and Security Agreement on the Premises by the Landlord to the Bank and an assignment of Landlord's interest in the Lease given by Landlord to the Bank; and in the event of a merger of Landlord and Tenant in any manner, the interest of Tenant and Landlord shall not merge.

9. Landlord and Tenant agree not to modify, amend, terminate, assign or otherwise change the Lease without the prior written consent of the Bank.

10. In the event of a default by Landlord under any of the terms or provisions of the Lease, Tenant shall give adequate notice to the Bank and sufficient time to cure such default.

Date: June 7, 1990

Very truly yours,

Biogen, Inc.

By: /s/ David W. Dennen David W. Dennen, Ph.D. Vice President of Operations Hereunto Duly Authorized

Exhibit 10.42

.

## Exhibit A

## ANNUAL RETAINER SUMMARY SHEET

	CURRENT	PROPOSED (EFFECTIVE AS OF 1/1/05)	
ANNUAL RETAINER	\$20,000	\$ 25,000	
COMMITTEE CHAIR FEES			
FINANCE AND AUDIT	Θ	\$ 20,000	
COMPENSATION AND MANAGEMENT DEVELOPMENT	0	\$ 10,000	
CORPORATE GOVERNANCE	0	\$ 10,000	
ANNUAL FINANCE AND AUDIT COMMITTEE ANNUAL FEE (EXCEPT CHAIR)	Θ	\$ 5,000	
FLE (LAGEFI GHAIR)	0	φ 5,000	

No change to per meeting fee or equity awards

110007-1 HARSHBAB

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

## **COMPUTATION OF RATIO OF EARNINGS TO FIXED CHARGES(1)**

		Years Ended December 31,		
	2004	2003	2002	
		(In thousands, except ratios)		
Income before income tax provision (benefit)	\$ 64,093	\$ (880,624)	\$ 231,522	
Fixed charges:				
Interest expense and amortization of original issue discount on all indebtedness	18,499	15,105	16,073	
Interest included in rent expense	5,312	1,943	1,541	
Total fixed charges	23,811	17,048	17,614	
Income before income tax provision (benefit) and fixed charges	87,904	(863,576)	249,136	
Ratio of earnings (loss) to fixed charges	3.69	—	14.14	

(1) The ratio of earnings to fixed charges was computed by dividing earnings (loss) before income taxes and fixed charges by fixed charges for the periods indicated. Fixed charges include (i) interest expense and amortization of original issue discount on all indebtedness and (ii) a reasonable approximation of the interest factor deemed to be included in rental expense.

# EXHIBIT 21.1

## LIST OF SUBSIDIARIES

ENTITY

# INCORPORATED

:

DOMESTIC	
Biogen Idec MA Inc.	MA
Biogen Idec U.S. Corporation	MA
Biogen Idec U.S. Limited Partnership	MA
Biogen Idec Holding I Inc.	DE
Biogen Idec Holding II Inc.	DE
The Biogen Idec Foundation Inc.	MA
Biogen Idec (RTP) Realty LLC	DE
Biogen Idec Realty Corporation	MA
Biogen Idec Realty Limited Partnership	MA
Biogen Idec U.S. West Corporation	DE
Biogen Idec U.S. Pacific Corporation	DE
Biogen Idec Nobel Research Center, LLC	DE
Biogen Idec Trade Services Building, LLC	DE
Biogen Idec Manufacturing Operations, LLC	DE

## FOREIGN

Biogen Idec Canada Inc. Biogen Idec Austria GmbH Biogen Idec Belgium SA/NV Biogen Idec International BV Biogen Idec International BV Biogen Idec (Denmark) A/S Biogen Idec (Denmark) Manufacturing ApS Biogen Idec Finland Oy Biogen Idec Finland Oy Biogen Idec GmbH Biogen Idec Iberia SL Biogen Idec Limited Biogen Idec Norway AS Biogen Idec Portugal - Sociedade Farmaceutica, Unipessoal, Lda Biogen Idec Sweden AB Biogen Idec (Switzerland) GmbH Biogen Dompe Srl Biogen Idec Australia Pty Ltd Biogen Idec Japan Ltd. Idec Seivaku KK	Canada Austria Belgium The Netherlands The Netherlands Denmark Denmark Finland France Germany Spain UK Norway Portugal Sweden Switzerland Italy Switzerland Australia Japan Japan
· · · · · ·	
Idec Seiyaku KK	Japan Japan
Biogen Idec (Bermuda) Investments Limited	Bermuda
Biogen Idec (Bermuda) Investments II Limited	Bermuda
Biotech Manufacturing C.V	Netherlands

#### Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-89792), Registration Statement on Form S-4 (No. 333-107098) and Registration Statements on Form S-8 (Nos. 333-97211, 333-106794, 333-65494, 333-47904, 333-81625, 333-110432 and 333-110433) of Biogen Idec Inc. of our report dated March 29, 2005 relating to the financial statements and financial statement schedule, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 31, 2005

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

The Board of Directors and Shareholders Biogen Idec Inc.:

We consent to incorporation by reference in the registration statements (Nos. 333-110432, 333-110433, 333-106794, 333-97211, 333-65494, 333-47904 and 333-81625) on Form S-8, in the registration statement (No. 333-107098) on Form S-4 and in the registration statement (No. 333-89792) on Form S-3 of Idec Pharmaceuticals Corporation and subsidiaries of our report dated January 29, 2003, relating to the consolidated statements of income, shareholders' equity and cash flows of Biogen Idec Inc. and subsidiaries for the year ended December 31, 2002, and the related consolidated financial statement schedule, which report appears in the 2002 Annual Report on Form 10-K of Idec Pharmaceuticals Corporation.

/s/ KPMG LLP

San Diego, California March 31, 2005

#### I, James C. Mullen, certify that:

1. I have reviewed this annual report of Biogen Idec Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ James C. Mullen

James C. Mullen Chief Executive Officer and President

Date: March 31, 2005

I, Peter N. Kellogg, certify that:

1. I have reviewed this annual report of Biogen Idec Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Peter N. Kellogg

Peter N. Kellogg Executive Vice President, Finance and Chief Financial Officer

Date: March 31, 2005

#### CERTIFICATION

#### Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Biogen Idec Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2004 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2005

/s/ James C. Mullen

James C. Mullen Chief Executive Officer and President [principal executive officer]

Date: March 31, 2005

/s/ Peter N. Kellogg

Peter N. Kellogg Executive Vice President, Finance and Chief Financial Officer [principal financial officer]

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.