BIOGEN IDEC INC. Form 10-K February 06, 2009

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

(Mark One)

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

For the fiscal year ended December 31, 2008

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

For the transition period from to

Commission file number: 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)

33-0112644

(I.R.S. Employer Identification No.) **02142**

 $(Zip\ code)$

(617) 679-2000

(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$0.0005 par value

The Nasdaq Global Select Market

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Non-accelerated filer o
(Do not check if a smaller reporting company)

Smaller reporting company o

Large accelerated filer b Accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes o No b

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 \$16,179,698,132.

As of February 2, 2009, the Registrant had 297,252,825 shares of Common Stock, \$0.0005 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2009 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 Year Ended December 31, 2008

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PART I

Item 1. Business

Overview

Biogen Idec Inc. (we or Biogen Idec) creates new standards of care in therapeutic areas with high unmet medical needs. Our business strategy is focused on discovering and developing first-in-class or best-in-class products that we can deliver to specialty markets globally. Patients in more than 90 countries benefit from Biogen Idec s significant products that address medical needs in the areas of neurology, oncology and immunology.

Marketed Products

We currently have four therapeutic products on the market, which are summarized in the table below.

Product	Product Indications	Revenues to 2008	Biogen Idec (2007	(in millions) 2006
AVONEX®	Relapsing multiple sclerosis	\$ 2,202.6	\$ 1,867.8	\$ 1,706.7
(interferon beta-1a)				
$RITUXAN^{@}*$	Certain B-cell non-Hodgkin s	1,128.2	926.1	810.9
(rituximab)	lymphoma			
	Rheumatoid arthritis			
TYSABRI®	Relapsing multiple sclerosis	588.6	229.9	35.8
(natalizumab)	Crohn s disease			
FUMADERM®	Severe psoriasis	43.4	21.5	9.5
(dimethylfumarate and	•			
monoethylfumarate salts)				

^{*} Outside the United States, Canada and Japan, MabThera is the trade name for rituximab. We refer to rituximab, RITUXAN and MabThera collectively as RITUXAN.

Other Sources of Revenue

We receive royalty revenues on sales by our licensees of other products covered under patents that we control. In 2008, 2007 and 2006, our royalty revenues were \$116.2 million, \$102.1 million and \$86.2 million, respectively.

Additional financial information about our product revenues, other revenues and geographic areas is set forth in Note 22, Segment Information in Notes to Consolidated Financial Statements.

Research and Development

We devote significant resources to research and development programs and external business and corporate development efforts. We intend to focus our research and development efforts on finding novel therapeutics in areas of high unmet medical need, both within our current focus areas of neurology, oncology, immunology and cardiology

as well as in new therapeutic areas. We have 22 pipeline products in Phase 2 trials or beyond. In 2008, 2007 and 2006, our research and development costs were \$1,072.1 million, \$925.2 million and \$718.4 million, respectively.

Available Information

We were formed as a California corporation in 1985 and became a Delaware corporation in 1997. Our principal executive offices are located at 14 Cambridge Center, Cambridge, Massachusetts 02142 and our telephone number is (617) 679-2000. 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. The contents of our website are not incorporated into this filing.

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Marketed Products

Our marketed products address multiple sclerosis (MS), non-Hodgkin s lymphoma (NHL), rheumatoid arthritis (RA), Crohn s disease (CD) and psoriasis. As part of our ongoing development efforts, we are also seeking to expand our marketed products into other diseases, such as chronic lymphocytic leukemia (CLL), lupus nephritis, ANCA-associated vasculitis, multiple myeloma and ulcerative colitis. The approved indications for, and ongoing development of, our marketed products are summarized in the table below.

Product	Product Indications	Status	Development and/or Marketing Collaborators
AVONEX	Relapsing MS	Approved numerous countries worldwide	None
	Ulcerative colitis	Phase 2	None
RITUXAN	Certain B-cell NHL	Approved numerous countries worldwide	All RITUXAN Indications: U.S. Genentech Japan Zenyaku and Chugai Outside U.S. and Japan Roche
	RA, anti-TNF-inadequate responders	Approved U.S.	See above
	RA, DMARD naïve and inadequate responders (IR)	Phase 3 complete (DMARD naïve) Filed with regulators (DMARD-IR)	See above
	CLL	Phase 3 complete and regulatory filings planned	See above
	Lupus nephritis	Phase 3	U.S. Genentech
	ANCA-associated vasculitis	Phase 2/3	U.S. Genentech
TYSABRI	Relapsing MS	Approved numerous countries worldwide	Elan
	CD	Approved U.S.	Elan
	Multiple myeloma	Phase 1/2	Elan
FUMADERM	Severe psoriasis	Approved Germany	Almirall
AVONEX			

We currently market and sell AVONEX worldwide for the treatment of relapsing MS. 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 that are 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 MS both to slow the accumulation of disability and to reduce the frequency of flare-ups. AVONEX is approved to treat relapsing MS, including patients with a first clinical episode and MRI features consistent with MS.

AVONEX is on the market in over 70 countries. Based on data from an independent third party research organization, information from our distributors and internal analysis, we believe that AVONEX is the most prescribed therapeutic product for the treatment of MS worldwide. Globally over 135,000 patients use AVONEX.

2008 Developments

We continue to work to expand the clinical data available about AVONEX and MS treatments, invest in AVONEX lifecycle development and focus on projects that will help patients adhere to therapy.

In September 2008, we announced that data from the follow-up study known as ASSURANCE showed the long-term benefits of AVONEX therapy in patients with relapsing MS for up to 15 years. The ASSURANCE study represents the long-term follow-up of patients who participated in the Multiple Sclerosis Collaborative Research Group (MSCRG) trial, the original Phase 3 pivotal trial from which AVONEX was approved. Specifically, the ASSURANCE study showed that patients currently taking AVONEX for up to 15 years versus those not on AVONEX therapy reported: (1) significantly lower disability progression as measured by a mean change in Expanded Disability Scale Scores (EDSS) of 2.3 vs. 3.3 from the MSCRG baseline; (2) lower disability progression

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to EDSS milestones four, six and seven; (3) greater quality of life as measured by the physical component score of the SF-36 health survey; (4) significantly greater sense of independence in self care; and (5) significantly more independent living.

We have also extended the five-year study known as CHAMPIONS for an additional five years. 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 ten years. We also continue to support Phase 4 investigator-run studies evaluating AVONEX in combination with other therapies.

Outside of MS, we are conducting a Phase 2 trial of AVONEX in ulcerative colitis, a form of inflammatory bowel disease.

RITUXAN

RITUXAN is one of the highest selling oncology therapeutics in the world and has had approximately 1.5 million patient exposures worldwide across all indications. In the United States, RITUXAN is approved for NHL with the following label indications:

The treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent;

The treatment of patients with previously untreated diffuse large B-cell, CD20-positive, NHL, or DLBCL, in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens;

The treatment of patients with previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP (cyclophosphamide, vincristine and prednisone) chemotherapy; and

The treatment of patients with non-progressing (including stable disease), low grade CD20-positive, B-cell NHL, as a single agent, after first line CVP chemotherapy.

NHL is a cancer that affects lymphocytes, which are a type of white blood cell that help to fight infection. RITUXAN is an immunotherapy that targets CD20-positive B-cell lymphocytes involved in certain types of NHL and helps the immune system to eliminate them.

RITUXAN, in combination with methotrexate, is also approved for reducing signs and symptoms and to slow the progression of structural damage in adult patients with moderately-to-severely active RA who have had an inadequate response to one or more tumor necrosis factor, or TNF, inhibitor therapies. RA is a chronic disease that occurs when the immune system mistakenly attacks the body s joints, resulting in inflammation, pain and joint damage. RITUXAN targets CD20-positive B-cell lymphocytes believed to be involved in RA and helps the immune system to eliminate them.

Our revenues from RITUXAN include three components:

<u>U.S. Co-Promotion Profits.</u> In the United States, we co-promote RITUXAN in collaboration with Genentech, Inc. All U.S. sales of RITUXAN are recognized by Genentech, and we record our share of the pre-tax

co-promotion profits on a quarterly basis. Genentech provides the primary support functions for the commercialization of RITUXAN in the United States and has worldwide manufacturing responsibilities.

<u>Rest of World Revenues.</u> Outside the United States, F. Hoffman-La Roche Ltd., or Roche, markets and sells RITUXAN, except in Japan where RITUXAN is co-marketed by Zenyaku Kogyo Co. Ltd., or Zenyaku, and Chugai Pharmaceutical Co., Ltd., or Chugai, an affiliate of Roche. In Canada, we receive our share of pre-tax co-promotion profits from Roche. Outside of the U.S. and Canada, we receive royalties through Genentech on sales of RITUXAN for a period of 11 years from the date of first commercial sale in each country. For the majority of European countries, the first commercial sale of RITUXAN occurred in the second half of 1998.

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Therefore, we expect a significant decrease in royalty revenues on sales of RITUXAN outside the United States beginning in the latter half of 2009. Specifically, the royalty period with respect to sales in France, Spain, Germany and the United Kingdom will expire in 2009. The royalty period with respect to sales in Italy will expire in 2010. The royalty period with respect to sales in other countries will expire through 2012.

<u>Expense Reimbursement.</u> We receive reimbursement from Genentech for our selling and development expenses incurred in the United States.

In the United States, we share responsibility with Genentech for continued development of RITUXAN. Such continued development includes conducting supportive research and post-approval clinical studies and seeking potential approval for additional indications. Under the terms of our collaboration agreement with Genentech, we also have the right to participate with Genentech in the development and commercialization of any anti-CD20 product acquired or developed by Genentech, which we refer to as a New Anti-CD20 Product, as well as the right to participate with Genentech in the development and commercialization of any anti-CD20 product that Genentech licenses from a third party, which we refer to as a Third Party Anti-CD20 Product. Under the terms of the collaboration agreement there are different rights and obligations that apply depending on whether an anti-CD20 product is a New Anti-CD20 Product or a Third Party Anti-CD20 Product. Currently, there is only one New Anti-CD20 Product, ocrelizumab, and only one Third Party Anti-CD20 Product, GA101. We have the right to co-promote with Genentech any New Anti-CD20 Products resulting from such development in the United States. We are currently in arbitration with Genentech as to whether Genentech has the right to develop collaboration products without our approval. See Note 19, Litigation, in Notes to Consolidated Financial Statements for a description of that arbitration. Our agreement with Genentech provides that the successful development and commercialization of the first New Anti-CD20 Product will decrease our percentage of co-promotion profits of the collaboration. Ocrelizumab is in Phase 3 trials for rheumatoid arthritis and lupus nephritis and is also in a Phase 2 trial for relapsing MS.

2008 Developments

In April 2008, we and Genentech announced that a Phase 2/3 study of RITUXAN in primary-progressive multiple sclerosis (PPMS) did not meet its primary endpoint, as measured by the time to confirmed disease progression during the 96-week treatment period.

In April 2008, we and Genentech also announced that a Phase 2/3 study of RITUXAN in systemic lupus erythematosus (SLE) did not meet its primary endpoint, defined as the proportion of RIXUTAN treated patients who achieved a major clinical response or partial clinical response compared to placebo at 52 weeks. The study also did not meet any of the six secondary endpoints.

In December 2008, we and Genentech announced the results of two global Phase 3 registrational studies of RITUXAN in CLL, a cancer affecting B-cell lymphocytes. These studies, known as the CLL8 and REACH studies, showed that RITUXAN plus chemotherapy significantly increased the time patients lived without their disease advancing, as defined by the primary endpoint of progression-free survival, when compared to chemotherapy alone. Specifically, in the CLL8 study, 817 patients newly diagnosed with CLL were given RITUXAN combined with chemotherapy, with 41% of such patients experiencing a reduction in the risk of death or cancer progression when compared with those treated with chemotherapy alone. In addition, the REACH study, involving 552 participants, found RITUXAN reduced the risk of cancer progression or death by 35 percent for patients who had a relapse of CLL symptoms after chemotherapy. We and Genentech anticipate submitting an application to the FDA for potential new indications for RITUXAN in first- and second-line treatment of CLL in 2009.

In December 2008, we and Genentech announced that a Phase 3 clinical study of RITUXAN in patients with early RA who have not previously been treated with methotrexate met its primary endpoint. In this study, known as IMAGE,

patients received two infusions of either 500 mg or 1000 mg of RITUXAN or placebo for up to two treatment courses in combination with a stable dose of methotrexate. At week 52, only patients in the 1000 mg treatment group met the primary endpoint and showed significantly less progression of joint damage compared to patients who received placebo in combination with methotrexate.

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We, along with Genentech and Roche, initiated a Phase 3 clinical trial of RITUXAN in RA patients who are inadequate responders to disease-modifying anti-rheumatic drugs, or DMARDs, in 2006. In January 2008, we announced that the trial, known as SERENE, met its primary endpoint of a significantly greater proportion of RITUXAN-treated patients achieving an American College of Rheumatology (ACR) 20 response (the proportion of patients who achieve at least 20% improvement) at week 24, compared to placebo. In this trial, patients who received either 500 mg or 1000 mg of RITUXAN as a single treatment course of two infusions in combination with a stable dose of methotrexate displayed a statistically significant improvement in symptoms compared to patients who received placebo in combination with methotrexate. In September 2008, we and Genentech filed for an expansion of the RITUXAN label to include treatment of RA patients who have had an inadequate response to DMARDs.

We, along with Genentech, are conducting a Phase 3 clinical trial of RITUXAN in lupus nephritis, an inflammation of the kidney caused by systemic lupus erythematosus, a disease of the immune system. We anticipate reporting results from this trial in the first half of 2009.

The National Institutes of Health is conducting a Phase 2/3 clinical trial of RITUXAN in ANCA-associated vasculitis, a type of inflammation of the blood vessels. We anticipate that data from this trial will be available in 2009.

TYSABRI

TYSABRI was initially approved by the FDA in November 2004 to treat relapsing MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and our collaborator Elan Corporation plc, or Elan, voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of cases of PML in patients treated with TYSABRI in clinical studies. In July 2006, TYSABRI was reintroduced in the United States, and introduced in the European Union, as a monotherapy treatment for relapsing MS to slow the progression of disability and reduce the frequency of clinical relapses.

TYSABRI is marketed under risk management or minimization plans as agreed to with local regulatory authorities. In the United States, TYSABRI was reintroduced with a risk minimization action plan known as the TOUCH Prescribing Program, a rigorous system intended to educate physicians and patients about the risks involved and assure appropriate use of the product. TYSABRI is currently approved for the treatment of MS in 39 countries.

In January 2008, we and Elan announced the FDA s approval of a supplemental biologics license application, or sBLA, for use of TYSABRI for inducing and maintaining clinical response and remission in adult patients with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. TYSABRI became available for the treatment of CD in the United States in the first quarter of 2008.

As of the end of 2008, approximately 37,000 patients were on commercial TYSABRI therapy worldwide. Cumulatively, approximately 48,300 patients have been treated with TYSABRI in the post-marketing setting.

Under the terms of our collaboration with Elan, we are solely responsible for the manufacture of TYSABRI worldwide, and we collaborate with Elan on the product s marketing, commercial distribution and ongoing development activities. The collaboration agreement with Elan is designed to effect an equal sharing of profits and losses generated by the activities of the collaboration between Elan and us. Under our agreement with Elan, however, if sales of TYSABRI exceed specified thresholds, Elan is required to make milestone payments to us in order to continue sharing equally in the collaboration s results. During 2008, Elan paid us \$75 million to maintain the current profit sharing under our collaboration agreement. In January 2009, Elan paid us an additional \$50 million milestone payment to maintain this profit sharing split.

In the United States, we sell TYSABRI to Elan who sells the product to third party distributors. Elan and we co-market the product. The sales price to Elan in the United States is set at the beginning of each quarterly period to effect an approximate equal sharing of the gross margin between Elan and us. In addition, in the United States both parties share equally in the operating costs, which include research and development, selling, general and administrative expenses and other similar costs. For sales outside of the United States, we are responsible for

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distributing TYSABRI to customers and are primarily responsible for all operating activities. We and Elan share equally in the operating results of TYSABRI outside the United States.

2008 Developments

The FDA s approval of TYSABRI to treat relapsing MS was based on one-year data from two Phase 3 clinical studies. In September 2008, we and Elan announced that a post hoc analysis of one of these studies showed TYSABRI treatment increases the probability of achieving sustained improvement in physical disability over two years when compared to placebo. This post-hoc analysis provides the first evidence that TYSABRI is associated with a significant improvement in functional outcome, rather than only slowing or preventing progression of disability, in those living with relapsing MS. These findings were presented as a poster presentation at the World Congress on Treatment and Research in Multiple Sclerosis in September 2008.

We initiated the first clinical trial of TYSABRI in oncology in 2008. The objectives of this Phase 1/2 study are to evaluate the safety and potential anti-tumor activity of TYSABRI in patients with relapsed or refractory multiple myeloma.

Since the reintroduction of TYSABRI in the United States and the introduction of TYSABRI outside the United States in July 2006, we have disclosed five cases of progressive multifocal leukoencephalopathy, or PML, a known side effect, in patients taking TYSABRI. These patients are the only confirmed cases of PML reported to us during this period.

FUMADERM

We acquired FUMADERM as part of our purchase of Fumapharm AG in June 2006 and subsequently acquired the right to distribute FUMADERM in Germany from Fumedica GmbH effective May 1, 2007. FUMADERM acts as an immunomodulator and is approved in Germany for the treatment of severe psoriasis. The product has been in commercial use in Germany since 1994 and is the most prescribed oral systemic treatment for severe psoriasis in Germany.

Other Sources of Revenue

Our product line previously included ZEVALIN (ibritumomab tiuxetan), which is part of a treatment regimen for certain B-cell non-Hodgkin s lymphoma, and AMEVIVE (alefacept), a treatment for certain psoriasis. We have sold or exclusively licensed the rights to these products to third parties and continue to receive royalty or supply agreement revenues based on those products.

We also receive royalties on 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, or Schering-Plough, on sales of its alpha interferon products in the United States pursuant to an interference settlement covering our alpha interferon patents and patent applications. Schering-Plough sells its INTRON® A (interferon alfa-2b) brand of alpha interferon in the United States 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 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 United States, 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,

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including Abbott Laboratories, the major worldwide marketer of hepatitis B diagnostic kits. See Patents and Other Proprietary Rights Recombinant Hepatitis B Antigens.

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

Our royalty revenues are dependent upon our licensees—sales of licensed products which could vary significantly due to competition, manufacturing difficulties and other factors. In addition, the expiration or invalidation of any underlying patents could reduce or eliminate the royalty revenues derived from such patents.

Late-Stage Product Candidates

BG-12

In addition to the ongoing development of our marketed products, we are currently developing the late stage product candidates that are set forth in the table below.

Product	Product Indications	Status	Development and/or Marketing Collaborators
BG-12	Relapsing MS	Phase 3	None
Anti-CD80 MAb (galiximab)	Relapsed NHL	Phase 3	None
Anti-CD23 MAb (lumiliximab)	Relapsed CLL	Phase 2/3	None
Humanized Anti-CD20 MAb (ocrelizumab)	RA	Phase 3	U.S. Genentech Japan Chugai and Zenyaku Outside U.S. and Japan Roche
	Lupus nephritis	Phase 3	See above
Lixivaptan	Hyponatremia, commonly seen in acute decompensated heart failure	Phase 3	Cardiokine
ADENTRI®	Acute decompensated heart failure with renal insufficiency	Phase 3	None

BG-12 is an oral fumarate derivative that is being tested in relapsing MS and appears to have neuroprotective and anti-inflammatory properties. We acquired BG-12 with the purchase of Fumapharm in June 2006. Two Phase 3 trials, known as DEFINE and CONFIRM, for relapsing MS are currently underway evaluating the effect of BG-12 on measurements of clinical relapse, the progression of disability and various MRI measures, with the CONFIRM trial including a glatiramer acetate (Copaxone®) reference comparator arm.

Anti-CD80 MAb (galiximab)

Galiximab is a monoclonal antibody (MAb) directed against the CD80 surface antigen on human B-cells that we developed using our Primatized[®] antibody technology. Anti-CD80 antibodies work by binding to a particular protein (the CD80 antigen) on the surface of normal and malignant B-cells. From there, they recruit the body s natural defenses to attack and kill the marked B-cells. A Phase 3 trial is currently underway that is designed to compare treatment with galiximab in combination with RITUXAN to treatment with RITUXAN in combination with placebo in patients with follicular NHL that have relapsed or failed to respond to initial therapy.

Anti-CD23 MAb (lumiliximab)

Lumiliximab is a monoclonal antibody directed against the CD23 surface antigen on human B-cells that we developed using our Primatized[®] antibody technology. Anti-CD23 antibodies work by binding to a particular protein (the CD23 antigen) on the surface of normal and malignant B-cells. From there, they recruit the body s natural defenses to attack and kill the marked B-cells. A Phase 2/3 study is currently underway that is designed to

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compare treatment with lumiliximab in combination with fludarabine, cyclophosphamide and RITUXAN, a standard chemotherapy regimen, to treatment with FCR alone in patients with relapsed or refractory CLL.

Humanized Anti-CD20 MAb (ocrelizumab)

This second generation anti-CD20 antibody is a humanized monoclonal antibody directed against the CD20 surface antigen on human B-cells, the same antigen that RITUXAN targets. Anti-CD20 antibodies work by binding to a particular protein (the CD20 antigen) on the surface of normal and malignant B-cells. From there, they recruit the body s natural defenses to attack and kill the marked B-cells. During 2008, our collaborator Genentech initiated a fourth Phase 3 study of ocrelizumab for rheumatoid arthritis to study the administration of anti-CD20 as a single infusion and a Phase 3 study of ocrelizumab for lupus nephritis. We are currently in arbitration with Genentech as to whether Genentech has the right to develop collaboration products, including ocrelizumab, without our approval. See Note 19, Litigation, in Notes to Consolidated Financial Statements for a description of that arbitration.

Lixivaptan

Lixivaptan, an oral compound for the potential treatment of hyponatremia and chronic heart failure, is being developed in conjunction with our collaborator Cardiokine Biopharma LLC, or Cardiokine. Lixivaptan is a highly potent, non-peptide, selective V2 vasopressin receptor antagonist. It antagonizes the action of vasopressin (also known as antidiuretic hormone) on the V2 receptors in the kidney collecting duct, causing water to be excreted from the kidney, without affecting sodium or other electrolytes. Based on this mechanism of action, lixivaptan shows promise in the treatment of disease states associated with water retention and electrolyte imbalance, including hyponatremia, which is the most common electrolyte disorder in clinical practice. Hyponatremia is recognized as an independent contributor to negative patient outcomes in many chronic diseases, most notably congestive heart failure, as well as cirrhosis and syndrome of inappropriate anti-diuretic hormone. Two Phase 3 studies of lixivaptan for hyponatremia are currently underway.

Pursuant to our collaboration agreement with Cardiokine, we paid \$50.0 million upfront to Cardiokine and will pay them up to \$170.0 million in milestone payments for successful development and global commercialization of lixivaptan, as well as royalties on commercial sales. We will be responsible for the global commercialization of lixivaptan, and Cardiokine has an option for limited copromotion in the United States.

ADENTRI

ADENTRI, an adenosine A1 receptor antagonist, is being developed under a licensing agreement with CV Therapeutics, Inc. A Phase 3 study is currently underway that is designed to evaluate the efficacy and safety of intravenous ADENTRI for acute decompensated heart failure patients with renal insufficiency.

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Other Research and Development Programs

We intend to continue to commit significant resources to research and development opportunities. We intend to focus our research and development efforts on finding novel therapeutics in areas of high unmet medical need. Our core focus areas are in neurology, oncology, immunology and cardiology, but our research and development efforts extend to additional therapeutic areas. We dedicate resources to the development of new product candidates and, in some cases, to new applications of existing marketed products and late-stage product candidates. Several of our preclinical and early stage product candidates are highlighted in the table below.

Therapeutic Area	Product Candidate	Indication	Status	Development and/or Marketing Collaborators
Neurology	BIIB014	Parkinson s disease early and late stage	Phase 2	Vernalis plc
	Daclizumab	Relapsing MS	Phase 2	Facet Biotech Corporation (formerly part of PDL BioPharma, Inc.)
	CDP323	Relapsing MS	Phase 2	UCB S.A.
	Humanized Anti-CD20 MAb(ocrelizumab)	Relapsing MS	Phase 2	U.S. Genentech Japan Chugai and Zenyaku Outside U.S. and Japan Roche
	PEG-IFN beta 1a	MS	Phase 1	
	Neublastin	Neuropathic pain	Preclinical	NsGene A/S
	LINGO	MS	Preclincal	
Oncology	Volociximab (M200)	Solid tumors non-small cell lung cancer	Phase 2	Facet Biotech
	Hsp90 Inhibitor (CNF2024)	Solid tumors gastrointestinal stromal tumors	Phase 2	
	GA101	NHL	Phase 2	U.S. Genentech (U.S. rights only)
	GA101	CLL	Phase 1	

U.S. Genentech

(U.S. rights only) Anti-IGF-1R (BIIB022) Solid tumors Phase 1 Anti-CRIPTO Solid tumors Phase 1 **RAF** Inhibitor Solid tumors Preclinical **Sunesis Pharmaceuticals** (BIIB024) Anti-Fn14 Solid tumors Preclinical Phase 2 Autoimmune and **BG-12** RA Inflammatory Diseases Anti-TWEAK RA Phase 1 Preclinical **UCB** Anti-CD40L Fab Systemic lupus erythematosus Preclinical Anti-FcRn Pemphigus Cardiovascular Phase 2 ADENTRI (BG9928) Chronic congestive heart failure **Aviptadil** Pulmonary arterial Phase 2 mondoBiotech AG hypertension Phase 1/2a Biovitrum **Emerging** Long acting rFactor IX Hemophilia B Therapeutic Areas

Research and Development Costs

For the years ended December 31, 2008, 2007 and 2006, our research and development costs were \$1,072.1 million, \$925.2 million and \$718.4 million, respectively. Additionally, for 2008, 2007 and 2006, we incurred charges associated with acquired in-process research and development of \$25.0 million, \$84.2 million and \$330.5 million, respectively.

Preclinical

Biovitrum

Long acting rFactor VIII Hemophilia A

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Patents and Other Proprietary Rights

We have filed numerous patent applications in the United States 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 United States 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 stand 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 United States 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, that 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 United States 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 United States 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 United States 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 and AVONEX 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. We employ other trademarks in the conduct of our business under license by third parties, for example, we utilize the mark

TYSABRI under license from Elan. In addition, AMEVIVE is a registered trademark of Astellas US LLC, and ZEVALIN is a registered trademark of Cell Therapeutics, Inc.

Recombinant Beta Interferon

Third parties have pending patent applications or issued patents in the United States, Europe and other countries with claims to key intermediates in the production of beta interferon. These are known as the Taniguchi patents.

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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 United States, 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 United States in May 2013 and have expired already in other countries of the world. The Roche patents expired in the United States in May 2008, which ended our obligation to pay Roche royalties on sales of AVONEX in the United States. The Roche patents also have generally expired elsewhere in the world. The Rentschler EU patent expires in July 2012.

RITUXAN 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. We have also been granted patents covering RITUXAN by the European and Japanese Patent Offices. In the United States 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. Our recently-granted patent in certain European countries claiming the treatment with anti-CD20 antibodies of certain auto-immune indications, including rheumatoid arthritis, has been revoked by the European Patent Office. We are appealing the decision. In addition, after revocation actions were filed against the same patent in the UK, we and Genentech agreed that the corresponding patent claims would cover only RITUXAN and not other CD20 antagonist drugs.

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 2007 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. In addition, we and our collaborator, Genentech, have filed numerous patent applications directed to anti-CD20 antibodies and their uses to treat various diseases. These pending patent applications have the potential of issuing as patents in the United States and abroad covering anti-CD20 antibody molecules for periods beyond that stated above for RITUXAN.

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 United States, Japan and all European countries. 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. In March 2008, we were issued an alpha interferon patent in Canada which triggered Schering-Plough s obligation to pay us additional royalties on sales of alpha interferon products in Canada until expiration of the patent in 2025.

Recombinant Hepatitis B Antigens

We have obtained numerous patents in countries around the world, including in the U.S. and in Europe, 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, as described above under Principal Licensed Products. The obligation of GlaxoSmithKline and Merck to pay royalties on sales of hepatitis

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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 United States, we were granted patents in the United States 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 and have also since expired in those countries in which we have obtained supplementary protection certificates. See Item 3 Legal Proceedings for a description of our litigation with Classen Immunotherapies, Inc.

TYSABRI

We are developing TYSABRI in collaboration with Elan. TYSABRI is presently claimed in a number of pending patent applications and issued patents held by both companies in the United States 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 United States the principal patents covering the product and methods of manufacturing the product generally expire between 2014 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 United States generally between 2012 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 use or disclosure of such information.

Sales, Marketing and Distribution

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, advertisements, professional symposia, direct mail, selling initiatives, public relations and other methods. We provide 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 United States which provide qualified uninsured or underinsured patients with commercial products at no charge. Additional information about our sales, marketing and distribution efforts for each of our commercialized products is set forth below.

AVONEX

We continue to focus our marketing and sales activities on maximizing the potential of AVONEX in the United States and the rest of world in the face of increased competition. In the United States, Canada, Brazil, Argentina, Australia, Japan and most of the major countries of the EU, we market and sell AVONEX through our own sales forces and marketing groups and distribute AVONEX principally through wholesale distributors of

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pharmaceutical products, mail order specialty distributors or shipping service providers. In other countries, we sell AVONEX to distribution partners who are then responsible for most marketing and distribution activities.

RITUXAN

In the United States, we market and sell RITUXAN in collaboration with Genentech through dedicated sales and marketing staffs. RITUXAN is generally sold to wholesalers, specialty distributors and directly to hospital pharmacies. Sales efforts are focused on hematologists, medical oncologists and rheumatologists in private practice, at community hospitals and at major medical centers in the United States. Genentech provides marketing support services for RITUXAN including customer service, order entry, shipping, billing, insurance verification assistance, managed care sales support, medical information and sales training.

Outside the United States, Roche markets and sells RITUXAN, except in Japan where RITUXAN is co-marketed by Zenyaku and Chugai, and we do not participate in these activities.

TYSABRI

In the United States, we are principally responsible for marketing TYSABRI for MS and Elan is principally responsible for marketing TYSABRI for Crohn s disease. We and Elan use our own respective sales force and marketing group for these marketing activities. In addition, Elan is responsible for TYSABRI distribution in the United States.

Outside the United States, we are responsible for TYSABRI marketing and distribution. We use a combination of our own sales force and marketing group and third party service providers for these activities.

FUMADERM

Since May 2007, we have marketed and distributed FUMADERM through Almirall Hermal, GmbH, a third party service provider, and we will assume marketing and distribution activities from Almirall Hermal at the end of February 2009.

Competition

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 United States, the European Union and elsewhere in the world and from many large pharmaceutical, chemical and other companies. Many of our competitors are working to develop products similar to those we are developing or already market. Certain of these companies have substantially greater financial, marketing, research and development and human resources than we do. 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.

Competition among products approved for sale may be based, among other things, on patent position, product efficacy, safety, convenience, reliability, availability and price. In addition, early entry of a new pharmaceutical

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product into the market may have important advantages in gaining product acceptance and market share. 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.

We may face increased competitive pressures as a result of the emergence of biosimilars. Most of our marketed products, including AVONEX, RITUXAN and TYSABRI, are licensed under the Public Health Service Act as biological products. Unlike small molecule drugs, which are subject to the generic drug provisions (Hatch-Waxman Act) of the U.S. Food, Drug, and Cosmetic Act, there currently is no process in the United States for the submission or approval of biological products based upon abbreviated data packages or a showing of sameness to another approved product. There is public dialogue at FDA and in the Congress, however, regarding the scientific and statutory basis upon which such products, known as biosimilars or follow-on biologics, could be approved and marketed in the United States. We cannot be certain when, or if, Congress will create a statutory pathway for the approval of biosimilars. In Europe, the European Medicines Agency, or EMEA, has issued guidelines for approval of biological products through an abbreviated pathway, and the first biosimilars have been approved. If a biosimilar version of one of our products were approved, it could have a negative effect on sales of that product.

AVONEX AND TYSABRI

AVONEX and TYSABRI both compete primarily with three other products:

REBIF® (*interferon-beta-1a*), which is co-promoted by EMD Serono (a subsidiary of Merck Serono) and Pfizer in the United States and sold by Merck Serono in Europe. REBIF generated worldwide revenues of approximately \$1.7 billion in 2007.

BETASERON® (*interferon-beta-1b*), sold by Bayer Healthcare Pharmaceuticals (the U.S. pharmaceuticals affiliate of Bayer Schering Pharma AG) in the United States and sold under the name BETAFERON® by Bayer Schering Pharma AG in the EU. EXTAVIA®, a branded version of interferon beta-1b from Novartis AG, has been approved in the European Union. BETASERON and BETAFERON together generated worldwide revenues of approximately \$1.4 billion in 2007.

COPAXONE® (*glatiramer acetate*), sold by Teva Neuroscience, Inc., or Teva, in the United States and copromoted by Teva and Sanofi-Aventis in Europe. COPAXONE generated worldwide revenues of approximately \$1.7 billion in 2007.

Along with us, a number of companies are working to develop products to treat MS that may in the future compete with AVONEX and TYSABRI. For example, alemtuzumab (marketed by Bayer HealthCare Pharmaceuticals Inc.) is in late-stage development for MS. 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 and TYSABRI. For example, FTY720 (fingolimod) (developed by Novartis AG) and cladribine (developed by Merck Serono) are in late-stage development as oral therapies for MS.

AVONEX and TYSABRI also face competition from off-label uses of drugs approved for other indications.

RITUXAN IN ONCOLOGY

A number of companies are working to develop products to treat B-cell NHLs and other forms of NHL that may ultimately compete with RITUXAN. Other potential competitive products include CAMPATH® (marketed by Bayer HealthCare Pharmaceuticals Inc.), which is indicated for B-cell CLL (an unapproved use of RITUXAN), VELCADE® (marketed by Millennium Pharmaceuticals, Inc.) which is indicated for multiple myeloma (an unapproved use of

RITUXAN), TREANDA® (marketed by Cephalon), and ARZERRA (marketed by GenMab), for which a BLA has been submitted to treat patients with refractory CLL. In addition to the foregoing products, we are aware of other anti-CD20 molecules in development that, if successfully developed and registered, may compete with RITUXAN.

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RITUXAN IN RA

RITUXAN competes with several different types of therapies in the RA market, including:

traditional therapies for RA, including disease-modifying anti-rheumatic drugs, such as steroids, methotrexate and cyclosporine, and pain relievers such as acetaminophen;

TNF inhibitors, such as REMICADE® (infliximab), a drug sold worldwide by Centocor, Inc., a subsidiary of Johnson & Johnson, HUMIRA® (adalimumab), a drug sold by Abbott Laboratories, and ENBREL® (etanercept), a drug sold by Amgen, Inc. and Wyeth Pharmaceuticals, Inc.;

ORENCIA® (abatacept), a drug developed by Bristol-Myers Squibb Company; and

drugs approved for other indications that are used to treat RA.

In addition, a number of companies are working to develop products to treat RA that may ultimately compete with RITUXAN in the RA marketplace. For example, Roche has submitted a BLA for ACTEMRA® (tocilizumab) for the treatment of RA.

FUMADERM

FUMADERM competes with several different types of therapies in the psoriasis market, including oral systemics such as methotrexate and cyclosporine and biologic agents such as RAPTIVA® (efalizumab), a drug sold by Genentech.

Regulatory

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

Regulation of Pharmaceuticals

Before new pharmaceutical products may be sold in the United States and other countries, clinical trials of the products must be conducted and the results submitted to appropriate regulatory agencies for approval. Clinical trial programs must establish efficacy, determine an appropriate dose and regimen, and define the conditions for safe use, a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. In the United States, the results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a Biologics License Application, or BLA, or a New Drug 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 an adequate basis for approval. Similar submissions are required by authorities in other jurisdictions who independently assess the product and may reach the same or different conclusions. Our initial focus for obtaining marketing approval outside the United States is typically the European Union. There are currently three potential tracks for marketing approval in EU countries: mutual recognition, decentralized procedures, and centralized procedures. 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.

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 or approvals from other regulatory agencies have 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.

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In the United States, the FDA may grant accelerated approval status to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments, but accelerated approval status does not ensure that FDA will ultimately approve the product. Under this pathway, the FDA may approve a product based on surrogate endpoints, or clinical endpoints other than survival or irreversible morbidity, or when the product is shown to be effective but can be safely used only if access to or distribution of the product is restricted. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional clinical studies to verify and describe clinical benefit. When accelerated approval requires restricted use or distribution, the sponsor may be required to establish rigorous systems to assure use of the product under safe conditions. These systems are usually referred to as Risk Minimization Action Plans, or RiskMAPs, or Risk Evaluation and Mitigation Strategies, or REMS. In addition, for all products approved under accelerated approval, sponsors must submit all copies of its promotional materials, including advertisements, to the FDA at least thirty days prior to their initial dissemination. The FDA may also withdraw approval under accelerated approval after a hearing if, for instance, post-marketing studies fail to verify any clinical benefit or it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use. The BLA for TYSABRI in MS was initially approved under the accelerated approval pathway based on surrogate endpoints. A stringent restricted distribution program was also imposed. The supplemental BLA for TYSABRI for second-line treatment of Crohn s disease was approved by FDA on January 14, 2008. This indication is subject to the same stringent distribution restrictions as TYSABRI for MS. We cannot be certain that the FDA will approve any products for the proposed indications whether under accelerated approval or another pathway.

If the FDA or other regulatory agency approves products or new indications, the agency may require us to conduct additional post-marketing studies. If we fail to conduct the required studies or otherwise fail to comply with the conditions of accelerated approval, the agency may take action to seek to withdraw that approval. Legislation has been passed in the United States to also provide the FDA with additional powers of sanction regarding non-completion of or non-compliance with certain post-marketing commitments, including RiskMAPs/REMS. In Europe, the EMEA has new powers of sanction for non-completion of post-marketing commitments. These sanctions range from a fine of 10% of global product revenue to removal of the product from the market.

Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. 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. These decisions were based on reports of cases of PML that occurred in patients treated with TYSABRI in clinical studies. PML is a rare and frequently fatal demyelinating disease of the central nervous system. In July 2006, TYSABRI was reintroduced in the United States, and introduced in the European Union, as a monotherapy for relapsing MS.

The FDA also has authority over drug products after approval. The FDA may conduct post-marketing safety surveillance and may require additional post-approval studies or clinical trials and mandate label changes as a result of safety findings. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

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 review and approval of regulatory authorities, including the FDA and EMEA, before the changes can be implemented.

In addition, the FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. However, physicians may prescribe legally available drugs for uses that are not described in the drug s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician s belief that the off-label use is the best treatment for patients. The

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FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA regulations do impose stringent restrictions on manufacturers communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

Good manufacturing practices. 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 approving a product. If, after receiving clearance from regulatory agencies, a company makes a material change 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 following product approval. The FDA, the EMEA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. 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.

Orphan Drug Act. Under the U.S. 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. 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, such as if the later product is shown to be clinically superior to the orphan product. Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the European Union.

Regulation Pertaining to Sales, Marketing and Product Pricing

In the United States, the federal government regularly considers reforming health care coverage and costs. For example, reforms to Medicare have reduced the reimbursement rates for many of our products. Effective January 1, 2005, Medicare pays physicians and suppliers that furnish our products under a payment methodology using average sales price, or ASP, information. Manufacturers, including us, are required to provide ASP information to the Centers for Medicare and Medicaid Services on a quarterly basis. The manufacturer-submitted information is used to compute Medicare payment rates, which are set at ASP plus 6 percent and updated quarterly. There is a mechanism for comparison of such payment rates to widely available market prices, which could cause further decreases in Medicare payment rates, although this mechanism has yet to be utilized. Effective January 1, 2006, Medicare began to use the same ASP plus 6 percent payment methodology to determine Medicare rates paid for products furnished by hospital outpatient departments. As of January 1, 2009, the reimbursement rate in the hospital outpatient setting is ASP plus 4 percent. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the statute provides for civil monetary penalties of up to \$10,000 for each misrepresentation and for each day in which the misrepresentation was applied.

Another payment reform is the addition of an expanded prescription drug benefit for all Medicare beneficiaries known as Medicare Part D. This is a voluntary benefit that is being implemented through private plans under contractual arrangements with the federal government. Like pharmaceutical coverage through private health insurance, Part D plans establish formularies that govern the drugs and biologicals that will be offered and the out- of-pocket obligations for such products. In addition, plans negotiate discounts from drug manufacturers and pass on some of those savings to Medicare beneficiaries.

Future legislation or regulatory actions implementing recent or future legislation 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 United States 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.

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We also participate in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, and under multiple subsequent amendments of that law. Sections 6001, 6002, and 6003 of the Deficit Reduction Act of 2005, or DRA, made significant changes to the Medicaid prescription drug provisions of the Social Security Act. These changes include, but are not limited to, revising the definition of average manufacturer price, or AMP, establishing an obligation to report AMP on a monthly basis, in addition to a quarterly basis, establishing a new formula for calculating Federal upper limits, or FULs, requiring rebates for certain physician-administered drugs, and clarifying rebate liability for authorized generic drugs. 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 the larger of 15.1% of AMP or the difference between AMP and the best price available from us to any commercial or non-governmental customer. The rebate amount must be adjusted upward where the AMP for a product s first full current quarter with the upward adjustment equal to the excess amount. The rebate amount is required to be recomputed each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare and Medicaid Services. The terms of our participation in the program imposes a requirement for us to report revisions to AMP or best price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. In addition, if we were found to have knowingly submitted false information to the government, the statute provides for civil monetary penalties in the amount not to exceed \$100,000 per item of false information in addition to other penalties available to the government.

The availability of federal funds to pay for our products under the Medicaid and Medicare Part B programs requires that we extend discounts under the 340B/PHS drug pricing program. The 340B/PHS drug 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 of the Federal Supply Schedule, or FSS, of the General Services Administration pursuant to our FSS contract with the Department of Veterans Affairs. Under the Veterans Health Care Act of 1992, or the VHC Act, we are required to offer deeply discounted FSS contract pricing to four Federal agencies—the Department of Veterans Affairs, the Department of Defense, the Coast Guard and the Public Health Service (including the Indian Health Service)—for federal funding to be made available for reimbursement of any of our products under the Medicaid program and for our products to be eligible to be purchased by those four Federal agencies and certain Federal grantees. FSS pricing to those four Federal agencies must be equal to or less than the Federal Ceiling Price,—which is, at a minimum, 24% off the Non-Federal Average Manufacturer Price, or Non-FAMP—for the prior fiscal year. In addition, if we are found to have knowingly submitted false information to the government, the VHC provides for civil monetary penalties of not to exceed \$100,000 per false item of information in addition to other penalties available to the government.

We are also subject to various federal and state laws pertaining to health care—fraud and abuse,—including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few 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. In addition, there is an ability for private individuals to bring similar actions. For a description of litigation in this area in which we are currently involved, see Note 19, Litigation, in Notes to Consolidated Financial Statements.

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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. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.

Other Regulations

Foreign Corrupt Practices Act. 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.

NIH Guidelines. We conduct relevant research at all of our research facilities in the United States 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, San Diego, California, and Research Triangle Park, North Carolina, and are required to operate pursuant to certain permits.

Other Laws. 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 are focused on the manufacture of biologics. We currently produce all of our bulk AVONEX, as well as AMEVIVE on a contract basis for Astellas, at our manufacturing facilities located in Research Triangle Park, North Carolina and Cambridge, Massachusetts. We currently produce TYSABRI at our Research Triangle Park facility. We supply the commercial requirements of the antibody for ZEVALIN on a contract basis for Cell Therapeutics, Inc. We manufacture ZEVALIN at our manufacturing facilities in Cambridge, Massachusetts. 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 Research Triangle Park, North Carolina and Cambridge, Massachusetts. Our existing licensed manufacturing facilities operate under multiple licenses from the FDA, regulatory authorities in the EU and other regulatory authorities. We use a third party to manufacture the active pharmaceutical ingredient of FUMADERM and another third party to further process that to produce the FUMADERM pill. The chart below outlines the location of our primary manufacturing locations and products manufactured therein:

Research Triangle				
Product	Park	Cambridge	Third Party	
AVONEX	X	X		

TYSABRI X

AMEVIVEX

ZEVALIN X

FUMADERM X

CLINICAL PRODUCTS X X X X

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We are constructing a large-scale biologic manufacturing facility in Hillerød, Denmark to be used to manufacture TYSABRI and other products in our pipeline. The first phase is complete, which included construction of a labeling and packaging facility, administrative building and lab facility; installation of major equipment; and partial completion of a bulk manufacturing facility. The second phase of the project, which we commenced in January 2007, involves the completion and fit out of the bulk manufacturing facility and construction of a warehouse. The large scale manufacturing facility is expected to be ready for commercial production in 2010. See the section of Item 1A Risk Factors entitled We have made a significant investment in constructing a manufacturing facility the success of which depends upon the completion and licensing of the facility and continued demand for our products.

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. Many of the raw materials and supplies required for the production of AVONEX, TYSABRI, FUMADERM, ZEVALIN and AMEVIVE are available from various suppliers in quantities adequate to meet our needs. However, due to the unique nature of the production of our products, we do have single source providers of several raw materials. We make efforts to qualify new vendors and to develop contingency plans so that production is not impacted by short-term issues associated with single source providers. Each of our third party service providers, suppliers and manufacturers 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.

While 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, additional manufacturing facilities and outside sources may be required to meet our long-term research, development and commercial production needs. See the sections of Item 1A Risk Factors entitled Problems with manufacturing or with inventory planning could result in our inability to deliver products, inventory shortages or surpluses, product recalls and increased costs , We rely on third parties to provide services in connection with the manufacture of our products and, in some instances, the manufacture of the product itself, and If we fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales.

Our Employees

As of December 31, 2008, we had approximately 4,700 employees.

Our Executive Officers

The following is a list of our executive officers, their ages as of February 6, 2009 and their principal positions.

Name	Age	Position
James C. Mullen	50	Chief Executive Officer and President
Cecil B. Pickett, Ph.D.	63	President, Research and Development
Hans Peter Hasler	53	Chief Operating Officer
Susan H. Alexander, Esq.	52	Executive Vice President, General Counsel and Corporate
_		Secretary
Paul J. Clancy	47	Executive Vice President, Finance and Chief Financial
·		Officer

Robert A. Hamm	57	Executive Vice President, Pharmaceutical Operations & Technology
Michael F. MacLean	43	Senior Vice President and Chief Accounting Officer
Craig Eric Schneier, Ph.D.	61	Executive Vice President, Human Resources, Public Affairs and Communications
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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.

James C. Mullen is our Chief Executive Officer and President and is a director, and has served in these positions since the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation, or 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 Chief Executive Officer and President 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). Mr. Mullen is a member of the board of directors and executive committee of the Biotechnology Industry Organization, or BIO, and is a former chairman of the board of BIO. Mr. Mullen is also a director of PerkinElmer, Inc.

Cecil B. Pickett Ph.D. is our President, Research and Development and has served in that position since September 2006 and has served as one of our directors since September 2006. Prior to joining Biogen Idec, he was Corporate Senior Vice President and President, Schering-Plough Research Institute from March 2002 to September 2006, and before that he was Executive VP of Discovery Research at Schering-Plough Corporation from September 1993 to March 2002. Mr. Pickett is a member of the Institute of Medicine of the National Academy of Sciences. Mr. Pickett is a director of Zimmer Holdings, Inc.

Hans Peter Hasler has served as our Chief Operating Officer since May 2008, served as our Executive Vice President, Global Neurology, Head of International from October 2007 to May 2008, and has managed our international business since the merger. He previously served as Senior Vice President, Head of International from November 2003 to October 2007. He served as Executive Vice President — International of Biogen, Inc. from July 2003 until the merger, and joined Biogen, Inc as Executive Vice President — Commercial Operations in August 2001. Mr. Hasler joined Biogen, Inc. from Wyeth-Ayerst Pharmaceuticals, Inc., an affiliate of American Home Products, Inc. (AHP), where he served as Senior Vice President, Head of Global Strategic Marketing from 1998 to 2001. Mr. Hasler was a member of the Wyeth/AHP Executive Committee and was chairman of the Commercial Council. From 1993 to 1998, Mr. Hasler served in a variety of senior management capacities for Wyeth-Ayerst Pharmaceuticals, including Managing Director of Wyeth Group, Germany, and General Manager of Wyeth/AHP in Switzerland and Central Eastern Europe. Prior to joining Wyeth-Ayerst Pharmaceuticals, Mr. Hasler served as the Head of Pharma Division at Abbott AG. Mr. Hasler is a director of Acino Holding AG and Santhera Pharmaceuticals Holding AG.

Susan H. Alexander is our Executive Vice President, General Counsel and Corporate Secretary and has served in these positions since January 2006. Prior to that, Ms. Alexander served as the Senior Vice President, General Counsel and Corporate Secretary of PAREXEL International Corporation since September 2003. From June 2001 to September 2003, Ms. Alexander served as General Counsel of IONA Technologies. Prior to that, Ms. Alexander served as Counsel at Cabot Corporation from January 1995 to May 2001. Prior to that, Ms. Alexander was a partner at the law firms of Hinckley, Allen & Snyder and Fine & Ambrogne.

Paul J. Clancy is our Executive Vice President, Finance and Chief Financial Officer and has served in that position since August 2007. Mr. Clancy joined Biogen Idec in 2001, and has held several senior executive positions, including Vice President of Business Planning, Portfolio Management and U.S. Marketing, and Senior Vice President of Finance with responsibilities for leading the Treasury, Tax, Investor Relations and Business Planning groups. Prior to joining Biogen Idec, he spent 13 years at PepsiCo, serving in a range of financial and general management positions.

Robert A. Hamm is our Executive Vice President, Pharmaceutical Operations & Technology, and has served in that position since October 2007. Previously, Mr. Hamm served as Senior Vice President, Neurology Strategic Business

Unit from January 2006 to October 2007; Senior Vice President, Immunology Business Unit from the merger in November 2003 until January 2006; and in the same capacity with Biogen, Inc. from November 2002 to November 2003. Before that, he served as Senior Vice President Europe, Africa, Canada and Middle East from October 2001 to November 2002. Prior to that, Mr. Hamm served as Vice President Sales and Marketing of

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Biogen, Inc. from October 2000 to October 2001. Mr. Hamm previously served as Vice President Manufacturing from June 1999 to October 2000, Director, Northern Europe and Distributors from November 1996 until June 1999 and Associate Director, Logistics from April 1994 until November 1996. From 1987 until April 1994, Mr. Hamm held a variety of management positions at Syntex Laboratories Corporation, including Director of Operations and New Product Planning, and Manager of Materials, Logistics and Contract Manufacturing. Mr. Hamm is a director of Inhibitex, Inc. and Progenitor Cell Therapy, LLC.

Michael F. MacLean is our Senior Vice President and Chief Accounting Officer and has served in that position since December 2006. Mr. MacLean joined us in October 2006 as Senior Vice President. Prior to joining us, Mr. MacLean was a managing director of Huron Consulting, where he provided support regarding financial reporting to management and boards of directors of Fortune 500 companies. From June 2002 to October 2005, Mr. MacLean was a partner at KPMG and he was a partner of Arthur Andersen LLP from September 1999 to May 2002.

Craig Eric Schneier, Ph.D. is our Executive Vice President, Human Resources, Public Affairs and Communications and has served in that position since October 2007. Prior to that he was Executive Vice President, Human Resources from November 2003 to October 2007. Mr. Schneier served as Executive Vice President, Human Resources of Biogen, Inc., a position he held from January 2003 until the merger. He joined Biogen, Inc. in 2001 as Senior Vice President, Strategic Organization Design and Effectiveness, after having served as an external consultant to us for eight years. Prior to joining Biogen, Inc., Mr. 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. Mr. 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, Columbia University, and at the Tuck School of Business, Dartmouth College.

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Item 1A. Risk Factors

We are substantially dependent on revenues from our two principal products.

Our current and future revenues depend substantially upon continued sales of our two principal products, AVONEX and RITUXAN, which represented approximately 81% of our total revenues in 2008. Any significant negative developments relating to these two products, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments, would have a material adverse effect on our results of operations. Although we have developed and continue to develop additional products for commercial introduction, we expect to be substantially dependent on sales from these two products for many years. A decline in sales from either of these two products would adversely affect our business.

Our near-term success depends on the market acceptance and successful sales growth of TYSABRI.

A substantial portion of our growth in the near-term is dependent on anticipated sales of TYSABRI. TYSABRI is expected to diversify our product offerings and revenues, and to drive additional revenue growth over the next several years. If we are not successful in growing sales of TYSABRI, it would result in a significant reduction in diversification and expected revenues and adversely affect our business.

Achievement of anticipated sales growth of TYSABRI will depend upon its acceptance by the medical community and patients, which cannot be certain given the significant restrictions on use and the significant safety warnings in the label. Since the reintroduction of TYSABRI in the United States and its introduction in the European Union in July 2006, we have disclosed five confirmed cases of PML, a known side effect, in patients taking TYSABRI. The occurrence of PML or the occurrence of other side effects could harm acceptance and limit TYSABRI sales or result in a withdrawal of TYSABRI from the market. Additional regulatory restrictions on the use of TYSABRI and safety-related labeling changes, whether as a result of reports of cases of PML or otherwise, may significantly reduce expected revenues and require significant expense and management time to address the associated legal and regulatory issues, including enhanced risk management programs. A significant reduction in the acceptance of TYSABRI by the medical community or patients would materially and adversely affect our growth and our plans for the future.

As a relatively new entrant to a maturing MS market, TYSABRI sales may be more sensitive to additional new competing products. A number of such products are expected to be approved for use in MS in the coming years. If these products have a similar or more attractive overall profile in terms of efficacy, convenience and safety, future sales of TYSABRI could be limited.

Our long-term success depends upon the successful development and commercialization of other products from our research and development activities.

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities. Product development and commercialization are very expensive and involve a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. 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 remains that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues may 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.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and

institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current good clinical practice requirements. We have recently opened clinical sites and are enrolling patients in a number of new countries where our experience is more limited, and we are in many cases using the services of third-party contract clinical trial providers. If we fail to adequately manage the design, execution and

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regulatory aspects of our large, complex and diverse clinical trials, our studies and ultimately our regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether.

Adverse safety events can negatively affect our assets, product sales, operations, products in development and stock price.

Even after we receive marketing approval for a product, adverse event reports may have a negative impact on our commercialization efforts. Later discovery of safety issues with our products that were not known at the time of their approval by the FDA could cause product liability events, additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market and the imposition of fines or criminal penalties. Any of these actions could result in, among other things, material write-offs of inventory and impairments of intangible assets, goodwill and fixed assets. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our stock price to decline or experience periods of volatility.

If we fail to compete effectively, our business and market position would suffer.

The biotechnology and pharmaceutical 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 and retention 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 not benefit from significantly greater sales and marketing capabilities, or will not develop products that are accepted more widely than ours. The introduction of alternatives to our products that offer advantages in efficacy, safety or ease of use could negatively affect our revenues and reduce the value of our product development efforts. In addition, potential governmental action in the future could provide a means for competition from developers of follow-on biologics, which could compete on price and differentiation with products that we now or could in the future market.

In addition to competing directly with products that are marketed by substantial pharmaceutical competitors, AVONEX, RITUXAN and TYSABRI also face 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 ours.

We depend, to a significant extent, on reimbursement from third party payors and a reduction in the extent of reimbursement could negatively affect our product sales and revenue.

Sales of our products are dependent, in large part, on the availability and extent of reimbursement from government health administration authorities, private health insurers and other organizations. Changes in government regulations or private third-party payors reimbursement policies may reduce reimbursement for our products and adversely affect our future results.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform healthcare and its cost, and such proposals have received increasing political attention. In the last few years, there have been a number of legislative changes that have affected the reimbursement for our products, including, but not limited to, the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Deficit Reduction Act of 2005. The Deficit Reduction Act made significant changes to the Medicaid prescription drug provisions of the Social Security Act, including changes that impose the monthly reporting of price information and that may have an impact on the Medicaid rebates we pay. In addition, states may more aggressively seek Medicaid rebates as a result of legislation enacted in 2006, which rebate activity could adversely affect our results of operations.

Managed care organizations as well as Medicaid and other government health administration authorities continue to seek price discounts. Government efforts to reduce Medicaid expenses may continue to increase the use of managed care organizations. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

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In addition, some states have implemented and other states are considering price controls or patient-access constraints under the Medicaid program and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid eligible. Other matters also could be the subject of U.S. federal or state legislative or regulatory action that could adversely affect our business, including the importation of prescription drugs that are marketed outside the United States and sold at lower prices as a result of drug price limitations imposed by the governments of various foreign countries.

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 cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices. Within the EU and other countries, some third party trade in our products occurs from markets with lower prices thereby undermining our sales in some markets with higher prices. Additionally, certain countries reference the prices in other countries where our products are marketed. Thus, inability to secure adequate prices in a particular country may also impair our ability to obtain acceptable prices in existing and potential new markets. This may create the opportunity for the third party cross border trade previously mentioned or influence our decision to sell or not to sell the product thus affecting our geographic expansion plans.

When a new medical product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our product candidates.

We depend on collaborators for both product and royalty revenue and the clinical development of future collaboration products, which are outside of our full control.

Collaborations between companies on products or programs are a common business practice in the biotechnology industry. Out-licensing typically allows a partner to collect up front payments and future milestone payments, share the costs of clinical development and risk of failure at various points, and access sales and marketing infrastructure and expertise in exchange for certain financial rights to the product or program going to the in-licensing partner. In addition, the obligation of in-licensees to pay royalties or share profits generally terminates upon expiration of the related patents. We have a number of collaborators and partners, and have both in-licensed and out-licensed several products and programs. These collaborations include several risks:

we are not fully in control of the royalty or profit sharing revenues we receive from collaborators, and we cannot be certain of the timing or potential impact of factors including patent expirations, pricing or health care reforms, other legal and regulatory developments, failure of our partners to comply with applicable laws and regulatory requirements, the introduction of competitive products, and new indication approvals which may affect the sales of collaboration products;

where we copromote and co-market products with our collaboration partners, any failure on their part to comply with applicable laws in the sale and marketing of our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings; and

collaborations often require the parties to cooperate, and failure to do so effectively could have an adverse impact on product sales by our collaborators and partners, and could adversely affect the clinical development of shared products or programs under joint control.

In addition, under our collaboration agreement with Genentech, the successful development and commercialization of the first anti-CD20 product acquired or developed by Genentech will decrease our percentage of co-promotion profits

of the collaboration.

If we do not successfully execute our growth initiatives through the acquisition, partnering and in-licensing of products, technologies or companies, our future performance could be adversely affected.

In addition to the expansion of our pipeline through spending on internal development projects, we anticipate growing through external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. If we are unable to

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complete or manage these external growth opportunities successfully, we may not be able to grow our business in the way that we currently expect. The availability of high quality opportunities is limited and we are not certain that we will be able to identify suitable candidates or complete transactions on terms that are acceptable to us. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the recent tightening of the global credit markets. In addition, even if we are able to successfully identify and complete acquisitions, we may not be able to integrate them or take full advantage of them and therefore may not realize the benefits that we expect. If we are unsuccessful in our external growth program, we may not be able to grow our business significantly and we may incur asset impairment charges as a result of acquisitions that are not successful.

If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and a loss of business.

Our activities, and the activities of our collaborators and third party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, submission of false claims for government reimbursement, antitrust violations, or violations related to environmental matters. Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales.

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 such compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and acceptance of the change by the FDA prior to release of product to the marketplace. 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 non-compliance could increase our costs, cause us to lose revenue or market share and damage our reputation.

Changes in laws affecting the healthcare industry could adversely affect our revenues and profitability.

We and our collaborators and third party providers operate in a highly regulated industry. As a result, governmental actions may 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;

changes in FDA and foreign regulations that may require additional safety monitoring after the introduction of our products to market, which could increase our costs of doing business and adversely affect the future permitted uses of approved products;

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new laws, regulations and judicial decisions affecting pricing or marketing practices; and

changes in the tax laws relating to our operations.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003, possible legislation which could ease the entry of competing follow-on biologics in the marketplace, and importation of lower-cost competing drugs from other jurisdictions are examples of changes and possible changes in laws that could adversely affect our business. In addition, the Food and Drug Administration Amendments Act of 2007 included new authorization for the FDA to require post-market safety monitoring, along with a clinical trials registry, and expanded authority for FDA to impose civil monetary penalties on companies that fail to meet certain commitments.

Problems with manufacturing or with inventory planning could result in our inability to deliver products, inventory shortages or surpluses, product recalls and increased costs.

We manufacture and expect to continue to manufacture our own commercial requirements of bulk AVONEX and TYSABRI. Our products are difficult to manufacture and problems in our manufacturing processes can occur. Our inability to successfully manufacture bulk product and to obtain and maintain regulatory approvals of our manufacturing facilities would harm our ability to produce timely sufficient quantities of commercial supplies of AVONEX and TYSABRI to meet demand. Problems with manufacturing processes could result in product defects or manufacturing failures that could require us to delay shipment of products or recall or withdraw products previously shipped, which could result in inventory write-offs and impair our ability to expand into new markets or supply products in existing markets. In the past, we have had to write down and incur other charges and expenses for products that failed to meet specifications. Similar charges may occur in the future. In addition, lower than expected demand for our products, including suspension of sales, or a change in product mix may result in less than optimal utilization of our manufacturing facilities and lower inventory turnover, which could result in abnormal manufacturing variance charges, facility impairment charges and charges for excess and obsolete inventory.

We rely solely on our manufacturing facility in Research Triangle Park, North Carolina, or RTP, for the production of TYSABRI. We have applied to the FDA and the EMEA for approval of a production process, known as a second generation high-titer process, which has higher yields of TYSABRI than the process we currently use. Approval has been granted by the EMEA, but is still pending from the FDA. If we do not obtain approval for that process, we may need to increase our capital spending to add capacity at our RTP manufacturing facility and at the Hillerød, Denmark facility we are completing to meet demand for TYSABRI. Such an increase in capital spending would affect our business, cash position and results of operations.

If we cannot produce sufficient commercial requirements of bulk product to meet demand, we would need to rely on third party contract manufacturers, of which there are only a limited number capable of manufacturing bulk products of the type we require. 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 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. 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 on third parties to provide services in connection with the manufacture of our products and, in some instances, the manufacture of the product itself.

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 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

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of our products require successful coordination among us and multiple third party providers. Our inability to coordinate these efforts, the lack of capacity available at a 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 impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share, diminish our profitability and damage our reputation. Any third party we use to fill-finish, package or store our products to be sold in the United States must be licensed by the FDA. As a result, alternative third party providers may not be readily available on a timely basis.

Due to the unique nature of the production of our products, there are single source providers of several raw materials. We make every effort to qualify new vendors and to develop contingency plans so that production is not impacted by short-term issues associated with single source providers. Nonetheless, our business could be materially impacted by long-term or chronic issues associated with single source providers.

The current credit and financial market conditions may exacerbate certain risks affecting our business.

Sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

Due to the recent tightening of global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including portions of our product manufacturing, royalty revenue, clinical development of future collaboration products, conduct of clinical trials, and raw materials. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

Our portfolio of marketable securities is significant and is subject to market, interest and credit risk that may reduce the value of our investments.

We maintain a significant portfolio of marketable securities. Our earnings may be adversely affected by changes in the value of this portfolio. In particular, the value of our investments may be adversely affected by increases in interest rates, downgrades in the corporate bonds included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the mortgage and asset-backed securities included in our portfolio, and by other factors which may result in other than temporary declines in value of the investments. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate risks within our marketable securities portfolio with the assistance of our investment advisors by investing in high quality securities and continuously monitoring the overall risk profile of our portfolio, the value of our investments may nevertheless decline.

We have made a significant investment in constructing a manufacturing facility the success of which depends upon the completion and licensing of the facility and continued demand for our products.

We are building a large-scale biologic manufacturing facility in Hillerød, Denmark. We anticipate that the facility will be ready for commercial production in 2010. If we fail to manage the project, or unforeseen events occur, we may incur additional costs to complete the project. Depending on the timing of the completion and licensing of the facility, and our other estimates and assumptions regarding future product sales, the carrying value of all or part of the

manufacturing facility or other assets may not be fully recoverable and could result in the recognition of an impairment in the carrying value at the time that such effects are identified. The recognition of impairment in the carrying value, if any, could have a material and adverse affect on our results of operations. For example, if the anticipated demand for TYSABRI does not materialize, the carrying values of our Hillerød, Denmark facility could be impaired, which would negatively impact our results of operations.

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If we are unable to attract and retain qualified personnel and key relationships, the growth of our business could be harmed.

Our success will depend, to a great extent, upon our ability to attract and retain qualified scientific, manufacturing, sales and marketing and executive personnel and our ability to develop and maintain relationships with qualified clinical researchers and key distributors. Competition for these people and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. Any inability we experience to continue to attract and retain qualified personnel or develop and maintain key relationships could have an adverse effect on our ability to accomplish our research, development and external growth objectives.

Our sales and operations are subject to the risks of doing business internationally.

We are increasing our presence in international markets, which subjects us to many risks, such as:

economic problems that disrupt foreign healthcare payment systems;

fluctuations in currency exchange rates;

the imposition of governmental controls;

less favorable intellectual property or other applicable laws;

the inability to obtain any necessary foreign regulatory or pricing approvals of products in a timely manner;

restrictions on direct investments by foreign entities and trade restrictions;

changes in tax laws and tariffs;

difficulties in staffing and managing international operations; and

longer payment cycles.

Our operations and marketing practices are also subject to regulation and scrutiny by the governments of the other countries in which we operate. In addition, the Foreign Corrupt Practices Act, or FCPA, prohibits U.S. companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the healthcare professionals we regularly interact with meet the definition of a foreign official for purposes of the FCPA. Additionally, we are subject to other U.S. laws in our international operations. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and the imposition of civil or criminal sanctions.

A portion of our business is conducted in currencies other than our reporting currency, the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period in which we incur those gains or losses. As a result, currency fluctuations among the U.S. dollar and the currencies in which we do business will affect our operating results, often in unpredictable ways.

Our business could be negatively affected as a result of the actions of activist shareholders.

During the first half of 2008, we defended against a proxy contest waged by Icahn Partners and certain of its affiliates that nominated three individuals for election to our Board of Directors and proposed amendments to our bylaws at our 2008 Annual Meeting of Stockholders. Although we were successful in having our Board s nominees elected as directors, the proxy contest was disruptive to our operations and caused us to incur substantial costs. Icahn Partners and certain of its affiliates have commenced a proxy contest relating to our 2009 Annual Meeting of Stockholders nominating four individuals to our Board of Directors, proposing amendments to our bylaws and requesting a change in our jurisdiction of incorporation. Our business could be adversely affected because:

Responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;

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Perceived uncertainties as to our future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and

If individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Our operating results are subject to significant fluctuations.

Our quarterly revenues, expenses and net income (loss) have fluctuated in the past and are likely to fluctuate significantly in the future due to the timing of charges and expenses that we may take. In recent periods, for instance, we have recorded charges that include:

impairments that we are required to take with respect to investments;

impairments that we are required to take with respect to fixed assets, including those that are recorded in connection with the sale of fixed assets:

inventory write-downs for failed quality specifications, charges for excess and/or obsolete inventory and charges for inventory write downs relating to product suspensions;

milestone payments under license and collaboration agreements; and

the cost of restructurings.

Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. Although we have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, our efforts to reduce currency exchange losses may not be successful. As a result, changes in currency exchange rates may have an adverse impact on our future operating results and financial condition. Additionally, our net income may fluctuate due to the impact of charges we may be required to take with respect to foreign currency hedge transactions. In particular, we may incur higher charges from hedge ineffectiveness than we expect or from the termination of a hedge relationship.

These examples are only illustrative and other risks, including those discussed in these Risk Factors, could also cause fluctuations in our reported earnings. In addition, our operating results during any one period do not necessarily suggest the anticipated results of future periods.

If we are unable to adequately protect and enforce our intellectual property rights, our competitors may take advantage of our development efforts or our acquired technology.

We have filed numerous patent applications in the United States 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 United States 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. Our patents may not afford us substantial protection or commercial benefit. Similarly, our pending patent applications or patent applications licensed from third parties may

not ultimately be granted as patents and we may not prevail if patents that have been issued to us are challenged in court. In addition, pending legislation to reform the patent system could also reduce our ability to enforce our patents. We do not know when, or if, changes to the U.S. patent system will become law. If we are unable to protect our intellectual property rights and prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect.

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If our products infringe the intellectual property rights of others, we may incur damages and be required to incur the expense of obtaining a license.

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 United States 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 that 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 United States 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 manufacture and market our products.

Uncertainty over intellectual property in the biotechnology industry has been the source of litigation, which is inherently costly and unpredictable.

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 United States 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 United States 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 and administrative 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 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 manufacture and market our products.

Pending and future product liability claims may adversely affect our business and our reputation.

The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our products or product candidates may cause, or may appear to have caused, injury or dangerous drug interactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time.

We are subject from time to time to lawsuits based on product liability and related claims. We cannot predict with certainty the eventual outcome of any pending or future litigation. We may not be successful in defending ourselves in the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business.

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Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

As a global biotechnology company, we are subject to taxation in numerous countries, states and other jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various countries, states and other jurisdictions in which we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of the countries, states and other jurisdictions in which we operate. Our effective tax rate, however, may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. In addition, unfavorable results of audits of our tax filings, our inability to secure or sustain arrangements with tax authorities, and recently enacted and future changes in tax laws in jurisdictions in which we operate, among other things, may cause us to be obligated to accrue for future tax payments in excess of amounts accrued in our financial statements.

Our level of indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business.

As of December 31, 2008, we had \$1,113.1 million of outstanding indebtedness, and we may incur additional debt in the future. Our level of indebtedness could have significant consequences to our business, for example, it could:

increase our vulnerability to general adverse economic and industry conditions;

require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts and mergers and acquisitions; and

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that may have less debt.

Our business involves environmental risks, which include the cost of compliance and the risk of contamination or injury.

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 contamination, 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 laboratory 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. Biologics manufacturing also requires permits from government agencies for water supply and wastewater discharge. If we do not obtain appropriate permits, or permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business.

Several aspects of our corporate governance and our collaboration agreements may discourage a third party from attempting to acquire us.

Several factors might discourage a takeover attempt that could 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

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the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;

our board of directors has the authority to issue, without a 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 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 acquirers;

our amended and restated collaboration agreement with Genentech provides that, in the event we undergo a change of control, within 90 days Genentech may present an offer to us to purchase our rights to RITUXAN. In an arbitration proceeding brought by Biogen Idec relating to the collaboration agreement, Genentech alleged that the November 2003 transaction in which Idec Pharmaceuticals acquired Biogen and became Biogen Idec constituted such a change of control, an assertion with which we strongly disagree. It is our position that the Biogen Idec merger did not constitute a change of control under our agreement with Genentech and that, even if it did, Genentech s rights under the change of control provision have long since expired. If the arbitrators decide this issue in favor of Genentech, or if a change of control were to occur in the future and Genentech were to present an offer for the RITUXAN rights, we must either accept Genentech s offer or purchase Genentech s rights to RITUXAN on the same terms as its offer. If Genentech presents such an offer, then they will be deemed concurrently to have exercised a right, in exchange for a royalty on net sales in the U.S. of any anti-CD20 product acquired or developed by Genentech or any anti-CD20 product that Genentech licenses from a third party that is developed under the agreement, to purchase our interest in each such product;

our directors are elected to staggered terms, which prevents the entire board from being replaced in any single year; and

advance notice is required for nomination of candidates for election as a director and for proposals to be brought before an annual meeting of stockholders.

Item 1B. Unresolved Staff Comments

None.

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Item 2. Properties

Cambridge, Massachusetts and Surrounding Area

Our principal executive offices are located in Cambridge, Massachusetts. In Cambridge, we own approximately 510,000 square feet of real estate space, consisting of a 250,000 square foot building that houses a research laboratory, office spaces and a cogeneration plant, and an approximately 260,000 square foot building that contains research, development and quality laboratories. We lease a total of approximately 440,000 square feet, consisting of additional office and manufacturing space, in all or part of four other buildings in Cambridge. In addition, we lease approximately 36,000 square feet of warehouse space in Somerville, Massachusetts, approximately 105,000 square feet of office space in Wellesley, Massachusetts, and approximately 25,000 square feet of office and lab space in Waltham, Massachusetts. The lease expiration dates for our leased sites in Massachusetts range from 2009 to 2015. We recently executed a fifteen year lease on a 356,000 square foot office building in Weston, Massachusetts, which will serve as the future location of our executive offices with a planned occupancy during the third quarter of 2010. We anticipate that the Weston facility will decrease our overall occupancy cost per employee.

San Diego and Oceanside, California

In San Diego, California, we own approximately 43 acres of land upon which we have our oncology research and development campus. The campus consists of five interconnected buildings, which primarily contain laboratory and office space, totaling approximately 350,000 square feet. In July 2007, we sold two parcels of undeveloped property in Oceanside, California, totaling approximately 28 acres of land.

Research Triangle Park, North Carolina

In Research Triangle Park, North Carolina, we own approximately 530,000 square feet of real estate space. This includes a 108,000 square foot biologics manufacturing facility, a 232,000 square foot large scale manufacturing plant, a second large-scale purification facility of 42,000 square feet, and a 150,000 square foot laboratory office building. We manufacture bulk AVONEX and TYSABRI at this facility. We plan to use this facility to manufacture other products in our pipeline and to meet any obligation to manufacture AMEVIVE resulting from our sale of that product to Astellas. We are continuing further upgrades in Research Triangle Park with ongoing construction of several projects to increase our manufacturing flexibility. In addition, we lease approximately 44,000 square feet of office space in Durham, North Carolina.

Hillerød, Denmark

We own approximately 60 acres of property in Hillerød, Denmark. We are constructing a large-scale biologics manufacturing facility in Hillerød, Denmark to be used to manufacture TYSABRI and other products in our pipeline. An administrative building, label and packaging facility and lab facility are currently in use. For a discussion of our plans for the Hillerød, Denmark large-scale manufacturing facility, see Manufacturing and Raw Materials.

Other International

We lease space in Zug, Switzerland, our international headquarters, the United Kingdom, Germany, Austria, Argentina, France, Belgium, Netherlands, Spain, Portugal, Czech Republic, Slovenia, Slovak Republic, Denmark, Sweden, Finland, Norway, Japan, India, China, Australia, New Zealand, Brazil, Hungary and Canada.

Item 3. Legal Proceedings

Please refer to Note 19, Litigation, in Notes to Consolidated Financial Statements of this annual report on Form 10-K, which is incorporated into this item by reference.

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

None.

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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 Global Select Market under the symbol BIIB. The following table shows the high and low sales price for our common stock as reported by The NASDAQ Global Select Market for each quarter in the years ended December 31, 2008 and 2007.

		Common Stock Price			
	20	2008		2007	
	High	Low	High	Low	
First Quarter	\$ 64.49	\$ 54.50	\$ 52.45	\$ 42.86	
Second Quarter	67.45	55.68	53.96	43.43	
Third Quarter	73.59	45.37	69.00	53.24	
Fourth Quarter	52.36	37.21	84.75	53.65	

Holders

As of February 2, 2009, there were approximately 1,121 stockholders of record of our common stock. In addition, as of February 2, 2009, 406 stockholders of record of Biogen, Inc. common stock have yet to exchange their shares of Biogen, Inc. common stock for our common stock as contemplated by the merger of Biogen, Inc. and Idec Pharmaceuticals Corporation, or 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.

Equity Compensation Plan Information

We incorporate information regarding the securities authorized for issuance under our equity compensation plans into this section by reference from the section entitled Disclosure With Respect To Our Equity Compensation Plans in the proxy statement for our 2009 Annual Meeting of Stockholders.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

A summary of issuer repurchase activity for 2008 is as follows:

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased (#)	rage Price Paid er Share (\$)	Total Number of Shares Purchased as Part of Publicly Announced Program (#)(a)	Number of Shares That May Yet Be Purchased Under Our Program (#)
March 2008	4,028,196	\$ 59.61	4,028,196	15,971,804
April 2008	4,971,804	\$ 64.27	4,971,804	11,000,000
December 2008	3,777,500	\$ 47.41	3,777,500	7,222,500
Total(a)(b)	12,777,500	\$ 57.82	12,777,500	7,222,500
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- (a) On October 13, 2006 the Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with authorized shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program does not have an expiration date. We publicly announced the repurchase program in our press release dated October 31, 2006, which was furnished to the SEC as Exhibit 99.1 to our current report on Form 8-K filed on October 31, 2006.
- (b) After December 31, 2008, we repurchased approximately 1.2 million additional shares at a total cost of \$57.6 million.

Stock Performance Graph

The graph below compares the five-year cumulative total stockholder return on our common stock, the S&P 500 Index and the Nasdaq Pharmaceutical Index, assuming the investment of \$100.00 on December 31, 2003 with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

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Item 6. Selected Financial Data

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

BIOGEN IDEC INC. AND SUBSIDIARIES

SELECTED FINANCIAL DATA

	Years Ended December 31,										
				2007							
	20	008 (6)		(4),(5)	20	06 (2),(3)	2	2005 (1)		2004	
				(In mi	illions	s, except pe	r sh	are			
					a	mounts)					
Product revenues	\$	2,839.7	\$	2,136.8	\$	1,781.3	\$	1,617.0	\$	1,486.4	
Revenue from unconsolidated joint business		1,128.2		926.1		810.9		708.9		615.7	
Other revenues		129.6		108.7		90.8		96.6		109.5	
Total revenues		4,097.5		3,171.6		2,683.0		2,422.5		2,211.6	
Total costs and expenses		2,883.9		2,391.8		2,243.0		2,186.5		2,168.1	
Income before income tax expense and											
cumulative effect of accounting change Income before cumulative effect of		1,148.9		910.6		492.2		256.2		64.1	
accounting change		783.2		638.2		213.7		160.7		25.1	
Cumulative effect of accounting change, net											
of income tax						3.8					
Net income		783.2		638.2		217.5		160.7		25.1	
Diluted earnings per share:											
Income before cumulative effect of											
accounting change		2.65		1.99		0.62		0.47		0.07	
Cumulative effect of accounting change, net		2.00		1.,,,		0.02		0.17		0.07	
of income tax						0.01					
of moonie tax						0.01					
Diluted earnings per share	\$	2.65	\$	1.99	\$	0.63	\$	0.47	\$	0.07	
Shares used in calculating diluted earnings											
per share		295.0		320.2		345.3		346.2		343.5	
Cash, cash equivalents and marketable											
securities	\$	2,262.8	\$	2,115.8	\$	2,314.9	\$	2,055.1	\$	2,167.6	
Total assets		8,479.0		8,628.8		8,552.8		8,381.7		9,165.8	
Notes payable, less current portion		1,085.4		51.8		96.7		43.4		101.9	
Shareholders equity		5,806.1		5,534.3		7,149.8		6,905.9		6,826.4	

⁽¹⁾ Included in costs and expenses in 2005 is a charge of \$118.1 million related to facility impairment charges.

⁽²⁾ Included in costs and expenses in 2006 is a charge of \$207.4 million for in-process research and development and a net gain of \$6.1 million on the settlement of license agreements associated with Fumapharm AG, or

Fumapharm, and Fumedica GmbH, or Fumedica and a charge of \$123.1 million for in process research and development related to the acquisition of Conforma Therapeutics, Inc. or Conforma.

- (3) In connection with the adoption of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-based Payments*, or SFAS 123(R), we recorded the cumulative effect of an accounting change of \$3.8 million, net, as of January 1, 2006.
- (4) Included in costs and expenses in 2007 is a charge of \$18.4 million for in-process research and development related to the acquisition of Syntonix Pharmaceuticals Inc., or Syntonix, and \$64.3 million related to our collaborations with Cardiokine Biopharma LLC and Neurimmune SubOne AG, which we consolidated under FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, or FIN 46(R). The \$64.3 million was offset by an equal amount of minority interest, resulting in no net impact to the results of our operations.

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- (5) In July 2007, we purchased 56,424,155 shares of our common stock pursuant to a tender offer. We funded the transaction through existing cash and cash equivalents of \$1,490.5 million and a short term loan of \$1,500.0 million.
- (6) Included in cost and expenses in 2008 is \$25.0 million for in process research and development related to a milestone payment made to the former shareholders of Conforma pursuant to the terms of our acquisition of Conforma in 2006.

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

Forward-Looking Information

In addition to historical information, this report contains forward-looking statements that are based on our current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking statements. These forward-looking statements do not relate strictly to historical or current facts and they may be accompanied by such words as anticipate, believe, estimate, forecast. intend, plan, project, target, may, will and other words and terms of similar meaning. made in particular to forward-looking statements regarding the anticipated level of future product sales, royalty revenues, expenses, contractual obligations, regulatory submissions and approvals, clinical trial results, our long-term growth, the development and marketing of additional products, the impact of competitive products, the incidence or anticipated outcome of pending or anticipated litigation, patent-related proceedings, tax assessments and other legal proceedings, our effective tax rate for future periods, our ability to finance our operations and meet our manufacturing needs, the completion of our manufacturing facility in Hillerød, Denmark, liquidity, and our plans to spend additional capital on external business development and research opportunities. 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 in the section entitled Risk Factors in Part II of this report and elsewhere in this report. Forward-looking statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated). Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

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.

Executive Summary

Biogen Idec Inc. was formed in 2003 upon the acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation in a merger transaction, or the Merger. We are a global biotechnology company that creates new standards of care in therapeutic areas of high unmet medical needs. We have two licensed biological bulk-manufacturing facilities, including our large-scale manufacturing plant in Research Triangle Park, NC, which is one of the world s largest cell culture facilities. An additional large-scale manufacturing plant is under construction in Hillerød, Denmark. We conduct research in San Diego, CA and Cambridge, MA. In 2008, we entered into an agreement with a real estate developer for the construction and leasing of a corporate headquarters in Weston, MA. We anticipate occupancy in 2010. We have additional offices in Canada, Brazil, Argentina, Australia, New Zealand, Japan, China, India and throughout Europe, including our international headquarters in Zug, Switzerland and operate a global distribution network, which covers over 70 countries. We currently employ approximately 4,700 people worldwide.

Results for the year ended December 31, 2008 included total revenue of \$4,097.5 million, net income of \$783.2 million and diluted net income per share of \$2.65. These results reflect continued growth in unit sales of TYSABRI, an increase in revenues from an unconsolidated joint business arrangement due to increased sales of

RITUXAN, as well as the impact of price increases in the United States and the favorable impact of exchange rates in rest of world on our AVONEX product. The effect of the increase in revenue was partially offset by an increase in research and development expense due to increased level of Phase 3 clinical trials and other projects, and an increase in selling, general and administrative expense related to a higher level of personnel to sustain AVONEX sales and drive TYSABRI growth. In the fourth quarter of 2008, we completed a reorganization of our domestic and

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international operations, which included the movement of certain personnel and operational functions between Biogen Idec subsidiaries, as well as a restructuring of our supply chain.

Marketed Products

We currently have four marketed products:

AVONEX® (interferon beta-1a);

RITUXAN® (rituximab);

TYSABRI® (natalizumab);

FUMADERM® (dimethylfumarate and monoethylfumarate salts)

Through December 2007 we recorded product revenue from sales of ZEVALIN (ibritumomab tiuxetan) in the U.S. In December 2007, we sold the U.S. marketing, sales, manufacturing and development rights of ZEVALIN to Cell Therapeutics, Inc., or CTI, for an upfront purchase price of \$10.0 million. In December 2008, pursuant to an amendment of the agreement, we received an additional \$2.2 million milestone payment. We may receive up to an additional \$20.0 million in milestone payments. In addition, we will receive royalty payments on future sales of ZEVALIN. As part of the overall agreement, we entered into a supply agreement with CTI to sell ZEVALIN product through 2014. Our sales of ZEVALIN to Bayer Schering Pharma AG, or Schering AG, for distribution in the EU will be recognized as product revenue and our supply of ZEVALIN to CTI is recognized as corporate partner revenue. We will continue to receive royalty revenues from Schering AG on their sales of ZEVALIN in the EU. The \$10.0 million upfront and \$2.2 million milestone payment have been deferred and are being recognized in our results of operations over the term of the supply agreement.

Through April 2006, we recorded product revenues from sales of AMEVIVE (alefacept). In April 2006, we sold the worldwide rights to this product to Astellas Pharma US, Inc., or Astellas. We will continue to manufacture and supply this product to Astellas for a period of up to 11 years. Under the terms of the supply agreement, we charge Astellas fixed amounts based on volume. Such amounts will be recognized as corporate partner revenue and are not significant.

Most of our revenues are currently dependent on sales of AVONEX, RITUXAN and TYSABRI. In the near term, we are dependent on the continued sales growth of TYSABRI to grow our overall revenues. In the longer term, our revenue growth is dependent on the successful clinical development, regulatory approval and launch of new commercial products currently being developed in our pipeline or products or programs that will be in-licensed or acquired.

Continued growth of global AVONEX unit sales is primarily dependent on maintaining AVONEX s position as the most prescribed multiple sclerosis, or MS, therapy in the world. In both the U.S. and rest of world, we face increasing competition in the MS market from currently marketed products and future products in late stage development, as well as increasing pricing pressure. We continue to generate data showing AVONEX to be an effective and safe choice for MS patients and physicians.

The majority of RITUXAN unit sales are currently from use in the oncology setting. We believe there is additional room for RITUXAN unit sales growth in the immunology setting, where RITUXAN is currently approved for patients with Rheumatoid Arthritis, or RA, with inadequate response to anti-tumor necrosis factor therapies, or TNF-IR. Additional immunology indications for RITUXAN that we are investigating include earlier stage RA patients with inadequate response to disease-modifying anti-rheumatic drugs, or DMARD-IR patients, DMARD-naïve RA patients

and lupus nephritis and ANCA-associated vaculitis.

In July 2006, we reintroduced TYSABRI in the U.S. and began to ship internationally for the first time. TYSABRI sales are currently for use in relapsing remitting MS and, following the FDA s approval in January 2008, Crohn s disease. Growth in TYSABRI revenue will be dependent on the generation of a larger and longer term safety database, as well as continued acceptance by physicians and MS patients. Since the reintroduction of TYSABRI in the U.S. and the introduction of TYSABRI in the rest of world, we have disclosed five cases of progressive multifocal leukoencephalopathy, or PML, a known side effect, in patients taking TYSABRI in the post

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marketing setting. These patients were the only confirmed cases of PML reported to us during this period. We continue to monitor the growth of TYSABRI unit sales in light of this news and we continue to develop protocols to potentially mitigate the risk and outcome of PML in patients being treated with TYSABRI.

Clinical Studies

Over the past few years, we have incurred significant expenditures related to conducting clinical studies to develop new pharmaceutical products and explore the utility of our existing products in treating disorders beyond those currently approved in their labels. For 2009, we expect to continue to incur significant levels of research and development expenditures. We have a number of pipeline products in late stage clinical trials, including over 13 pipeline products in Phase 2 or Phase 3 clinical trials. We are currently developing the late stage product candidates that are set forth below.

Product	Product Indications	Status	Development and/or Marketing Collaborators
BG-12	Relapsing MS	Phase 3	None
Anti-CD80 MAb (galiximab)	Relapsed NHL	Phase 3	None
Anti-CD23 MAb (lumiliximab)	Relapsed CLL	Phase 2/3	None
Humanized Anti-CD20 MAb (ocrelizumab)	RA	Phase 3	U.S. Genentech Japan Chugai and Zenyaku Outside U.S. and Japan Roche
	Lupus nephritis	Phase 3	See above
Lixivaptan	Hyponatremia, commonly seen in acute decompensated heart failure	Phase 3	Cardiokine Biopharma LLC
ADENTRI®	Acute decompensated heart failure with renal insufficiency	Phase 3	None

In addition to the expense associated with these late stage trials, other pipeline products are in ongoing or are expected to enter proof of concept trials in 2009.

Business Development

As part of our business strategy, we have made acquisitions of other businesses, products, product rights or technologies and may continue to make acquisitions in the future. Our cash reserves and other liquid assets are substantial, but these sources of capital may be inadequate to consummate larger acquisitions and it may be necessary

for us to raise substantial additional funds in the future to complete transactions. Due to the recent tightening of global credit and the disruption in the financial markets, it may be more difficult to secure such additional financing. In addition, as a result of our acquisition efforts, we may experience significant charges to earnings for merger and related expenses that may include transaction costs, closure costs or acquired in-process research and development charges.

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Results of Operations

Revenues

Revenues were as follows (in millions):

	Year Ended December 31,									
	2008		2007		2006					
Product Sales										
United States	\$ 1,472.9	35.9%	\$ 1,203.6	37.9%	\$ 1,069.5	40.0%				
Rest of world	1,366.8	33.4%	933.2	29.5%	711.8	26.5%				
Total product revenues	2,839.7	69.3%	2,136.8	67.4%	1,781.3	66.5%				
Unconsolidated Joint Business	1,128.2	27.5%	926.1	29.2%	810.9	30.2%				
Other Revenues	129.6	3.2%	108.7	3.4%	90.8	3.3%				
Total revenues	\$ 4,097.5	100.0%	\$ 3,171.6	100.0%	\$ 2,683.0	100.0%				

Product Revenues

Product revenues were as follows (in millions):

	Year Ended December 31,										
	2008		2007	,	2006						
AVONEX	\$ 2,202.6	77.6%	\$ 1,867.8	87.4%	\$ 1,706.7	95.9%					
TYSABRI	588.6	20.7%	229.9	10.8%	35.8	2.0%					
FUMADERM	43.4	1.5%	21.5	1.0%	9.5	0.5%					
ZEVALIN	4.8	0.2%	16.9	0.8%	17.8	1.0%					
AMEVIVE	0.3	%	0.7		11.5	0.6%					
Total product revenues	\$ 2,839.7	100.0%	\$ 2,136.8	100.0%	\$ 1,781.3	100.0%					

Cost of Sales

Cost of sales includes the following (in millions):

	Year Ended December 31,									
	2008	2008			2007			6		
Cost of product revenues Cost of royalty revenues	\$ 397.0 5.0	98.8% 1.2%	\$	330.5 4.7	98.6% 1.4%	\$	270.0 4.4	98.4% 1.6%		

Cost of sales \$ 402.0 100.0% \$ 335.2 100.0% \$ 274.4 100.0%

During the years ended December 31, 2008, 2007, and 2006, we wrote down approximately \$29.8 million, \$21.6 million, and \$13.0 million, respectively, of inventory which was charged to cost of sales.

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Cost of Product Revenues

Cost of product revenues, included in cost of sales, by product are as follows (in millions):

	Year Ended December 31,									
AVONEX	2008	2007	7	2006						
	\$ 272.0	68.5%	\$ 258.3	78.2%	\$ 234.7	86.9%				
TYSABRI	68.5	17.3%	10.4	3.1%	5.3	2.0%				
FUMADERM	3.9	1.0%	1.6	0.5%	3.1	1.2%				
ZEVALIN	5.6	1.4%	14.0	4.2%	16.2	6.0%				
AMEVIVE	8.0	2.0%	3.1	0.9%	10.0	3.7%				
Other	39.0	9.8%	43.1	13.1%	0.7	0.2%				
Cost of product revenues	\$ 397.0	100.0%	\$ 330.5	100.0%	\$ 270.0	100.0%				

AVONEX

Revenues from AVONEX were as follows (in millions):

	2008	3	Year Ended Dec 2007	cember 31,	2006		
AVONEX U.S. Rest of world	\$ 1,276.5 926.1	58.0% 42.0%	\$ 1,085.0 782.8	58.1% 41.9%	\$ 1,022.2 684.5	59.9% 40.1%	
Total AVONEX revenues	\$ 2,202.6	100.0%	\$ 1,867.8	100.0%	\$ 1,706.7	100.0%	

For 2008 compared to 2007, U.S. sales of AVONEX increased \$191.5 million, or 17.6%, due to price increases, partially offset by decreased product demand. For 2008 compared to 2007, rest of world sales of AVONEX increased \$143.3 million, or 18.3%, due to increased unit shipments, the impact of exchange rates and the establishment of additional direct market affiliates.

For 2007 compared to 2006, U.S. sales of AVONEX increased \$62.8 million, or 6.1%, primarily due to the impact of price increases. These increases were offset by lower demand. For 2007 compared to 2006, rest of world sales of AVONEX increased \$98.3 million, or 14.4%, primarily due to the impact of exchange rates and higher sales volume.

We expect to face increasing competition in the MS marketplace in both the U.S. and rest of world from existing and new MS treatments, including TYSABRI and our other pipeline products, which may have a negative impact to the unit sales of AVONEX. We expect future unit sales of AVONEX to be dependent to a large extent on our ability to compete successfully with the products of our competitors.

TYSABRI

Revenues from TYSABRI were as follows (in millions):

						Ended December 31, 2007			5
TYSABRI U.S. Rest of world		196.4 392.2	33.4% 66.6%	\$	104.4 125.5	45.4% 54.6%	\$	25.8 10.0	72.1% 27.9%
Total TYSABRI revenues	\$ 5	588.6	100.0%	\$	229.9	100.0%	\$	35.8	100.0%

Under the terms of a collaboration agreement with Elan, we manufacture TYSABRI and collaborate with Elan on the product s marketing, commercial distribution and on-going development activities. We recognize revenue

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for sales of TYSABRI in the U.S. upon Elan s shipment of the product to third party distributors. We recognize revenue for sales of TYSABRI in rest of world at the time of product delivery to our customers and distributors.

Since the reintroduction of TYSABRI in the U.S. and the introduction of TYSABRI in the rest of world in July 2006, we have disclosed five cases of PML, a known side effect, in patients taking TYSABRI in the post marketing setting. These patients were the only confirmed cases of PML reported to us during this period. We continue to monitor the growth of TYSABRI unit sales in light of these results and we continue to develop protocols to potentially mitigate the risk and outcome of PML in patients being treated with TYSABRI.

For 2008 and 2007, we recorded revenue on sales of TYSABRI of \$588.6 million and \$229.9 million, respectively. The increase in 2008 sales as compared to 2007 sales is primarily due to increased unit shipments due to the growth in the number of patients using TYSABRI.

For 2007 and 2006, we have recorded revenue on sales of TYSABRI of \$229.9 million and \$35.8 million, respectively. The increase in 2007 sales as compared to 2006 sales is primarily due to increased unit shipments due to the growth in the number of patients using TYSABRI and due to the product being shipped for the entire 12 months during 2007 versus being shipped for only six months in 2006.

During 2007 and 2006, we had product on hand that had been fully written-off in 2005 due to the uncertainties surrounding the TYSABRI suspension but which was available to fill future orders. As we sold TYSABRI in 2007 and 2006, we realized lower than normal cost of sales and, therefore, higher margins, as we shipped the inventory that had been previously written-off. For 2007 and 2006, cost of sales was approximately \$12.6 million and \$2.6 million, respectively, lower due to the sale of TYSABRI that had been previously written-off. All TYSABRI inventory that had been previously written-off had been shipped by December 31, 2007.

During the year ended December 31, 2008, pursuant to our collaboration agreement with Elan, Elan paid us a \$75.0 million milestone payment in order to maintain the current collaboration profit sharing split. We recorded this amount as deferred revenue upon receipt and are recognizing this \$75.0 million as product revenue in our consolidated statement of income over the term of our collaboration with Elan based on a units of revenue method whereby the revenue recognized is based on the ratio of units shipped in the current period over the total units expected to be shipped over the remaining term of the collaboration. We recognized \$1.5 million of this milestone as revenue for the year ended December 31, 2008. Based on the TYSABRI sales levels achieved through the fourth quarter of 2008, in January 2009, Elan paid us an additional milestone payment of \$50.0 million in order to maintain the current collaboration profit sharing split. Revenue from this milestone payment will also be deferred and recognized on a units of revenue model.

FUMADERM

In connection with our June 2006 acquisition of Fumapharm, we began recognizing revenue on sales of FUMADERM to our distributor, Fumedica, in July 2006. In December 2006, we acquired the right to distribute FUMADERM in Germany from Fumedica effective May 1, 2007. In connection with the acquisition of the FUMADERM distribution rights in Germany, we committed to the repurchase of any inventory Fumedica did not sell by May 1, 2007. As a result of this provision, we deferred the recognition of revenue on shipments made to Fumedica through April 30, 2007. We resumed recognizing revenue on sales of FUMADERM into the German market in May 2007. Sales of FUMADERM for 2008, 2007, and 2006 were \$43.4 million, \$21.5 million, and \$9.5 million, respectively. These increases in sales were primarily due to increased volumes.

ZEVALIN

In 2008, 2007, and 2006 sales of ZEVALIN were \$4.8 million, \$16.9 million, and \$17.8 million, respectively. The decrease in total ZEVALIN sales in 2008 as compared to 2007 is primarily due to the sale of the rights to market, sell, manufacture, and develop ZEVALIN in the U.S. to CTI during the fourth quarter of 2007. Beginning in 2008, ZEVALIN product revenue consists only of ZEVALIN sales to Schering AG.

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AMEVIVE

In 2008, 2007, and 2006, sales of AMEVIVE were \$0.3 million, \$0.7 million, and \$11.5 million, respectively. The decrease in total AMEVIVE sales is due to the sale, in April 2006, of our worldwide rights and infrastructure related to sales, production, and marketing of AMEVIVE to Astellas.

Although we sold the rights to this product, we continue to report a small amount of product revenues related to shipments made by certain of our overseas joint ventures, which we consolidate.

Provisions for Discounts and Allowances

Revenues from product sales are recognized when 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. Revenues are recorded net of applicable allowances for trade term discounts, wholesaler incentives, Medicaid rebates, Veteran s Administration, or VA, rebates, managed care rebates, product returns, other applicable allowances and, in 2006, patient assistance and patient replacement goods. The estimates we make with respect to these allowances represent significant judgments.

Effective January 1, 2007, we changed the manner in which we administer our patient assistance and patient replacement goods programs. Prior to January 1, 2007, AVONEX product shipped for these programs was invoiced and recorded as gross product revenue and an offsetting provision for discount and returns was recorded for expected credit requests from the distributor that administers these programs on our behalf (as such, no net revenue was recorded for these shipments). Effective January 1, 2007, we entered into a new arrangement with a distributor. Under the new sales model, gross revenue is not recorded for product shipped to satisfy these programs, and cost of sales is recorded when the product is shipped.

Provisions for discounts and allowances reduced gross product revenues as follows (in millions):

		Year Ended December 31,							
	2008			2007	2006				
Discounts Contractual adjustments	\$	67.1 149.0	\$	45.7 105.2	\$	102.9 93.3			
Total allowances	\$	12.2 228.3	\$	22.1 173.0	\$	38.7 234.9			
Gross product revenues	\$	3,068.0	\$	2,309.8	\$	2,016.2			
Percent of gross product revenues		7.4%		7.5%		11.7%			

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An analysis of the amount of, and change in, reserves is as follows (in millions):

	Discounts		Contractual Adjustments		Returns		,	Total
2008								
Beginning Balance	\$	6.4	\$	33.1	\$	20.4	\$	59.9
Current provisions relating to sales in current year		67.1		150.6		14.7		232.4
Adjustments relating to prior years				(1.6)		(2.5)		(4.1)
Payments/returns relating to sales in current year		(57.8)		(101.2)		(0.1)		(159.1)
Payments/returns relating to sales in prior years		(6.5)		(32.8)		(14.4)		(53.7)
Ending Balance	\$	9.2	\$	48.1	\$	18.1	\$	75.4
2007								
Beginning Balance	\$	12.7	\$	30.5	\$	17.8	\$	61.0
Current provisions relating to sales in current year		45.7		113.1		17.1		175.9
Adjustments relating to prior years				(7.9)		5.0		(2.9)
Payments/returns relating to sales in current year		(39.4)		(72.3)		(0.4)		(112.1)
Payments/returns relating to sales in prior years		(12.6)		(30.3)		(19.1)		(62.0)
Ending Balance	\$	6.4	\$	33.1	\$	20.4	\$	59.9
2006								
Beginning Balance	\$	11.6	\$	35.7	\$	2.3	\$	49.6
Current provisions relating to sales in current year		102.9		96.4		31.6		230.9
Adjustments relating to prior years				(3.1)		7.1		4.0
Payments/returns relating to sales in current year		(90.2)		(63.1)		(16.1)		(169.4)
Payments/returns relating to sales in prior years		(11.6)		(35.4)		(12.5)		(59.5)
Other adjustments						5.4		5.4
Ending Balance	\$	12.7	\$	30.5	\$	17.8	\$	61.0

Our product revenue reserves are based on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration our historical experience, current contractual requirements, statutory requirements, specific known market events and trends and forecasted customer buying patterns. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

Product revenue reserves are categorized as follows: discounts, contractual adjustments and returns.

Discount reserves include trade term discounts, wholesaler incentives and, in 2006, patient assistance. For 2008 compared to 2007, discounts increased \$21.4 million, or 46.8%, primarily resulting from increases in trade term discounts and wholesaler incentives as a result of price increases. For 2007 compared to 2006, discounts decreased \$57.2 million, or 55.6%, resulting from a \$67.5 million reduction related to the change of patient assistance to a consignment model, offset by increases in trade term discounts and wholesaler incentives.

Contractual adjustment reserves relate to Medicaid, VA and managed care rebates and other applicable allowances. For 2008 compared to 2007, contractual adjustments increased \$43.8 million, or 41.6%, primarily due to the impact of higher reserves for managed care (associated with higher level of activity with respect to rebates and 2008 price increases in the U.S.) and Medicaid and VA programs (associated with 2007 price increases in the U.S.). For 2007 compared to 2006, contractual adjustments increased \$11.9 million, or 12.8%, primarily due to the impact of higher reserves for managed care (associated with higher level of activity with respect to rebates and associated with 2007 price increases in the U.S.) and Medicaid and VA programs (associated with 2007 price increases in the U.S.).

Product return reserves are established for returns made by wholesalers and our patient replacement goods program in 2006. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. We also accept returns from our patients for various reasons. For 2008 compared to

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2007, return reserves decreased \$9.9 million, or 44.8%, primarily due to a decrease in estimated product returns. For 2007 compared to 2006, return reserves decreased \$16.6 million, or 42.9%, primarily due to a \$15.0 million decrease related to patient replacement goods under the new sales model.

Reserves for product returns are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. The majority of wholesaler returns are due to product expiration. Expired product return reserves are estimated through a comparison of historical return data, as adjusted, to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product.

Unconsolidated Joint Business Revenues

We have a collaboration with Genentech Inc., or Genentech, that was created and operates by agreement rather than through a joint venture or other legal entity. Our rights under the terms of our amended and restated collaboration agreement with Genentech include co-exclusive rights to develop, commercialize and market RITUXAN in the United States and Canada with Genentech. Genentech has the exclusive right to develop, commercialize and market RITUXAN in the rest of the world. We have assigned our rights to develop, commercialize and market RITUXAN in Canada to F. Hoffman-La Roche Ltd., or Roche. Genentech shares a portion of the pretax U.S. co-promotion profits with us and Roche shares a portion of the pretax Canadian co-promotion profits of RITUXAN with us.

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, Roche is responsible for commercialization of RITUXAN outside the U.S., except in Japan where RITUXAN is co-marketed by Zenyaku Kogyo Co. Ltd., or Zenyaku, and Chugai Pharmaceutical Co. Ltd., or Chugai, an affiliate of Roche. There is no direct contractual arrangement between us and Roche, Zenyaku or Chugai.

Revenues from unconsolidated joint business consists of (1) our share of pretax co-promotion profits in the U.S. and Canada and (2) royalty revenue from sales of RITUXAN outside the U.S. and Canada by Roche, Zenyaku and Chugai. Pre-tax co-promotion profits are calculated and paid to us by Genentech in the U.S. and by Roche in Canada. Pre-tax co-promotion profits consist of U.S. and Canadian sales of RITUXAN to third-party customers net of discounts and allowances less the cost to manufacture RITUXAN, third-party royalty expenses, distribution, selling, and marketing expenses, and joint development expenses incurred by Genentech, Roche and us.

Revenues from unconsolidated joint business consist of the following (in millions):

	Year Ended December 31,					
		2008	2007	2006		
Co-promotion profits in the U.S.	\$	733.5	\$ 616	.8 \$ 555.8		
Reimbursement of selling and development expenses in the U.S.		59.7	58	.5 61.1		
Revenue on sales of RITUXAN outside the U.S.		335.0	250	.8 194.0		
	\$	1,128.2	\$ 926	.1 \$ 810.9		

Co-promotion profits in the U.S. consist of the following (in millions):

	Year Ended December 31,					
	2008	2007	2006			
Product revenues, net Costs and expenses	\$ 2,587.4 741.0	\$ 2,284.8 730.2	\$ 2,071.2 669.3			
Co-promotion profits in the U.S.	\$ 1,846.4	\$ 1,554.6	\$ 1,401.9			
Biogen Idec s share of co-promotion profits in the U.S.	\$ 733.5	\$ 616.8	\$ 555.8			

Net sales of RITUXAN to third-party customers in the U.S. recorded by Genentech for 2008 were \$2,587.4 million compared to \$2,284.8 million in 2007, and \$2,071.2 million in 2006. These increases were primarily due to increased unit sales in treatments of B-cell NHL and chronic lymphocytic leukemia (an unapproved use of RITUXAN), increased utilization for RA and increases in the wholesale price of RITUXAN.

In 2008, 2007, and 2006, reimbursements of selling and development expenses in the U.S. were \$59.7 million, \$58.5 million and \$61.1 million, respectively. The increase in 2008 from 2007 was primarily due to development costs we incurred related to the development of RITUXAN in RA. The decrease in 2007 from 2006 was primarily due to the reimbursement of development costs when Roche exercised its option to participate in the relapsing remitting multiple sclerosis development program.

Revenue on sales of RITUXAN outside the U.S. consists of our share of co-promotion profits in Canada and royalty revenue on sales of RITUXAN outside the U.S. and Canada. Our royalty revenue on sales of RITUXAN is based on Roche, Zenyaku and Chugai s net sales to third-party customers. We record our royalty revenue and co-promotion profit revenue on sales of RITUXAN outside the U.S. on a cash basis. Revenues on sales of RITUXAN outside the U.S. in 2008, 2007, and 2006 were \$335.0 million, \$250.8 million, and \$194.0 million, respectively. These increases were due to several factors, including increased market penetration. The royalty period with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis. For the majority of European countries, the first commercial sale of RITUXAN occurred in the second half of 1998. Therefore, we expect a significant decrease in royalty revenues on sales of RITUXAN outside the US and Canada beginning in the latter half of 2009. Specifically, the royalty period with respect to sales in France, Spain, Germany and the United Kingdom will expire in 2009. As a result, royalty revenue is expected to be in the range of \$250.0 million to \$290.0 million in 2009. The royalty period with respect to sales in Italy will expire in 2010. The royalty period with respect to sales in other countries will expire through 2012.

Under the amended and restated collaboration agreement, our current pretax co-promotion profit-sharing formula, which resets annually, is as follows:

Biogen Idec s Share of Co-promotion
Co-promotion Operating Profits
Profits

First \$50 million
Greater than \$50 million
40%

In 2008, 2007, and 2006, the 40% threshold was met during the first quarter.

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For each calendar year or portion thereof following the approval date of the first New Anti-CD20 Product, the pretax co-promotion profit-sharing formula for RITUXAN and New Anti-CD20 Products sold by us and Genentech will change.

Co-promotion Operating Profits	First New Anti-CD20 Product U.S. Gross Product Sales	Biogen Idec s Share of Co-promotion Profits
First \$50 million(1)	N/A	30%
Greater than \$50 million	Until such sales exceed \$150 million in any calendar year(2) Or	38%
	After such sales exceed \$150 million in any calendar year until such sales exceed \$350 million in any calendar year(3) Or	35%
	After such sales exceed \$350 million in any calendar year(4)	30%

- (1) not applicable in the calendar year the first New Anti-CD20 Product is approved if \$50 million in co-promotion operating profits has already been achieved in such calendar year through sales of RITUXAN.
- (2) if we are recording our share of RITUXAN co-promotion profits at 40%, upon the approval date of the first New Anti-CD20 Product, our share of co-promotion profits for RITUXAN and the New Anti-CD20 Product will be immediately reduced to 38% following the approval date of the first New Anti-CD20 Product until the \$150 million in first New Anti-CD20 Product sales level is achieved.
- (3) if \$150 million in first New Anti-CD20 Product sales is achieved in the same calendar year the first New Anti-CD20 Product receives approval, then the 35% co-promotion profit-sharing rate will not be effective until January 1 of the following calendar year. Once the \$150 million in first New Anti-CD20 Product sales level is achieved then our share of co-promotion profits for the balance of the year and all subsequent years (after the first \$50 million in co-promotion operating profits in such years) will be 35% until the \$350 million in first New Anti-CD20 Product sales level is achieved.
- (4) if \$350 million in first New Anti-CD20 Product sales is achieved in the same calendar year that \$150 million in new product sales is achieved, then the 30% co-promotion profit-sharing rate will not be effective until January 1 of the following calendar year (or January 1 of the second following calendar year if the first New Anti-CD20 Product receives approval and, in the same calendar year, the \$150 million and \$350 million in first New Anti-CD20 Product sales level are achieved). Once the \$350 million in first New Anti-CD20 Product sales level is achieved then our share of co-promotion profits for the balance of the year and all subsequent years will be 30%.

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 Anti-CD20 Product is approved, at which time we will record our share of pretax co-promotion profits related to the New Anti-CD20 Product in revenues from unconsolidated joint business.

Under our collaboration agreement with Genentech, we will receive a lower royalty percentage of revenue from Genentech on sales by Roche and Zenyaku of New Anti-CD20 Products, as compared to the royalty percentage of revenue on sales of RITUXAN.

In 2008, under the terms of our collaboration agreement, we paid Genentech \$31.5 million to participate in a license agreement with Roche for the development of a Third Party Anti-CD20 Product. This was recorded as research and development cost in our consolidated statement of operations as the product had no alternative future use. In addition, in 2008 we received \$12.4 million from Genentech pursuant to Roche choosing to participate in a study of RITUXAN in primary-progressive multiple sclerosis. This was recorded as revenue from unconsolidated joint business in our consolidated statement of operations.

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Other Revenue

Other revenues consist of the following (in millions):

	2008	Ye	ear Ended Dec 2007	*	200	6
Royalties Corporate partner	\$ 116.2 13.4	89.7% 10.3%	\$ 102.1 6.6	93.9% 6.1%	\$ 86.2 4.6	94.9% 5.1%
	\$ 129.6	100.0%	\$ 108.7	100.0%	\$ 90.8	100.0%

Royalty Revenues

We receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control. Our royalty revenues on sales of RITUXAN outside the U.S. are included in revenues from unconsolidated joint business in the accompanying consolidated statements of income.

For 2008 compared to 2007, royalty revenue increased \$14.1 million, or 13.8%, primarily due to an increase in sales levels of certain products under license partially offset by the expiration of certain contracts and decreased sales level of certain products under license. For 2007 compared to 2006, royalty revenues increased \$15.9 million, or 18.4%, primarily due to an increase in sales levels of products under license partially offset by the expiration of royalties under certain contracts.

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 represent contract revenues such as ZEVALIN and AMEVIVE and license fees.

Costs and Expenses

Costs and expenses are as follows (in millions):

	Year Ended December 31,							
		2008			2007		2006	
Cost of sales, excluding amortization of acquired intangible assets Research and development	\$	402.0 1,072.1	13.9% 37.2%	\$	335.2 925.2	14.0% 38.7%	\$ 274.4 718.4	12.3% 32.0%
Selling, general, and administrative		925.3 136.0	32.1% 4.7%		776.1 14.0	32.4% 0.6%	685.0 (9.7)	30.5% (0.4)%

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Collaboration profit (loss)						
sharing						
Acquired in-process research and						
development	25.0	0.9%	84.2	3.5%	330.5	14.7%
Amortization of acquired						
intangible assets	332.7	11.5%	257.5	10.8%	267.0	11.9%
Facility impairments and (gain)						
loss on disposition, net	(9.2)	(0.3)%	(0.4)		(16.5)	(0.7)%
Gain on termination of license						
agreements, net					(6.1)	(0.3)%
Total costs and expenses	\$ 2,883.9	100.0%	\$ 2,391.8	100.0%	\$ 2,243.0	100.0%

Inventory Write-Offs

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 net realizable value is less than that

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estimated by us, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Additionally, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. Periodically, certain batches or units of product may no longer meet quality specifications or may expire. As a result, included in product cost of revenues were write-downs of commercial inventory that did not meet quality specifications or that became obsolete due to expiration. In all cases product inventory was written-down to its estimated net realizable value.

The shelf life associated with our products is generally between 3 and 48 months, depending on the product. 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.

We have written-down the following inventory, which was charged to cost of sales (in millions):

	Year E	Year Ended December 31,			
	2008	2007	2006		
AVONEX	\$ 14.9	\$ 11.1	\$ 4.4		
TYSABRI	7.6	4.0	2.9		
FUMADERM		0.1			
AMEVIVE	6.0	0.1	2.4		
ZEVALIN	1.3	6.3	3.3		
	\$ 29.8	\$ 21.6	\$ 13.0		

The write-downs were the result of the following (in millions):

	Year I	Year Ended December 31,			
	2008	2007	2006		
Failed quality specifications		\$ 12.0	\$ 11.2		
Excess and/or obsolescence	13.8	9.6	1.8		
	\$ 29.8	\$ 21.6	\$ 13.0		

Research and Development Expenses

Research and development expenses totaled \$1,072.1 million in 2008 compared to \$925.2 million in 2007, and \$718.4 million in 2006.

For 2008 compared to 2007, research and development expenses increased \$146.9 million, driven by an increase of \$56.4 million related to the continued advancement of our pipeline into Phase 3 clinical trials. In 2008, we initiated registrational trials in the Lixivaptan and Adentri programs and continued to execute development plans of our BG-12, Anti-CD23, and Anti-CD80 programs. Costs associated with Phase 3 clinical trials are, in most cases, more significant

than those incurred in earlier stages of our pipeline. In 2008, we had 8 programs in Phase 3 clinical trials as compared to 5 in 2007. We also increased spend in our Anti-CD20 programs, which is being developed in both Phase 2 and Phase 3 clinical trials by \$46.2 million primarily due to a \$31.5 million opt-in payment to participate in the Roche-led GA101 program. The balance of the increase of \$44.3 million is due to other research and development investments, primarily in our pre clinical and early stage pipeline programs including HSP90, BIIB014, BART and LINGO programs.

For 2007 compared to 2006, research and development expenses increased \$206.8 million, primarily due to an increase of \$129.1 million related to the continued advancement of our late stage pipeline which includes a \$50.0 million upfront payment to Cardiokine Biopharma LLC for the Lixivaptan collaboration entered into in August of 2007. In addition, in 2007, we initiated registrational trials for the Anti-CD23 and BG-12 programs. In 2007, we had 5 programs in Phase 3 clinical trials as compared to 3 in 2006. The balance of the \$77.7 million is due to other research and development investments, primarily in pre clinical and early stage pipeline programs driven by

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our business development deals with Syntonix and Conforma, as well as increased spend for the Baminercept-alpha (LTBR-Fc) program in anticipation of the 2007 and 2008 data read outs.

We expect that research and development expenses will increase in 2009 primarily due to the greater number of product candidates in late stage clinical trials.

Selling, General and Administrative Expenses

Selling, general and administrative expenses totaled \$925.3 million in 2008 compared to \$776.1 million in 2007, and \$685.1 million in 2006.

For 2008 compared to 2007, selling, general and administrative expenses increased \$149.2 million, or 19.2%, primarily due to a \$90.0 million increase in sales and marketing, of which \$55.3 million related to international sales and marketing activities primarily for AVONEX and TYSABRI and a \$43.6 million increase in salaries and benefits related to general and administrative personnel as well as increases in fees and services.

For 2007 compared to 2006, selling, general and administrative expenses increased \$91.0 million, or 13.3%, primarily due to a \$65.0 million increase in sales and marketing activities for TYSABRI, primarily in international sales and marketing, a \$25.5 million net increase in salaries and benefits related to increased headcount in general and administrative personnel, a \$19.0 million increase in fees and services related to general and administrative matters offset by a \$12.1 million decrease in sales and marketing activities for ZEVALIN due to decreased commercial efforts due to the planned divestiture of this product line.

We do not anticipate a significant increase in total selling, general, and administrative expenses in 2009 as compared to the amount incurred in 2008.

Severance and Other Restructuring Costs

Severance and other restructuring costs totaled \$5.0 million in 2008 as compared to \$1.8 million in 2007 and \$3.6 million in 2006. These costs are included in research and development expense and selling, general and administrative expense in our consolidated statements of income. At December 31, 2008, there are no remaining material severance or restructuring accruals on our consolidated balance sheet.

Amortization of Intangible Assets

For 2008, 2007, and 2006, amortization expense was \$332.7 million, \$257.5 million, and \$267.0 million, respectively.

Our most significant intangible asset is the core technology related to our AVONEX product. Our amortization policy for our core technology intangible asset is based on the principles of Statement of Financial Standards No. 142, *Goodwill and Other Intangible Assets*, or SFAS 142, which requires the amortization of intangible assets to reflect the pattern in which the economic benefits of the intangible asset are consumed. Every year during the third quarter we complete our long range planning cycle, which includes an analysis of the anticipated product sales of AVONEX. The results of this forecast serve as the basis for our assumptions used in the economic consumption amortization model for our core technology intangible asset. We also establish minimum annual amortization amounts to ensure amortization charges are not unreasonably deferred to future periods. See Note 1, Business Overview and Summary of Significant Accounting Policies, for a detailed description of our accounting policy for amortization of intangible assets.

For 2008 compared to 2007, amortization expense increased \$75.2 million, or 29.2%, primarily due to the changes in the estimate of the future revenue of AVONEX, which serves as the basis for the calculation of economic consumption for core technology that occurred as part of our annual reassessment of amortization expense in the third quarters of 2008 and 2007. The change in the estimate of the future revenue of AVONEX is attributable to the expected impact of competitor products, including commercialization of our own pipeline product candidates.

For 2007 compared to 2006, amortization expense decreased \$9.5 million, or 3.6%, primarily due to the changes in estimate of the future revenue of AVONEX, which serves as the basis in our calculation of economic consumption for core technology.

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We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. No such events or changes in circumstances occurred in 2008. 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.

In-Process Research and Development (IPR&D)

For 2008, 2007, and 2006, IPR&D charges were \$25.0 million, \$84.2 million, and \$330.5 million, respectively.

In 2008, we recorded an IPR&D charge of \$25.0 million related to a HSP90-related milestone payment made to the former shareholders of Conforma, pursuant to the terms of our acquisition of Conforma in 2006.

During the year ended December 31, 2007, we recorded IPR&D charges of \$84.2 million. The principal components of this amount are as follows: \$18.4 million related to the acquisition of Syntonix, approximately \$30 million related to the collaboration with Cardiokine Biopharma LLC, or Cardiokine and \$34.3 million related to the collaboration with Neurimmune. Cardiokine and Neurimmune are variable interest entities, as defined in FIN 46(R). The consolidation of these entities resulted in IPR&D charges. The IPR&D charges have been recorded as a component of operating income. However, because the IPR&D charges relate to the fair value of the underlying technology retained by the parent companies of Cardiokine and Neurimmune, these amounts were allocated to the respective minority interests. Consequently, minority interest of \$64.3 million was recorded as a component of non-operating income. In 2006, we recorded \$207.4 million and \$123.1 million in IPR&D related to the acquisitions of Fumapharm and Conforma, respectively.

Through December 31, 2008, research and development expenditures related to in-process research and development projects acquired in prior years are \$42.9 million, \$36.3 million, and \$129.3 million related to Syntonix, Conforma, and Fumapharm, respectively.

See Note 2, Acquisitions and Dispositions, and Note 16, Research Collaborations of the Consolidated Financial Statements.

Facility Impairments and (Gain) Loss on Disposition, net

In 2008, as part of the lease agreement described in Note 18, Commitments and Contingencies, we sold the development rights on a parcel of land in Cambridge, MA in a non-monetary transaction for \$11.4 million. We recorded a pre-tax gain of approximately \$9.2 million on the sale. In 2006, we completed the sale of one of the buildings in our Cambridge, Massachusetts facility, known as Bio 1. Proceeds from the sale were approximately \$39.5 million. We recorded a pre-tax gain of approximately \$15.6 million on the sale. We continued to occupy a minor portion of the building under a leasing arrangement. In 2006, we also sold our clinical manufacturing facility in Oceanside, California, known as NICO for total consideration of \$29.0 million. We recorded an immaterial net gain pursuant to this transaction.

Gain on Settlement of License Agreements, net

In 2006, we recorded a net gain on settlement of license agreements, net of \$6.1 million as discussed below.

Fumapharm

During 2006, we recorded a gain of \$34.2 million coincident with the acquisition of Fumapharm in accordance with EITF 04-1, *Accounting for Preexisting Relationships between the Parties to a Business Combination*, or EITF 04-1.

The gain related to the settlement of a preexisting collaboration agreement between Fumapharm and us. The collaboration agreement was entered into in October 2003 and required payments to Fumapharm of certain royalty amounts. The market rate for such payments was higher at the acquisition date, primarily due to the increased technical feasibility of BG-12. The gain relates to the difference between the royalty rates at the time the agreement was entered into as compared to the rates at the time the agreement was effectively settled by virtue of our acquisition of Fumapharm.

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Fumedica

During 2006, we recorded a charge of \$28.1 million in connection with a settlement agreement with Fumedica Arzneimittel AG and Fumedica Arzneimittel GmbH, collectively Fumedica. The charge related to the settlement of the agreement with Fumedica under which we were contingently obligated to make royalty payments with respect to a successful launch of BG-12 for psoriasis in Germany. Under the terms of the settlement agreement, we will not be required to make any royalty payments to Fumedica if BG-12 is successfully launched for psoriasis in Germany. The \$28.1 million was expensed in 2006, as it related to a product that had not reached technological feasibility.

Share-based Compensation Expense

In the year ended December 31, 2008 and 2007, we recorded share-based compensation expense of \$146.2 million, and \$123.1 million, respectively, associated with SFAS 123(R). In the year ended December 31, 2006, we recorded share-based compensation expense of \$126.8 million associated with SFAS 123(R), which is net of a cumulative effect pre-tax adjustment of \$5.6 million, or \$3.8 million after-tax. The cumulative effect results from the application of an estimated forfeiture rate for current and prior period unvested restricted stock awards.

Our share-based compensation programs consist of share-based awards granted to employees including stock options, restricted stock, performance-based restricted stock units, and restricted stock units, or RSUs, as well as our employee stock purchase plan, or ESPP. The fair value of performance based stock units is based on the market price of our stock on the date of grant and assumes that the performance criteria will be met and the target payout level will be achieved. Compensation expense is adjusted for subsequent changes in the outcome of performance-related conditions until the vesting date.

Other Income (Expense), Net

Other income (expense), net, is as follows (in millions):

	Year Ended December 31,		
	2008	2007	2006
Interest income	\$ 72.1	\$ 103.6	\$ 101.2
Interest expense	(52.0)	(40.5)	(0.9)
Impairments of investments	(60.3)	(24.4)	(34.4)
Gain (loss) on sales of investments, net	(1.1)	16.7	(2.8)
Minority interest income (expense)	(6.9)	58.4	(6.8)
Foreign exchange gains (losses), net	(9.8)	3.0	4.9
Settlement of litigation and claims		0.1	(4.6)
Gain on sale of property		7.1	
Other, net	(6.7)	6.8	(4.5)
Total other income (expense), net	\$ (64.7)	\$ 130.8	\$ 52.1

Interest Income

For 2008 compared to 2007, interest income decreased \$31.5 million, or 30.4%, primarily due to a reduction in cash and cash equivalents due to the funding of our tender offer in July 2007, a net payment of \$525.5 million for our term

loan facility and other debt, and lower investment yields. For 2007 compared to 2006, interest income increased \$2.4 million, or 2.4%, primarily due to higher yields offset by a reduction in cash and cash equivalents due to the funding of our tender offer in July 2007. We expect that further reductions in yields may impact our interest income in 2009.

Interest Expense

For 2008 compared to 2007, interest expense increased \$11.5 million, or 28.4%, primarily due to an increased average debt balance in 2008 as compared to 2007 as well as \$8.9 million due to the impact of hedge ineffectiveness

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as discussed in Note 4, Financial Instruments. For 2007 compared to 2006, interest expense increased \$39.6 million, primarily due to the increased debt levels relating to our tender offer funded in July 2007 (see Note 21, Tender Offer). As discussed in Note 4, Financial Instruments, in 2008 we terminated certain interest rate swaps. Upon termination of the swaps, the carrying amount of the 6.875% Senior Notes due in 2018 increased by \$62.8 million as it was accounted for as a fair value hedge. This amount will be recognized as a reduction of interest expense and amortized using the effective interest rate method over the remaining life of the Senior Notes.

Impairment on Investments

In 2008, the impairment on investments was due to an other than temporary decline in the fair value of marketable debt securities of \$41.7 million related primarily to non agency mortgage and asset backed securities and corporate securities classified as available for sale as well as other than temporary declines in the fair values of our strategic investments of \$18.6 million. In 2007 and 2006, the impairment of investments is primarily due to the other than temporary decline in value in our strategic investments portfolio. We may incur additional impairment charges on these investments in the future.

Minority Interest

For 2008 compared to 2007, minority interest decreased \$65.3 million, primarily due to the recording in 2007 of \$64.3 million in minority interest pursuant to the initial consolidation of Cardiokine in August 2007 and Neurimmune in November 2007. For 2007 compared to 2006, minority interest increased \$65.2 million, also primarily due to the initial consolidation of Cardiokine and Neurimmune in 2007. The minority interest related to Cardiokine and Neurimmune recorded in 2007 offset an equal charge to IPR&D, which resulted in no net impact to our results of operations for these IPR&D and minority interest charges. Excluding the impact of these consolidations, minority interest expense was \$6.9 million, \$5.9 million and \$6.8 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Gain on Sale of Property

In 2007, we sold approximately 28 acres of land in Oceanside, California for \$16.5 million. We recorded a pre-tax gain of approximately \$7.1 million on the sale.

Income Tax Provision

Due to tax law changes in certain jurisdictions, during 2008 we completed a reorganization of our domestic and international corporate structure and moved certain personnel and operational functions between affiliates. We anticipate the restructuring will impact amounts subject to future taxation in the U.S. and foreign jurisdictions. We anticipate the changes in our international structure will have a slight unfavorable impact on our effective tax rate for 2009 and beyond, as compared to our tax rate in 2008. We do not anticipate that the domestic reorganization will have a significant impact on our tax rate in 2009 and beyond as compared to our 2008 tax rate.

Our effective tax rate was 31.8%, 29.9% and 56.6% on pre-tax income for the years ended December 31, 2008, 2007 and 2006, respectively. The effective tax rate in 2008 was higher than that in 2007, primarily due to an increased percentage of our foreign earnings being subject to U.S. income tax and the effects of our reorganization of our international operations during 2008, partially offset by certain tax credits and deferred tax assets which will be realized, as a result of our domestic reorganization.

Our effective rate for 2006 was higher than the rate for 2007 primarily due to the write-off of non-deductible IPR&D in connection with the acquisitions of Conforma and Fumapharm, offset by a non-deductible gain on settlement of the

Fumapharm license agreement, and the impact of acquisition-related intangible amortization related to foreign jurisdictions and state taxes, offset by the effect of lower income tax in certain non-U.S. jurisdictions.

Refer to Note 15, Income Taxes, in $\,$ Notes to Consolidated Financial Statements $\,$, for full income tax rate reconciliations for 2008, 2007 and 2006.

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Financial Condition and Liquidity

Our financial condition is summarized as follows (in millions):

	December 31, 2008			December 31, 2007		
Cash and cash equivalents Marketable securities and loaned securities current and non-current	\$	622.4 1,640.4	\$	659.7 1,456.1		
Total cash, cash equivalents, and marketable securities (including loaned securities)	\$	2,262.8	\$	2,115.8		
Working capital Outstanding borrowings current and non-current	\$ \$	1,534.8 1,113.1	\$ \$	179.2 1,563.0		

Our cash, cash equivalents, and marketable securities at December 31, 2008, are relatively consistent with the balances at December 31, 2007. However, there were several significant cash flow activities including the net repayment of approximately \$513.0 million of indebtedness, \$738.9 million used to fund share repurchases, as well as \$276.0 used to purchase property plant and equipment offset by cash generated from operations of \$1,566.5 million and cash received from the termination of our interest rate swaps of \$53.9 million. During the year ended December 31, 2008, we paid approximately \$72.5 million in milestone and other payments pursuant to our research and development programs, including \$31.5 million pursuant to our Genentech agreement, \$25.0 million of contingent purchase price in connection with our Conforma acquisition and \$10.5 million related to the development of the Beta-Amyloid antibody under our arrangement with Neurimmune Therapeutics AG. We also received \$75.0 million pursuant to our Elan collaboration. All of these milestone payments are included in cash from operations except the conforma payment which is included in investing activities on the consolidated statement of cash flows.

Until required for use in the business, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, foreign and U.S. government instruments, and other interest bearing marketable debt instruments in accordance with our investment policy. The value of these securities may be adversely affected which could impact our financial position and our overall liquidity. In particular, the value of our investments may be adversely affected by increases in interest rates, downgrades in the corporate bonds included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the mortgage, auto and credit card asset backed securities included in our portfolio, and by other factors which may result in other than temporary declines in value of the investments. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. We attempt to mitigate these risks with the assistance of our investment advisors by investing in high quality securities and continuously monitoring the overall risk profile of our portfolio. We also maintain a well diversified portfolio that limits our credit exposure through concentration limits set within our investment policy.

As noted in Note 3, Fair Value Measurements, in Notes to Consolidated Financial Statements, a majority of our financial assets and liabilities have been classified as Level 2. These assets and liabilities have been initially valued at the transaction price and subsequently valued utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates, other industry, and economic events. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other

pricing sources, and analyzing pricing data in certain instances. The fair values of our foreign currency forward contracts, interest rate swaps, debt instruments and plan assets for deferred compensation are based on market inputs and have been classified as Level 2. While we believe the valuation methodologies are appropriate, the use of valuation methodologies is highly judgmental and changes in methodologies can have a material impact on the values of these assets, our financial position, and overall liquidity. Refer to Item 7A of this Form 10-K, Quantitative and Qualitative Disclosure About Market Risk, for further discussion of the impact of changes in interest rates on these investments.

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We have financed our operating and capital expenditures through cash flows from our operations. We financed our common stock tender offer in July 2007 through the use of debt and existing cash. We expect to finance our current and planned operating requirements principally through cash from operations, as well as existing cash resources. 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, additional equity and debt financings or from other sources.

On December 4, 2008, Standard & Poor s upgraded our credit rating from BBB to BBB+. According to public records, the rating action reflects the prospects for continued growth of our multiple sclerosis (MS) franchise and our conservative financial policies. Specifically, Standard & Poor s stated that our liquidity is more than adequate and that no significant debt is maturing in the near term, which for us is 2013. We have sufficient liquid funds in cash and marketable securities and have access to a \$360.0 million credit facility.

See Part I, Item 1A, Risk Factors of this Form 10-K for risk factors that could negatively impact our cash position and ability to fund future operations.

Operating activities

Cash provided by operations is primarily driven by our net income and adjusted for non-cash items. On an ongoing basis, we expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures. In 2008, 2007, and 2006, net cash provided by operating activities was \$1,566.5 million, \$1,020.6 million, and \$841.3 million, respectively.

The increase in cash from operating activities for 2008 as compared to 2007, was primarily due to higher earnings net of a higher investment in working capital and the proceeds received from the termination of the interest rate swap.

The increase in cash from operating activities in 2007 as compared to 2006 was primarily due to higher earnings. Movements in working capital accounts, which were a use of funds of \$77.9 million in 2007 as compared to a use of funds of \$103.3 million in 2006, also contributed to this increase.

Investing activities

In 2008, 2007, and 2006, net cash used in investing activities was \$365.9 million, \$286.6 million, and \$599.8 million, respectively.

In 2008, our sources of cash from investing activities consisted primarily of the net proceeds from sales and purchases of marketable securities. Our primary use of cash in investing activities consisted primarily of the purchases of property plant and equipment of \$275.9 million. Payments pursuant to acquisitions and licenses were \$25.0 million, which related to our 2006 acquisition of Conforma. The change in balance of collateral received under securities lending is reflected as a source of cash in investing activities offset by a use of cash from financing activities.

In 2007, net proceeds from sales of marketable securities of \$209.0 million, were used to partially fund the tender offer described in Note 21, Tender Offer. Purchases of property, plant and equipment totaled \$284.1 million in 2007. Payments made for acquisitions were \$95.8 million in 2007, which primarily related to our acquisition of Syntonix for \$42.3 million, and our collaboration payments to Cardiokine Biopharma LLC for \$50.0 million and Neurimmune of \$2.0 million. The change in balance of collateral received under securities lending is reflected as a use of cash in investing activities offset by a source of cash from financing activities. Additionally, in 2007 we sold our position in a strategic investment for \$99.5 million.

In 2006, net cash used to purchase marketable securities was \$162.8 million. Purchases of property, plant and equipment totaled \$198.3 million for 2006. Payments made for acquisitions were \$363.3 million in 2006, which related to our acquisitions of Fumapharm and Conforma. Proceeds from the sale of product lines were \$59.8 million in 2006, which related to the sale of AMEVIVE.

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Financing activities

In 2008, 2007, and 2006, net cash used in financing activities was \$1,236.7 million, \$735.2 million, and \$148.4 million, respectively.

The primary increase in use of cash in 2008 was the repayment of our term loan facility of \$1,500.0 million, and the purchase of our common stock of \$738.9 million, offset in part by the issuance of long-term debt, net, of \$987.0 million, and proceeds of \$178.5 million relating to the exercise of stock options and purchases of our stock under our share based compensation arrangements.

In 2007, the primary use of cash related to the repurchase of treasury stock via the tender offer of \$2,990.5 million. This repurchase was partially funded with cash proceeds from a short-term note of \$1,500.0 million. This transaction is described in Note 21, Tender Offer. Additionally, cash proceeds from issuance of stock for our share based compensation arrangements were \$489.2 million, which was primarily attributable to the exercise of stock options and participation in our ESPP plan. The change in balance of collateral received under securities lending is reflected as a use of cash in investing activities offset by a source of cash from financing activities.

In 2006, the primary use of cash was \$320.3 million for the purchase of treasury stock, offset by \$147.0 million in proceeds from issuance of stock for our share based compensation arrangements.

Borrowings

On March 4, 2008, we issued \$450.0 million aggregate principal amount of 6.0% Senior Notes due March 1, 2013 and \$550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 for proceeds of \$987.0 million, net of issuance costs. Additionally, in connection with the note issuance, we entered into interest rate swaps, which were terminated in December 2008 and are further described in Note 4, Financial Instruments.

We used the proceeds of this offering, along with cash and the proceeds from the liquidation of marketable securities, to repay the \$1,500.0 million term loan facility we had entered into in July 2007 in connection with the funding of our June 2007 tender offer.

In June 2007, we also entered into a five-year \$400.0 million Senior Unsecured Revolving Credit Facility, which we may use for working capital and general corporate purposes. The bankruptcy of Lehman Brothers Holdings Inc. in September 2008 has eliminated their \$40.0 million commitment, thereby reducing the availability of the credit facility to \$360.0 million. The terms of this revolving credit facility include various covenants, including financial covenants that require us to not exceed a maximum leverage ratio and under certain circumstance, an interest coverage ratio. As of December 31, 2008, we were in compliance with these covenants and there were no borrowings outstanding under this credit facility.

Tender Offer

On June 27, 2007, pursuant to the terms of a modified Dutch Auction tender offer, we accepted for payment 56,424,155 shares of our common stock at a price of \$53.00 per share for a purchase price of \$2,990.5 million. We funded the tender offer through existing cash and cash equivalents of \$1,490.5 million and a \$1,500.0 million term loan facility as described in Note 8, Indebtedness. All of the shares repurchased were retired in July 2007.

Commitments

As of December 31, 2008, we have completed the first phase of construction of our large-scale biologic manufacturing facility in Hillerød, Denmark, which included partial completion of a bulk manufacturing component, a labeling and packaging component, and installation of major equipment. We are proceeding with the second phase of the project, including the completion of the large scale bulk manufacturing component and construction of a warehouse. As of December 31, 2008, we had contractual commitments of approximately \$14.5 million for the second phase. This second phase of the project is expected to be ready for commercial production in 2010.

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The timing of the completion and anticipated licensing of the bulk manufacturing facility is in part dependent upon market acceptance of TYSABRI. See Risk Factors Our near-term success depends on the market acceptance and successful sales growth of TYSABRI. We continue to evaluate our requirements for TYSABRI inventory and additional manufacturing capacity in light of the approved label and our judgment of the potential market acceptance of TYSABRI in MS, and additional approved indications in the U.S., EU and other jurisdictions.

Share Repurchase Programs

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock that expired October 4, 2006, under this program we repurchased 7.5 million shares at a cost of \$320.3 million in 2006. In October 2006, our Board of Directors authorized the repurchase of up to an additional 20.0 million shares of our common stock. This repurchase program does not have an expiration date. We have repurchased approximately 12.8 million shares of our common stock for \$738.9 million under the share repurchase program as of December 31, 2008. Subsequent to December 31, 2008, we repurchased approximately 1.2 million additional shares under this program at a total cost of \$57.6 million and have approximately 6.0 million shares remaining for repurchase available under this program.

Contractual Obligations and Off-Balance Sheet Arrangements

At December 31, 2008, we have funding commitments of up to approximately \$25.5 million as part of our investment in biotechnology oriented venture capital funds. In addition, we have committed to make potential future milestone payments to third parties of up to approximately \$1,237.7 million as part of our various collaborations including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2008, such contingencies have not been recorded in our financial statements. We expect to make approximately \$29.0 million of milestone payments in 2009.

At December 31, 2008, we have several clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to clinical research organizations, or CROs. The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses of \$25.4 million recorded in accrued expenses on our consolidated balance sheet for work done by CROs at December 31, 2008. We have approximately \$221.7 million in cancellable future commitments based on existing CRO contracts at December 31, 2008.

We do not have any significant relationships with 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. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We consolidate entities within the scope of FIN 46(R) if we are the primary beneficiary.

The following summarizes our contractual obligations (excluding funding and contingent milestone payments as described above and construction commitments disclosed above under Commitments) at December 31, 2008, and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

	Payments Due by Period									
	ı	Total		ss than Year	Y	1-3 Years		4-5 Years		After Years
Non-cancellable operating leases	\$	399.2	\$	31.4	\$	67.2	\$	54.0	\$	246.6
Notes payable, including interest		1,515.0		92.9		142.6		562.0		717.5

 Other long-term obligations
 24.1
 9.8
 8.9
 5.4

 Total contractual cash obligations
 \$ 1,938.3
 \$ 134.1
 \$ 218.7
 \$ 616.0
 \$ 969.5

This table includes our obligation of approximately \$12.8 million pursuant to a dedicated resource agreement whereby a laboratory will provide us with dedicated services through 2010. This table excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. In connection with the adoption of FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109, or FIN 48, we reclassified

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approximately \$113.0 million in reserves for uncertain tax positions from current taxes payable to long term liabilities. At December 31, 2008, we have approximately \$145.2 million of long term liabilities associated with uncertain tax positions.

Legal Matters

See Note 19, Litigation, to the consolidated financial statements for a discussion of legal matters as of December 31, 2008.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its critical estimates and judgments, including, among others, those related to revenue recognition, investments, inventory, research and development expenses, purchase accounting, goodwill impairment, stock-based compensation, and income taxes. Those critical estimates and assumptions are based on our historical experience, our observance of trends in the industry, and various other factors that are believed to be reasonable under the circumstances and 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 estimates affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue Recognition and Accounts Receivable

Product Revenues

We recognize revenue when 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.

Revenues are recorded net of applicable reserves for trade term discounts, wholesaler incentives, Medicaid rebates, VA rebates, managed care rebates, product returns and other applicable allowances. Our product revenue reserves are based on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends and forecasted customer buying patterns. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment. These estimates we make with respect to these allowances represent the most significant judgments that we make with regard to revenue recognition.

Royalties

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 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.

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Investments

We invest in various types of securities, including:

short-term and long-term marketable securities, principally corporate notes, government securities and other asset backed securities, in which our excess cash balances are invested. Restrictions that limit the amount of investment exposure by institution, maturity and type are detailed in our Investment Policy. The objectives of this policy are safety of principal, liquidity and lastly yield.

equity securities in certain publicly-traded biotechnology companies some of which we have collaborative agreements with; and

equity securities of certain companies whose securities are not publicly traded and where fair value is not readily available.

These investments are accounted for in accordance with Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities, or SFAS 115, or APB No. 18, The Equity Method of Accounting for Investments in Common, or APB 18, as appropriate.

In accordance with Statement of Financial Accounting Standards No. 157, *Fair Value Measurement*, or SFAS 157, we have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

As noted in Note 3, Fair Value Measurements, a majority of our financial assets and liabilities have been classified as Level 2. These assets and liabilities have been initially valued at the transaction price and subsequently valued utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates, other industry, and economic events. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and analyzing pricing data in certain instances.

We also have some investments classified as Level 3 whose fair value is initially measured at transaction prices and subsequently valued using the pricing of recent financing and/or by reviewing the underlying economic fundamentals and liquidation value of the companies. We apply judgments and estimates when we validate the prices provided by third parties. While we believe the valuation methodologies are appropriate, the use of valuation methodologies is highly judgmental and changes in methodologies can have a material impact on our results of operations.

Impairment

In accounting for investments, we evaluate if a decline in the fair value of a marketable security below our cost basis is other-than-temporary, and if so, we record an impairment charge in our consolidated statement of income. The factors that we consider in our assessments for our investments in debt securities include the fair market value of the security, the duration of the security s decline, and our ability and intent to hold to maturity. For our investments in equity securities, we consider the fair market value of the security, the duration of the security s decline as well as prospects for the investee, including favorable clinical trial results, new product initiatives, new collaborative agreements and our intent and ability to hold to recovery. The determination of whether a loss is other than temporary

is highly judgmental and can have a material impact on our financial results.

Inventory

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out, or 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.

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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, *Elements of Financial Statements* A Replacement of FASB Concepts No. 3, or 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 any changes we make in these judgments may have a material impact on our results in future periods.

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 net 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-downs will be required. Additionally, our products are subject to strict quality control and monitoring throughout the manufacturing process. Periodically, certain batches or units of product may no longer meet quality specifications or may expire. As a result, included in costs of goods sold are write-downs of commercial inventory that do not meet quality specifications or became obsolete due to expiration.

Research and Development Expenses

Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development expenses 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 expenses include expenses 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 site management, monitoring costs, and project management costs. We maintain regular communication with our CRO vendors to gauge the reasonableness of our estimates. Differences between actual clinical trial expenses and estimated clinical trial expenses recorded have not been material and are adjusted for in the period in which they become known.

Valuation of Acquired Intangible Assets and In-process Research and Development Expenses

We have acquired, and expect to continue to acquire, intangible assets primarily through the acquisition of biotechnology companies. These intangible assets primarily consist of technology associated with human therapeutic products and in-process product candidates. When significant identifiable intangible assets are acquired, an independent third-party valuation firm is generally engaged to assist in determining the fair values of these assets as of the acquisition date. Management will determine the fair value of less significant identifiable intangible assets acquired. Discounted cash flow models are typically used in these valuations, and these models require the use of

significant estimates and assumptions including but not limited to:

estimating the timing of and expected costs to complete the in-process projects;

projecting regulatory approvals;

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estimating future cash flows from product sales resulting from completed products and in-process projects; and developing appropriate discount rates and probability rates by project.

We believe the fair values assigned to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates.

FIN 46(R)

Under FIN 46(R), we consolidate variable interest entities for which we are the primary beneficiary. In determining whether we are the primary beneficiary, we consider a number of factors, including determining the expected losses and residual returns of the technologies being developed pursuant to collaborations and other economic risk and reward of such collaborations. Discounted cash flow models are typically used in these analyses and these models require the use of significant estimates and assumptions including but not limited to:

assuming that the research and development efforts will result in an approved commercial product;

estimating the timing of and expected costs to complete the in-process projects;

projecting timing of regulatory approvals;

estimating future cash inflows from product sales or funding from partners resulting from completed products and in-process projects; and

developing appropriate discount rates and probability rates by project.

For such consolidated entities that we own less than a 100% interest, we record minority interest in our statement of income for the current results allocated to the outside equity interests. FIN 46(R) impacts the way we account for certain collaborations and future events may result in our consolidation of companies or related entities with which we have a collaborative arrangement. The consolidation of variable interest entities may have a material effect on our financial condition and/or results of operation in future periods.

Goodwill

We annually assess our goodwill balance to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. To do this, in the case of goodwill we estimate the fair value of each of our reporting units and compare it to the book value of their net assets. Calculating fair value involves identifying future cash flows, which requires that we make a number of critical legal, economic, market and business assumptions that reflect our best estimates as of the testing date. We believe the methods we use to determine these underlying assumptions and estimates are reasonable. Notwithstanding this, our assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause us to conclude that an impairment now exists or that we previously understated the extent of impairment.

Share-based Compensation

We make certain assumptions in order to value and expense our share-based compensation. In connection with valuing stock options and our employee stock purchase plan, we use the Black-Scholes model, which requires us to estimate certain subjective assumptions. The key assumptions we make are: the expected volatility of our stock; the

expected term of the award; and the expected forfeiture rate. In connection with our restricted stock programs, we make assumptions principally related to the forfeiture rate.

We review our valuation assumptions periodically and, as a result, we may change our valuation assumptions used to value share-based awards granted in future periods. Such changes may lead to a significant change in the expense we recognize in connection with share-based payments.

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Income Taxes

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, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

FASB Interpretation No. 48

Effective January 1, 2007, we adopted FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*, or SFAS 109. FIN 48 also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of each tax position taken or expected to be taken in a tax return. As a result of the adoption of FIN 48, we recognized a reduction in the liability for unrecognized tax benefits of \$14.2 million, which was recorded as a \$1.8 million reduction to the January 1, 2007 balance of our accumulated deficit, a \$9.1 million reduction in goodwill and a \$3.3 million increase in our deferred tax liability.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in millions):

	2008	2007	
Balance at January 1	\$ 221.1	\$ 196.8	
Additions based on tax positions related to the current period	21.8	29.7	
Additions for tax positions of prior periods	20.4	83.5	
Reductions for tax positions of prior periods	(13.7)	(70.2)	
Settlements		(18.7)	
Balance at December 31	\$ 249.6	\$ 221.1	

Included in the balance of unrecognized tax benefits at December 31, 2008, December 31, 2007, and January 1, 2007, are \$155.1 million, \$110.5 million, and \$98.2 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in any future periods. We do not anticipate any significant changes in our positions in the next twelve months.

New Accounting Standards

See Note 27, New Accounting Pronouncements, for a discussion of new accounting standards.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We have operations in Canada, Brazil, Argentina, Australia, New Zealand, Japan, China, India and throughout Europe in connection with the sale of AVONEX, TYSABRI and FUMADERM. 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 market fluctuations in foreign currency exchange rates (primarily Euro, Danish kroner, Swedish krona, British pound, Japanese yen, Canadian dollar and Swiss franc).

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We use foreign currency forward contracts to manage foreign currency risk but 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 decrease in the fair value of forward contracts of approximately \$52.4 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.

Certain of our debt instruments are variable rate instruments and our interest expense associated with these instruments is, therefore, subject to changes in market interest rates. A 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately \$0.2 million.

In addition, the fair value of our marketable securities is 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 result in a hypothetical loss in fair value of approximately \$12.2 million to our interest rate sensitive instruments.

The returns from cash, cash equivalents and marketable securities will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease interest income by approximately \$11.9 million.

We are exposed to equity price risks on the marketable portion of equity securities included in our portfolio of investments entered into for the promotion of business and strategic objectives. These investments are generally in small capitalization stocks in the biotechnology industry sector. We regularly review the market prices of these investments for impairment purposes. A hypothetical adverse 10% movement in market values would result in a hypothetical loss in fair value of approximately \$0.9 million.

Item 8. Consolidated Financial Statements and Supplementary Data