BIOGEN IDEC INC.
Form 10-K
February 05, 2013
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012

or

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

Commission file number: 0-19311

BIOGEN IDEC INC.
(Exact name of registrant as specified in its charter)

Delaware	33-0112644
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

133 Boston Post Road, Weston, Massachusetts 02493
(781) 464-2000
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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 þ No ¨

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

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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes þ No ¨

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

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.

Large accelerated filer þ	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

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 $34,138,379,832.

As of January 31, 2013, the registrant had 236,312,191 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2013 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are based on our current beliefs and expectations. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. Refe made in particular to forward-looking statements regarding:

- the anticipated amount, timing and accounting of revenues, contingency payments, milestone, royalty and other payments under licensing, collaboration or acquisition agreements, tax positions and contingencies, doubtful accounts, cost of sales, research and development costs, compensation and other expenses, amortization of intangible assets, and foreign currency forward contracts;
- the anticipated regulatory actions relating to and the commercial launch of TECFIDERA (BG-12);
- our plans to develop further risk stratification protocols for TYSABRI and the impact of such protocols;
- anticipated regulatory filings for, regulatory actions relating to, and commercial launch of our long-lasting blood clotting factor candidates;
- additional planned launches and future development costs of FAMPYRA;
- the timing, outcome and impact of proceedings related to: patents and other intellectual property rights; tax audits, assessments and settlements; product liability and other legal proceedings;
- loss to be incurred in connection with Genentech's ongoing arbitration with Hoechst;
- the deferral of TYSABRI revenue in Italy;
- the expected lifetime revenue of AVONEX and amortization recorded in relation to its core technology;
- the costs, timing and therapeutic scope of the development and commercialization of our pipeline products;
- our arrangement with Knopp Neurosciences related to dexpramipexole;
- the timing and impact of U.S. healthcare reform, including the annual fee on prescription drug manufacturers, and other measures worldwide designed to reduce healthcare costs;
- the impact of the deterioration of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- patent terms, patent term extensions, patent office actions and market exclusivity rights;
- fair value estimates in connection with our acquisitions of Stromedix and other entities;
- lease commitments and purchase obligations;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the impact of new laws and accounting standards;
- the availability of our unrepatriated foreign earnings and dividend activity;
- repayment of outstanding debt;
- the timing and expected financial impact of relocating our corporate headquarters from our facility in Weston, Massachusetts to Cambridge, Massachusetts;
- manufacturing capacity;
- the licensure of and plans for our manufacturing facility in Hillerød, Denmark; and
- the drivers for growing our business, including our plans to pursue business development and research opportunities, and competitive conditions.

These forward-looking statements involve risks and uncertainties, including those that are described in the “Risk Factors” section of this report and elsewhere within this report that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements.

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NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Throughout this report, “Biogen Idec,” the “Company,” “we,” “us” and “our” refer to Biogen Idec Inc. and its consolidated subsidiaries. References to “RITUXAN” refer to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan), and “ANGIOMAX” refers to both ANGIOMAX (the trade name for bivalirudin in the U.S., Canada and Latin America) and ANGIOX (the trade name for bivalirudin in Europe).

NOTE REGARDING TRADEMARKS

AVONEX®, AVONEX PEN® and RITUXAN® are registered trademarks of Biogen Idec. FUMADERM™ and TECFIDERA™ are trademarks of Biogen Idec. TYSABRI® and TOUCH® are registered trademarks of Elan Pharmaceuticals, Inc. The following are trademarks of the respective companies listed: ACTEMRA® — Chugai Seiyaku Kabushiki Kaisha; AUBAGIO® — Sanofi Societe Anonyme France; ANGIOMAX® and ANGIOX® — The Medicines Company; ARZERRA® — Glaxo Group Limited; BENLYSTA® — Human Genome Sciences, Inc.; BETASERON® and BETAFERON® — Bayer Schering Pharma AG; CAMPATH® and LEMTRADA® — Genzyme Corporation; CIMZIA® — UCB Pharma, S.A.; COPAXONE® — Teva Pharmaceutical Industries Limited; ENBREL® — Immunex Corporation; EXTAVIA® and GILENYA® — Novartis AG; FAMPYRA® — Acorda Therapeutics, Inc.; HUMIRA® — AbbVie Biotechnology Ltd.; ORENCIA® — Bristol-Myers Squibb Company; REBIF® — Ares Trading S.A.; REMICADE® — Centocor Ortho Biotech Inc.; SIMPONI® — Johnson & Johnson; and TREANDA® — Cephalon, Inc.

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PART I

Item 1. Business

Overview

Biogen Idec is a global biotechnology company focused on discovering, developing, manufacturing and marketing therapies for the treatment of multiple sclerosis (MS) and other autoimmune disorders, neurodegenerative diseases and hemophilia. We also collaborate on the development and commercialization of RITUXAN and anti-CD20 product candidates for the treatment of non-Hodgkin's lymphoma and other conditions. Summary information about our marketed products is set forth in the table below.

			Product Revenues to Biogen Idec (in millions)		
Product	Indications	Development or Marketing Collaborator	2012	2011	2010
AVONEX (1)	Multiple sclerosis	None	$2,913.1	$2,686.6	$2,518.4
TYSABRI (2)	Multiple sclerosis Crohn’s disease	Elan Pharma International	$1,135.9	$1,079.5	$900.2
FAMPYRA (3)	Multiple sclerosis (walking ability)	Acorda Therapeutics	$57.4	$13.6	$—
FUMADERM (4)	Psoriasis	None	$59.7	$54.7	$51.2

			Unconsolidated Joint Business Revenues to Biogen Idec (in millions)		
Product	Indications	Development or Marketing Collaborator	2012	2011	2010
RITUXAN (5)	Non-Hodgkin’s lymphoma Rheumatoid arthritis Chronic lymphocytic leukemia ANCA-associated vasculitis	Genentech (Roche Group)	$1,137.9	$996.6	$1,077.2

(1) AVONEX (interferon beta-1a) is indicated for the treatment of patients with relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations.

(2) TYSABRI (natalizumab) is indicated (1) for the treatment of relapsing forms of MS as a monotherapy to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations and (2) in the U.S. for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional Crohn's disease therapies and TNF inhibitors.

(3) FAMPYRA (prolonged-release fampridine tablets) is indicated for the improvement of walking ability in adult patients with MS who have walking disability.

(4) FUMADERM (fumaric acid esters) is only approved in Germany and is indicated for the treatment of adult patients with moderate to severe plaque psoriasis for whom topical therapy is ineffective.

(5) RITUXAN (rituximab) is indicated for the treatment of (1)(a) relapsed or refractory, low-grade or follicular, CD20-positive, B-cell Non-Hodgkin's lymphoma (NHL) as a single agent, (b) previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to RITUXAN in combination with chemotherapy, as a single-agent maintenance therapy, (c) non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent, after first-line CVP chemotherapy, and (d) previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens, (2) CD20-positive chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide, (3) moderately- to severely-active rheumatoid arthritis, in combination with methotrexate, in adult patients who have had an inadequate response to one or more TNF antagonist therapies, and (4) Wegener's Granulomatosis and Microscopic Polyangiitis, in

combination with glucocorticoids, in adult patients.

Additional financial information about our product revenues, other revenues and geographic areas in which we operate is set forth in our consolidated financial statements, in Note 26, Segment Information to our consolidated financial statements, and in Item 6. Selected Consolidated Financial Data included in this report. A discussion of the risks attendant to our international operations is set forth in the “Risk Factors” section of this report.

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We devote significant resources to research and development programs and external business development opportunities, as summarized in the table below:

(In millions)	2012	2011	2010	
Research and development	$1,334.9	$1,219.6	$1,248.6	
Amortization of acquired intangible assets	$202.2	$208.6	$208.9	
Fair value adjustment of contingent consideration	$27.2	$36.1	$—	
Acquired in-process research and development	$—	$—	$245.0	*

* $145.0 million attributed to noncontrolling interests, net of tax.

Additional information about our research and development programs and business development activity during 2012 is set forth below under the subsections entitled “Research and Development Programs” and “Business Development.”

We were formed as a California corporation in 1985 and became a Delaware corporation in 1997. In 2003, we acquired Biogen, Inc. and changed our corporate name from IDEC Pharmaceuticals Corporation to Biogen Idec Inc. Our principal executive offices are located at 133 Boston Post Road, Weston, MA 02493 and our telephone number is (781) 464-2000. Our website address is www.biogenidec.com. We make available free of charge through the Investors 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 (SEC). We include our website address in this report 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.

Marketed Products

AVONEX

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. 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 the interferon beta protein produced in the body in response to viral infection.

2012 Developments

In February 2012, the U.S. Food and Drug Administration (FDA) approved two separate dosing innovations designed to improve the treatment experience for patients receiving once-a-week AVONEX for relapsing forms of MS: AVONEX PEN and a new dose titration regimen. AVONEX PEN is the first intramuscular autoinjector approved for MS and is designed to enhance the self-injection process for patients receiving AVONEX therapy. A new dose titration regimen, facilitated by the AVOSTARTGRIP titration devices, provides patients with the option to gradually increase the dose of AVONEX at treatment initiation to reduce the incidence and severity of flu-like symptoms that patients may experience with therapy. These AVONEX dosing innovations are commercially available in the E.U., U.S. and other countries.

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TYSABRI

TYSABRI has advanced the treatment of MS patients with its established efficacy. TYSABRI is a monoclonal antibody approved in numerous countries as a monotherapy for relapsing MS and is also approved in the U.S. to treat Crohn's disease, an inflammatory disease of the intestines.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic infection of the brain by the JC virus that usually leads to death or severe disability. Infection by the JC virus (JCV) is required for the development of PML and patients who are anti-JCV antibody positive have a higher risk of developing PML. Factors that increase the risk of PML are presence of anti-JCV antibodies, prior immunosuppressant use, and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML. Reports of cases of PML in patients treated with TYSABRI in clinical studies led us to voluntarily suspend the marketing and commercial distribution of TYSABRI in February 2005 until its reintroduction to the market in July 2006. Because of the risk of PML, TYSABRI has a boxed warning and is marketed under risk management or minimization plans approved by regulatory authorities. In the U.S., for example, TYSABRI is marketed under the

TOUCH Prescribing Program, a restricted distribution program designed to assess and minimize the risk of PML, minimize death and disability due to PML, and promote informed benefit-risk decisions regarding TYSABRI use.

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U.S. and E.U. regulators continue to monitor and assess on an ongoing basis the criteria for confirming PML diagnosis, the number of PML cases, the incidence of PML in TYSABRI patients, the risk factors for PML, and TYSABRI's benefit-risk profile, which could result in modifications to the approved labels or other restrictions on TYSABRI treatment. We continue to research and develop protocols and therapies that may reduce risk and improve outcomes of PML in patients.

We collaborate with Elan Pharma International, Ltd (Elan) on the development and commercialization of TYSABRI. For information about this collaboration, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

2012 - 2013 Developments

- In January 2013, we and Elan Corporation, plc announced the submission of applications to the FDA and European Medicines Agency (EMA) requesting updates to the TYSABRI product labels. The applications request an expanded indication that would include first-line use for people living with certain relapsing forms of MS who have tested negative for antibodies to the JC virus.

- In January 2012, the FDA approved the inclusion in the U.S. product label for TYSABRI of anti-JCV antibody status as an additional factor in stratifying patients for developing PML. The FDA also approved the inclusion of a table summarizing the estimated incidence of PML according to the duration of TYSABRI treatment, prior immunosuppressant use and anti-JCV antibody status. In addition, the FDA granted Quest Diagnostics a de novo classification petition for the STRATIFY JCV Antibody ELISA testing service, which allows neurologists to determine their MS patients' anti-JCV antibody status.

RITUXAN

RITUXAN is a widely prescribed monoclonal antibody used to treat non-Hodgkin's lymphoma, rheumatoid arthritis, chronic lymphocytic leukemia and two forms of ANCA-associated vasculitis. Non-Hodgkin's lymphoma and chronic lymphocytic leukemia are cancers that affect lymphocytes, which are a type of white blood cell that help to fight infection. Rheumatoid arthritis is a chronic disease that occurs when the immune system mistakenly attacks the body's joints, resulting in inflammation, pain and joint damage. ANCA-associated vasculitis is a rare autoimmune disease that largely affects the small blood vessels of the kidneys, lungs, sinuses, and a variety of other organs.

We collaborate with Genentech, a wholly-owned member of the Roche Group, on the development and commercialization of RITUXAN. For information about this collaboration, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

FAMPYRA

FAMPYRA is the first treatment that addresses the unmet medical need of walking improvement in adult patients with MS who have walking disability. FAMPYRA is a prolonged-release tablet formulation of the drug fampridine. FAMPYRA is commercially available throughout the European Union and in Canada, Australia, New Zealand, Israel and South Korea, and we anticipate making FAMPYRA commercially available in additional markets in 2013.

We have a license from Acorda Therapeutics, Inc. to develop and commercialize FAMPYRA in all markets outside the U.S. For information about this relationship, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

2012 Developments

- The European Commission previously granted a conditional marketing authorization for FAMPYRA in the E.U. in July 2011. A conditional marketing authorization is renewable annually and is granted to a medicinal product with a positive benefit-risk assessment that fulfills an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. This marketing authorization was renewed as of July 2012. To meet the conditions of this marketing authorization, we will provide additional data from on-going clinical studies regarding FAMPYRA's benefits and safety in the long term.

FUMADERM

FUMADERM is approved for the treatment of moderate to severe psoriasis in Germany. Psoriasis is a skin disease in which cells build up on the skin surface and form scales and red patches.

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Other Sources of Revenue

Our other sources of revenue consist of royalties we receive from net sales of products related to patents that we licensed (royalty revenues) and revenues from our contract manufacturing, product supply and biosimilar arrangements (corporate partner revenues). Summary information about our other sources of revenue is set forth in the table below:

(In millions)	2012	2011	2010
Royalty revenues	$168.7	$158.5	$137.4
Corporate partner revenues	$43.8	$57.4	$31.7

Our most significant source of royalty revenue is derived from net worldwide sales of ANGIOMAX, which is licensed to The Medicines Company (TMC). TMC markets ANGIOMAX primarily in the U.S. and Europe for use as an anticoagulant in patients undergoing percutaneous coronary intervention. For a description of this royalty arrangement, please read the subsection entitled “Other Revenues - Royalty Revenues” in the “Management's Discussion and Analysis of Financial Condition and Results of Operations” section of this report.

2012 Developments

- In March 2012, the U.S. Patent and Trademark Office granted the extension of the term of the principal U.S. patent that covers ANGIOMAX to December 15, 2014. Under the terms of our royalty arrangement for ANGIOMAX, TMC is obligated to pay us royalties earned, on a country-by-country basis, until the later of (1) twelve years from the date of the first commercial sale of ANGIOMAX in such country or (2) the date upon which the product is no longer covered by a licensed patent in such country. The annual royalty rate is reduced by a specified percentage in any country where the product is no longer covered by a licensed patent and where sales have been reduced to a certain volume-based market share. TMC began selling ANGIOMAX in the U.S. in January 2001.

Research and Development Programs

A commitment to research is fundamental to our mission at Biogen Idec. Our research and development strategy is to discover and develop first-in-class molecules or best-in-class molecules that improve safety or efficacy for unmet medical needs. By applying our expertise in biologics and our growing capabilities in small-molecule drug discovery and development, we target specific medical needs where new or better treatments are needed.

We intend to continue committing significant resources to research and development opportunities and business development activity. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels. The table below highlights our current research and development programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in the “Risk Factors” section of this report.

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Therapeutic Area	Product Candidate	Targeted Indications	Status
Neurology	TECFIDERA (BG-12)	MS	Marketing applications submitted and under regulatory review
	Peginterferon beta-1a	MS	Expect to submit marketing applications by mid - 2013
	Daclizumab	MS	Phase 3
	TYSABRI	Secondary-progressive MS	Phase 3
	Anti-LINGO	Optic Neuritis	Phase 2
		MS	Phase 1
	BIIB037	Alzheimer’s disease	Phase 1
	ISIS - SMN_{Rx}	Spinal muscular atrophy	Phase 1b/2a
	Neublastin	Neuropathic pain	Phase 1
Hemophilia	Factor IX	Hemophilia B	U.S. BLA submitted and under regulatory review
	Factor VIII	Hemophilia A	Expect to submit U.S. BLA in 1H 2013
Immunology	STX-100	Idiopathic pulmonary fibrosis	Phase 2
	Anti-TWEAK	Lupus nephritis	Phase 2
	Anti-CD40 Ligand	General lupus	Phase 1
Other	GA101	Chronic lymphocytic leukemia	Phase 3
	GA101	Non-Hodgkin’s lymphoma	Phase 3

Late Stage Product Candidates

Additional information about our late stage product candidates is set forth below.

TECFIDERA (BG-12)

In February 2012, we submitted a New Drug Application to the FDA for marketing approval of TECFIDERA, our oral small molecule candidate for the treatment of MS. The regulatory submission was based on TECFIDERA's comprehensive development program, in which TECFIDERA demonstrated significant reductions in MS disease activity coupled with favorable safety and tolerability in the Phase 3 DEFINE and CONFIRM studies. The FDA accepted our application for TECFIDERA and granted us a standard review timeline. In October 2012, we announced that the FDA extended the initial PDUFA date for its review of our application by three months, which is a standard extension period. The extended PDUFA target date is in late March 2013. The FDA has indicated that the extension of the PDUFA date is needed to allow additional time for review of our application. The agency has not asked for additional studies.

In March 2012, we submitted a Marketing Authorisation Application for TECFIDERA to the EMA. The EMA has validated our application for review of TECFIDERA in the E.U. We have submitted additional regulatory applications for TECFIDERA in Australia, Canada and Switzerland.

We acquired TECFIDERA as part of our acquisition of Fumapharm AG in 2006. For more information about this acquisition and associated milestone obligations, please read the subsection entitled “Contractual Obligations and Off-Balance Sheet Arrangements-Contingent Consideration” in the “Management's Discussion and Analysis of Financial Condition and Results of Operations” section of this report.

Peginterferon beta-1a

Peginterferon beta-1a (Peginterferon) is designed to prolong the effects and reduce the dosing frequency of interferon beta-1a. The FDA has granted Peginterferon fast track status, which may result in priority review.

In January 2013, we released the primary efficacy analysis and safety data from our Phase 3 study, ADVANCE. Results support Peginterferon as a potential treatment dosed every two weeks or every four weeks for relapsing-remitting MS. The primary endpoint of ADVANCE, annualized relapse rate at one year, was met for both the two-week and four-week dosing regimens. Results showed that Peginterferon also met the secondary endpoints of risk of 12-week confirmed disability progression, proportion of patients who relapsed and magnetic resonance imaging assessments for both dose regimens. We plan to submit marketing applications for Peginterferon in the U.S. and E.U. by mid - 2013.

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Daclizumab

Daclizumab is a monoclonal antibody that is being tested in relapsing MS. In May 2010, we began patient enrollment in a Phase 3 study of daclizumab in relapsing MS, known as DECIDE, evaluating the efficacy and safety of daclizumab compared to interferon beta-1a (AVONEX). The DECIDE study is designed to have a two year endpoint and is expected to involve approximately 1,800 patients.

In August 2011, we announced positive results from SELECT, a global, registrational Phase 2b study designed to evaluate daclizumab in relapsing MS over one year. Results showed that daclizumab, administered subcutaneously once every four weeks, met primary and key secondary study endpoints, compared to placebo.

We collaborate with AbbVie Biotherapuetics, Inc., a subsidiary of AbbVie, Inc. on the development and commercialization of daclizumab. For information about this collaboration, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

TYSABRI (SPMS)

As part of our efforts with Elan to identify additional applications for TYSABRI, in September 2011 we began patient enrollment in a Phase 3b study of TYSABRI in secondary progressive MS, known as ASCEND. The study is designed to have an endpoint of approximately two years and involve approximately 850 patients. Secondary progressive MS is characterized by a steady progression of nerve damage, symptoms and disability.

Long-Lasting Recombinant Factors VIII and IX

In October 2012, we announced positive top-line results from the Phase 3 study, known as A-LONG, investigating our long-lasting recombinant Factor VIII-Fc fusion protein in hemophilia A, a rare inherited disorder which inhibits blood coagulation. We plan to submit a Biologics License Application to the FDA for our long-lasting Factor VIII product candidate in the first half of 2013.

We submitted a Biologics License Application to the FDA for marketing approval of our long-lasting recombinant Factor IX-Fc fusion protein in hemophilia B, a rare inherited disorder which inhibits blood coagulation, in the fourth quarter of 2012. The regulatory submission was based on the positive top-line results from the Phase 3 study known as B-LONG.

Pediatric data will be required as part of the Marketing Authorization Applications for our long-lasting Factor VIII and IX product candidates that we plan to submit to the EMA, and we have initiated two global pediatric studies of our long-lasting Factor VIII and IX product candidates.

We collaborate with Swedish Orphan Biovitrum AB on the commercialization of long-lasting recombinant Factors VIII and IX. For information about this collaboration, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

GA101

We collaborate with Genentech, Inc., a wholly-owned member of the Roche Group, on the development and commercialization of GA101, a monoclonal antibody. Genentech and Roche are managing the following Phase 3 studies of GA101:

- GOYA: investigating the efficacy and safety of GA101 in combination with CHOP chemotherapy compared to RITUXAN with CHOP chemotherapy in previously untreated patients with CD20-positive diffuse large B-cell lymphoma.
- GALLIUM: investigating the efficacy and safety of GA101 in combination with chemotherapy followed by maintenance with GA101 compared to RITUXAN in combination with chemotherapy followed by maintenance with RITUXAN in previously untreated patients with indolent non-Hodgkin's lymphoma.
- GADOLIN: investigating the efficacy and safety of GA101 plus bendamustine compared with bendamustine alone in patients with RITUXAN-refractory, indolent non-Hodgkin's lymphoma.
- CLL11: investigating the safety and efficacy of GA101 plus chlorambucil, a chemotherapy, compared to RITUXAN plus chlorambucil or chlorambucil alone in previously untreated chronic lymphocytic leukemia patients with co-morbidities.

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In January 2013, the Roche Group announced that stage 1 of the CLL11 study met its primary endpoint with an improvement in progression-free survival (PFS): GA101 plus chlorambucil significantly reduced the risk of disease worsening or death compared to chlorambucil alone. The CLL11 study includes two separate stages. Stage 1 evaluated GA101 plus chlorambucil compared to chlorambucil alone and included a pre-planned PFS futility analysis comparing GA101 plus chlorambucil to RITUXAN plus chlorambucil. The goal of the futility analysis was to evaluate the likelihood that the study would meet its pre-specified endpoint criteria during stage 2 analysis: improved efficacy (PFS) in the direct comparison of GA101 plus chlorambucil versus RITUXAN plus chlorambucil. The independent Data and Safety Monitoring Board assessment concluded that stage 2 of the study should continue until its final analysis.

For information about our collaboration with Genentech, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Former Registrational Program

At the end of December 2012, we learned that a Phase 3 trial investigating dexpramipexole in people with amyotrophic lateral sclerosis (ALS) did not meet its primary endpoint, a joint rank analysis of function and survival, and no efficacy was seen in the individual components of function or survival. The trial also failed to show efficacy in its key secondary endpoints. Based on these results, we have discontinued development of dexpramipexole in ALS. Dexpramipexole was being developed pursuant to a license agreement with Knopp Neurosciences, Inc. For more information about this relationship, please read Note 20, Investments in Variable Interest Entities to our consolidated financial statements included in this report.

Business Development

In December 2012, we entered into an arrangement with Eisai, Inc. to lease a portion of their facility in Research Triangle Park, North Carolina (RTP) to manufacture our and Eisai's oral solid dose products and for Eisai to provide us with vial-filling services for biologic therapies and packaging services for oral solid dose products. For additional information about this transaction, please read Note 12, Property, Plant and Equipment to our consolidated financial statements included in this report.

In December, June and January 2012, we entered into three separate exclusive, worldwide option and collaboration agreements with Isis Pharmaceuticals, Inc. (Isis) under which both companies will develop and commercialize antisense therapeutics for up to three gene targets, Isis' product candidates for the treatment of myotonic dystrophy type 1 (DM1) and the treatment of spinal muscular atrophy (SMA), respectively. For additional information about these transactions, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

In March 2012, we acquired Stromedix, Inc., a privately held biotechnology company involved in the discovery of antibodies designed to treat fibrosis disorders. Stromedix' lead candidate, STX-100, is in a Phase 2 study for idiopathic pulmonary fibrosis, a disease in which lung tissue becomes scarred over time. There is no FDA-approved treatment for idiopathic pulmonary fibrosis at this time. For additional information about this transaction, please read Note 2, Acquisitions to our consolidated financial statements included in this report.

In February 2012, we finalized an agreement with Samsung Biologics that established an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. For additional information about this transaction, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Patents and Other Proprietary Rights

Patents are important to developing and protecting our competitive position. We regularly seek patent protection in the U.S. and in selected countries outside the U.S. for inventions originating from our research and development efforts. In addition, we license rights to various patents and patent applications, generally, in return for the payment of royalties to the patent owner. U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest (priority) application was filed; however, U.S. patents that issue on applications filed before June 8, 1995 may be effective until 17 years from the issue date, if that is later than the 20 year date. In some cases, the patent term may be extended to recapture a portion of the term lost during FDA regulatory review or because of U.S. Patent and Trademark Office (USPTO) delays in prosecuting the application. The duration of foreign patents varies similarly, in accordance with local law.

Regulatory data protection also can provide meaningful protection for our products. Regulatory data protection provides to the holder of a drug or biologic marketing authorization, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it compiled at significant cost and submitted to the applicable regulatory authority to obtain approval of its product. After the set period of time, third parties are then permitted to rely upon the data to obtain approval of their abbreviated applications to market generic drugs and biosimilars. Although the World Trade Organization's agreement on

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trade-related aspects of intellectual property rights (TRIPS) requires signatory countries to provide regulatory data protection to innovative pharmaceutical products, implementation and enforcement varies widely from country to country.

We also rely upon other forms of unpatented confidential information to remain competitive. We protect such information principally through confidentiality agreements with our employees, consultants, outside scientific collaborators, scientists whose research we sponsor and other advisers. In the case of our employees, these agreements also provide, in compliance with relevant law, that inventions and other intellectual property conceived by such employees during their employment shall be our exclusive property.

Our trademarks, including RITUXAN and AVONEX, are important to us and are generally covered by trademark applications or registrations in the USPTO and the patent or trademark offices of other countries. We also use trademarks licensed from third parties, such as the mark TYSABRI which we license from Elan. Trademark protection varies in accordance with local law, and continues in some countries as long as the mark is used and in other countries as long as the mark is registered. Trademark registrations generally are for fixed but renewable terms.

A discussion of certain risks and uncertainties that may affect our patent position and proprietary rights is set forth in the “Risk Factors” section of this report.

Additional information about the patents and other proprietary rights covering our marketed products and several of our late-stage product candidates is set forth below.

AVONEX and Pegylated Beta Interferon

Our U.S. patent No. 7,588,755, granted in September 2009, claims the use of recombinant beta interferon for immunomodulation or treating a viral condition, viral disease, cancers or tumors. This patent, which expires in September 2026, covers, among other things, the treatment of MS with our product AVONEX, as well as the treatment of MS with pegylated beta interferon. A discussion of legal proceedings related to this patent is set forth in Note 22, Litigation to our consolidated financial statements included in this report.

We have non-exclusive rights under certain third-party patents and patent applications to manufacture, use and sell AVONEX, including a patent owned by the Japanese Foundation for Cancer Research, which expires in 2013 in the U.S. Additionally, we and third parties own pending U.S. patent applications related to recombinant interferon-beta protein and nucleic acid. These applications, which fall outside of the GATT amendments to the U.S. patent statute, are not published by the USPTO and, if they mature into granted patents, may be entitled to a term of seventeen years from the grant date. There are two pending interference proceedings in the USPTO involving such third party applications, and additional interferences could be declared in the future. We do not know which, if any, such applications will mature into patents with claims relevant to our AVONEX product or to pegylated beta interferon.

Additional protection for our pegylated beta interferon is provided by patents and patent applications with expiration dates in 2021 in the U.S. and 2019 in the E.U., with the potential for patent term extension. We also expect our pegylated beta interferon to be granted regulatory exclusivity until 2026 in the U.S. and 2024 in the E.U.

TYSABRI

We and our collaborator, Elan, have patents and patent applications covering TYSABRI in the U.S. and other countries. These patents and patent applications cover TYSABRI and related manufacturing methods, as well as various methods of treatment using the product. In the U.S., the principal patents covering the product and use of the product to treat MS generally expire between 2015 and 2020. Additional U.S. patents and applications covering other indications, including treatment of inflammatory bowel disease, and methods of manufacturing, generally expire between 2012 and 2020. In the rest of world, patents on the product and methods of manufacturing the product generally expire between 2015 and 2020, subject to any supplemental protection (i.e., patent term extension) certificates that may be obtained. In the rest of world, patents and patent applications covering methods of treatment using TYSABRI generally expire between 2012 and 2020.

RITUXAN and Anti-CD20 Antibodies

We have several U.S. patents and patent applications, and numerous corresponding foreign counterparts, directed to anti-CD20 antibody technology, including RITUXAN. The principal patents with claims to RITUXAN or its uses expire in the U.S. between 2015 and 2018 and in the rest of the world in 2013, subject to any available patent term extensions. 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 U.S. and in the rest of world with claims to anti-CD20 antibody molecules for periods beyond those stated above for RITUXAN. In 2008, a European patent of ours claiming the treatment with anti-CD20 antibodies of certain auto-immune indications, including RA, was revoked by the European Patent Office. We are appealing that decision.

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Genentech, our collaborator on 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. We, along with Genentech, share the cost of any royalties due to Xoma in our co-promotion territory on sales of RITUXAN.

FAMPYRA

We have an exclusive license under two European granted patents, several pending European patent applications and numerous corresponding non-U.S. counterpart applications related to FAMPYRA. European patent EP0484186B1 claims pharmaceutical formulations containing aminopyridines including fampridine. This patent expired in November 2011 but is subject to pending and granted supplemental protection (i.e., patent term extension) certificates which, if granted, will extend the patent term to 2016 on a country-by-country basis. European patent EP1732548B1, which claims sustained-release aminopyridine compositions for increasing walking speed in patients with MS, expires in 2025 but is subject to pending and granted supplemental protection certificates which, if granted, will extend the patent term to 2026 on a country-by-country basis. In addition to these patent rights, FAMPYRA is covered by regulatory data protection in Europe until 2021.

TECFIDERA

We have several U.S. patents and patent applications, and a number of corresponding foreign counterparts, related to TECFIDERA. The principal U.S. patents are U.S. 6,509,376, having claims to formulations of dimethyl fumarate (the active ingredient of TECFIDERA) for use in the treatment of autoimmune diseases including MS, and U.S. 7,320,999 having claims to a method of treating MS using dimethyl fumarate. U.S. 6,509,376 and U.S. 7,320,999, expire in 2019 and 2020, respectively, subject to any available patent term extension following product approval. We also own a patent application, recently determined to be allowable by the USPTO, that covers the dosing regimen (240 mg of dimethyl fumarate administered twice a day) stated on our label under current review at the FDA. Once granted, this patent will expire in 2028. The granted European patent, EP 1131065, is directed to formulations of dimethyl fumarate and to uses thereof for treating autoimmune diseases, including MS. EP 1131065 expires in 2019, subject to any potential supplemental patent certificates that may be available. The E.U. counterpart to our recently allowed dosing regimen application is pending at the European Patent Office. Our pending patent applications, if granted, would expire as late as 2033, subject to any potential patent term adjustments or extensions that may be available.

In addition to patent protection, TECFIDERA is entitled to regulatory data protection in both the U.S. and the E.U. In the U.S., TECFIDERA is entitled to the 5 year data exclusivity given to new chemical entities. In the E.U. there are a number of ways to obtain data exclusivity and the EMA has informed us that TECFIDERA is, in principle, eligible for 8 years data exclusivity plus 2 years market exclusivity through the European centralized filing pathway. In both the US and the EU, the period of data exclusivity runs from the date of approval of the marketing application.

Long-Lasting Recombinant Factors VIII and IX

We have several U.S. patents and patent applications, and a number of corresponding foreign counterparts, related to our long-lasting recombinant Factor VIII and Factor IX product candidates and their use, including U.S. patents nos. U.S. 7,404,956; U.S. 8,329,182; U.S. 7,348,004; and U.S. 7,862,820. These patents will expire in 2024 - 2025, and some may be entitled to additional patent term pursuant to the patent term adjustment or patent term extension provisions of the U.S. patent laws. A related European patent, EP 1624891, expires in 2024 and may be entitled to additional patent term in at least some countries. Additionally, pending patent applications, if granted, would provide additional patent protection through 2033.

Sales, Marketing and Distribution

We focus our sales and marketing efforts on specialist physicians in private practice or at major medical centers. We use customary pharmaceutical company practices to market our products and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, direct mail, 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 U.S. which provide qualified uninsured or underinsured patients with marketed products at no or reduced charge, based on specific eligibility criteria. Additional information about our sales, marketing and distribution efforts for our marketed products is set forth below.

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AVONEX

We continue to focus our marketing and sales activities on maximizing the potential of AVONEX in the U.S. and the rest of world in the face of increased competition. The principal markets for AVONEX are the U.S., Germany, France, Italy and the United Kingdom. In the U.S., Canada, Brazil, Argentina, Australia, Japan and most of the major countries of the E.U., we market and sell AVONEX through our own sales forces and marketing groups and distribute AVONEX principally through wholesale distributors of 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.

TYSABRI

The principal markets for TYSABRI are the U.S., the United Kingdom, France, Germany, Italy and Spain.

In the U.S., we are principally responsible for marketing TYSABRI for MS and use our own sales force and marketing group for this. Elan is responsible for TYSABRI distribution in the U.S. and uses a third party distributor to ship TYSABRI directly to customers.

In the rest of world, we are responsible for TYSABRI marketing and distribution and we use a combination of our own sales force and marketing group and third party service providers.

RITUXAN

The Roche Group and its sub-licensees market and sell RITUXAN worldwide. We collaborate with Genentech, a wholly-owned member of the Roche Group, on the development and commercialization of RITUXAN, but Genentech maintains sole responsibility for the U.S. sales and marketing efforts related to RITUXAN. RITUXAN is generally sold to wholesalers, specialty distributors and directly to hospital pharmacies.

FAMPYRA

We market and sell FAMPYRA outside the U.S. through our own sales forces and marketing groups. Our development and commercialization rights do not include the U.S. market.

FUMADERM

FUMADERM is marketed only in Germany, through our own sales force and marketing group.

Competition

Competition in the biotechnology and pharmaceutical industries is intense and comes from many and varied sources, including specialized biotechnology firms and large pharmaceutical companies. Many of our competitors are working to develop products similar to those we are developing or already market and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. Certain of these companies have substantially greater financial, marketing and research and development resources than we do.

We believe that competition and leadership in the industry is based on managerial and technological superiority and establishing patent and other proprietary positions through research and development. 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. Another key aspect of remaining competitive within the industry is recruiting and retaining qualified scientists and technicians. We believe that we have been successful in attracting skilled and experienced scientific personnel.

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 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 products will have an important impact on our competitive position.

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We may face increased competitive pressures as a result of the emergence of biosimilars. In the U.S., most of our marketed products, including AVONEX, TYSABRI and RITUXAN, are licensed under the Public Health Service Act (PHSA) as biological products. In March 2010, U.S. healthcare reform legislation amended the PHSA to authorize the FDA to approve biological products, known as biosimilars or follow-on biologics, that are shown to be highly similar to previously approved biological products based upon potentially abbreviated data packages. The approval pathway for biosimilars does, however, grant a biologics manufacturer a 12 year period of exclusivity from the date of approval of its biological product before biosimilar competition can be introduced. Biosimilars legislation has also been in place in the E.U. since 2003. In December 2012, guidelines issued by the EMA for approving biosimilars of marketed monoclonal antibody products became effective. If a biosimilar version of one of our products were approved, it could reduce our sales of that product.

Additional information about the competition that our marketed products face is set forth below.

AVONEX AND TYSABRI

Each of AVONEX and TYSABRI competes with the following products:

- COPAXONE (glatiramer acetate), which is marketed by Teva Pharmaceutical Industries Ltd. COPAXONE generated worldwide revenues of approximately $3.9 billion in 2011.
- REBIF (interferon-beta-1a), which is marketed by Merck (and co-promoted with Pfizer Inc. in the U.S.). REBIF generated worldwide revenues of approximately $2.2 billion in 2011.
- BETASERON/BETAFERON (interferon-beta-1b), which is marketed by the Bayer Group. BETASERON/BETAFERON generated worldwide revenues of approximately $1.4 billion in 2011.
- EXTAVIA (interferon-beta-1b), which is marketed by Novartis AG. EXTAVIA generated worldwide revenues of approximately $154.0 million in 2011.
- GILENYA (fingolimod), which is marketed by Novartis AG. GILENYA generated worldwide revenues of approximately $494.0 million in 2011.
- AUBAGIO (teriflunomide), which is marketed by Sanofi-Aventis. AUBAGIO was approved in the U.S. in September 2012.

Along with us, a number of companies are working to develop additional treatments for MS that may in the future compete with AVONEX, TYSABRI or both. For example, a marketing application for LEMTRADA (alemtuzumab) (developed by Sanofi-Aventis) has been filed as a potential treatment for MS. In addition, the commercialization of certain of our own pipeline product candidates, such as TECFIDERA, may also negatively impact future sales of AVONEX, TYSABRI or both.

FAMPYRA

FAMPYRA is indicated as a treatment to improve walking in adult patients with MS who have walking disability and is the first treatment that addresses this unmet medical need with demonstrated efficacy in people with all types of MS. The product benefits from exclusivity rights that prohibit generic versions from being manufactured. However, the exclusivity rights are set to expire in 2017, which is the earliest predictable date that a generic version may be available. There are no commercially available generic versions of FAMPYRA.

FUMADERM

FUMADERM competes with several different types of therapies in the psoriasis market within Germany, including oral systemics such as methotrexate and cyclosporine.

RITUXAN IN ONCOLOGY

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

- TREANDA (bendamustine HCL) (marketed by Cephalon), which is indicated for patients with indolent B-cell NHL that has progressed within 6 months of treatment with RITUXAN and for CLL.
- ARZERRA (ofatumumab) (marketed by GenMab in collaboration with GlaxoSmithKline), which is indicated for refractory CLL patients to both alemtuzumab and fludarabine.

We are also aware of other anti-CD20 molecules in development, including our own product candidate GA101, that, if successfully developed and registered, may compete with RITUXAN in the oncology market.

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RITUXAN IN RHEUMATOID ARTHRITIS (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) and SIMPONI (golimumab) (marketed by Johnson & Johnson), HUMIRA (adalimumab) (marketed by AbbVie, Inc.), ENBREL (etanercept) (marketed by Amgen, Inc. and Pfizer) and CIMZIA (certolizumab pegol) (marketed by UCB, S.A.).
- ORENCIA (abatacept) (marketed by Bristol-Myers Squibb Company).
- ACTEMRA (tocilizumab) (marketed by the Roche Group).

We are also aware of other products in development that, if successfully developed and registered, may compete with RITUXAN in the RA market.

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

Product Approval and Post-Approval Regulation in the United States

Before new pharmaceutical products may be sold in the U.S., preclinical studies and clinical trials of the products must be conducted and the results submitted to the FDA for approval. With limited exceptions, the FDA requires companies to register both pre-approval and post-approval clinical trials and disclose clinical trial results in public databases. Failure to register a trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties. Clinical trial programs must establish efficacy, determine an appropriate dose and dosing regimen, and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. 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 (BLA) or a New Drug Application (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.

The receipt of regulatory approval often takes a number of years, involves 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, potential safety signals observed in preclinical or clinical tests, and the risks and benefits of the product as demonstrated in clinical trials. The FDA has substantial discretion in the product approval process, and it is impossible to predict with any certainty whether and when the FDA will grant marketing approval. The agency may on occasion require the sponsor of a BLA or NDA to conduct additional clinical studies or to provide other scientific or technical information about the product, and these additional requirements may lead to unanticipated delay or expense. Furthermore, even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the existing pre-clinical or clinical data.

The FDA has developed four distinct approaches intended to make therapeutically important drugs available as rapidly as possible, especially when the drugs are the first available treatment or have advantages over existing treatments: accelerated approval, fast track, breakthrough therapy, and priority review.

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. Under this pathway, the FDA may approve a product based on surrogate endpoints, or clinical endpoints other than survival or irreversible morbidity. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. Under the agency's accelerated approval regulations, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it may require certain post-marketing restrictions as necessary to assure safe use. In addition, for products approved under accelerated approval, sponsors may be required to submit all copies of their promotional materials, including advertisements, to the FDA at least thirty days prior to initial dissemination. The FDA may withdraw approval under accelerated approval after a hearing if, for instance,

post-marketing studies fail to verify any clinical benefit, it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use, or if a sponsor fails to comply with the conditions of the accelerated approval.

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In addition, the FDA may grant “fast track” status to products that treat serious diseases or conditions and fill an unmet medical need. Fast track is a process designed to expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product's development plan, more frequent written correspondence from the FDA about trial design, eligibility for accelerated approval, and rolling review, which allows submission of individually completed sections of a NDA or BLA for FDA review before the entire filing is completed. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval.

The FDA may also grant “breakthrough therapy” status to drugs designed to treat, alone or in combination with another drug or drugs, a serious or life-threatening disease or condition and for which preliminary evidence suggests a substantial improvement over existing therapies. Such drugs need not address an unmet need, but are nevertheless eligible for expedited review if they offer the potential for an improvement. Breakthrough therapy status entitles the sponsor to earlier and more frequent meetings with the FDA regarding the development of nonclinical and clinical data and permits the FDA to offer product development or regulatory advice for the purpose of shortening the time to product approval. Breakthrough therapy status does not guarantee that a product will be developed or reviewed more quickly and does not ensure FDA approval.

Finally, the FDA may grant “priority review” status to products that offer major advances in treatment or provide a treatment where no adequate therapy exists. Priority review is intended to reduce the time it takes for the FDA to review a NDA or BLA, with the goal for completing a priority review being six months (compared to ten months under standard review).

Regardless of the approval pathway employed, the FDA may require a sponsor to conduct additional post-marketing studies as a condition of approval to provide data on safety and effectiveness. If a sponsor fails to conduct the required studies, the agency may withdraw its approval. In addition, regardless of the approval pathway, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it can mandate post-marketing restrictions as necessary to assure safe use. In such a case, 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 Evaluation and Mitigation Strategies (REMS). The FDA can impose financial penalties for failing to comply with certain post-marketing commitments, including REMS. In addition, any changes to an approved REMS must be reviewed and approved by the FDA prior to implementation.

The FDA tracks information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with the FDA's safety reporting requirements may result in civil or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Based on new safety information that emerges after approval, the FDA can mandate product labeling changes, impose a new REMS or the addition of elements to an existing REMS, require new post-marketing studies (including additional clinical trials), or suspend or withdraw approval of the product. 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 types of 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, the FDA will need to review and approve such changes in advance. In the case of a new indication, we are required to demonstrate with additional clinical data that the product is safe and effective for a use other than that initially approved. FDA regulatory review may result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

In addition, the FDA regulates all advertising and promotion activities and communications for products under its jurisdiction both before 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. 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 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.

Product Approval and Post-Approval Regulation Outside the United States

We market our products in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, where most of our ex-U.S. efforts are focused, there are several tracks for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing application is similar to the NDA or BLA in the U.S. and is evaluated by the Committee for Medicinal Products for Human Use (CHMP), the expert scientific committee of the EMA. If the CHMP determines that the marketing application fulfills the requirements for quality, safety, and efficacy, it will submit a favorable opinion to the European Commission (EC). The CHMP opinion is not binding,

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but is typically adopted by the EC. A marketing application approved by the EC is valid in all member states. The centralized procedure is required for all biological products, orphan medicinal products, and new treatments for neurodegenerative disorders, and it is available for certain other products, including those which constitute a significant therapeutic, scientific or technical innovation.

In addition to the centralized procedure, Europe also has: (1) a nationalized procedure, which requires a separate application to and approval determination by each country; (2) a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval; and (3) a mutual recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision. Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection, and evaluation of adverse events post-approval, including national authorities, the EMA, the EC, and the marketing authorization holder. In some regions, it is possible to receive an “accelerated” review whereby the national regulatory authority will commit to truncated review timelines for products that meet specific medical needs.

Good Manufacturing Practices

Regulatory agencies regulate and inspect equipment, facilities, and processes used in the manufacturing and testing 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 (cGMP) and product-specific regulations enforced by regulatory agencies following product approval. The FDA, the EMA and other regulatory agencies also conduct 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 or remedies against us, including significant financial penalties and the suspension of our manufacturing operations.

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the rights and welfare of trial participants are adequately protected (commonly referred to as current Good Clinical Practices (cGCP)). Regulatory agencies enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites, contract research organizations (CROs), and institutional review boards. If our studies fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. Noncompliance can also result in civil or criminal sanctions. We rely on third parties, including CROs, to carry out many of our clinical trial-related activities. Failure of such third parties to comply with cGCP can likewise result in rejection of our clinical trial data or other sanctions.

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 U.S. Orphan Drug Act has been enacted in other countries to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases. In the E.U., medicinal products intended for diagnosis, prevention or treatment of life-threatening or very serious diseases affecting less than five in 10,000 people receive 10-year market exclusivity, protocol assistance, and access to the centralized procedure for marketing authorization.

Regulation Pertaining to Pricing and Reimbursement

In both domestic and foreign markets, sales of our products depend, in part, on the availability and amount of reimbursement by third party payers, including governments and private health plans. Governments may regulate

coverage, reimbursement and pricing of our products to control cost or affect utilization of our products. Private health plans may also seek to manage cost and utilization by implementing coverage and reimbursement limitations. Substantial uncertainty exists regarding the reimbursement by third party payors of newly approved health care products. The U.S. and foreign governments regularly consider reform measures that affect health care coverage and costs. Such reforms may include changes to the coverage and reimbursement of our products which may have a significant impact on our business.

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Within the U.S.

Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law as the greater of 23.1% of the average manufacturer price (AMP) or the difference between AMP and the best price available from us to any customer (with limited exceptions). The rebate amount must be adjusted upward if AMP increases more than inflation (measured by the Consumer Price Index - Urban). The adjustment can cause the rebate amount to exceed the minimum 23.1% rebate amount. The rebate amount is calculated each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services. The requirements for calculating AMP and best price are complex. We are required to report any revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate Program provides for civil monetary penalties.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners; are provided in connection with certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price (ASP) of the drugs. Manufacturers, including us, are required to provide ASP information to the Centers for Medicare & Medicaid Services on a quarterly basis. The manufacturer-submitted information is used to calculate Medicare payment rates. The current payment rate for Medicare Part B drugs is ASP plus 6% outside the hospital outpatient setting and ASP plus 4% for most drugs in the hospital outpatient setting. The payment rates for drugs in the hospital outpatient setting are subject to periodic adjustment. The Centers for Medicare & Medicaid Services also has the statutory authority to adjust payment rates for specific drugs outside the hospital outpatient setting based on a comparison of ASP payment rates to widely available market prices or to AMP, which could decrease Medicare payment rates, but the authority has not yet been implemented. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the governing statute provides for civil monetary penalties.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Manufacturers, including us, are required to provide a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

Our products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for our products to be covered and reimbursed by the Veterans Administration, Department of Defense, Coast Guard, and Public Health Service (PHS). Coverage under Medicaid, the Medicare Part B program and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing equal to 76% of the non-federal average manufacturer price (non-FAMP). An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties in addition to other penalties available to the government.

To maintain coverage of our products under the Medicaid Drug Rebate Program and Medicare Part B, we are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for

discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

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Outside the U.S.

Outside the U.S., the E.U. represents our major market. Within the E.U., our products are paid for by a variety of payors, with governments being the primary source of payment. Governments may determine or influence reimbursement of products. Governments may also set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of our products. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price). Recent budgetary pressures in many E.U. countries are causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates, and expanded generic substitution and patient cost-sharing. If budget pressures continue, governments may implement additional cost-containment measures. For additional information related to our concentration of credit risk associated with certain international accounts receivable balances, please read the subsection below entitled “Market Risk-Credit Risk” in the “Management's Discussion and Analysis of Financial Condition and Results of Operations” section of this report.

Regulation Pertaining to Sales and Marketing

We are 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 generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. There is therefore a possibility that our practices might be challenged under the 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 or civil sanctions, including fines and civil monetary penalties, and exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers or require disclosure to the government and public of such interactions. The laws include federal “sunshine” provisions enacted in 2010 as part of the comprehensive federal health care reform legislation. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Other Regulations

Foreign Anti-Corruption

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or

influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

The laws to which we are subject also include the U.K. Bribery Act 2010 (Bribery Act) which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

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NIH Guidelines

We conduct research at our U.S. facilities in compliance with the current U.S. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). By local ordinance, we are required to, among other things, comply with the NIH Guidelines in relation to our facilities in Cambridge, Massachusetts and RTP 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 international antitrust regulatory control, the effect of which 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 have two “state-of-the-art” licensed biologics manufacturing facilities in RTP and Cambridge, Massachusetts. The RTP site includes a 100,000 square foot manufacturing plant, which contains 6,000 (3 x 2,000) liters of bioreactor capacity, as well as a 250,000 square foot Large-Scale Manufacturing (LSM) plant which contains 90,000 (6 x 15,000) liters of bioreactor capacity. The Cambridge site is a 70,000 square foot facility that contains 10,000 (5 x 2,000) liters of bioreactor capacity. We also have a large-scale biologics manufacturing facility in Hillerød, Denmark which contains 90,000 liters of bioreactor capacity and, based on our current global manufacturing strategy, is expected to begin commercial operations in 2013, upon completion of the facility's validation activities. In December 2012, we entered into an arrangement with Eisai, Inc. to lease a portion of their facility in RTP to manufacture our and Eisai's oral solid dose products and for Eisai to provide us with vial-filling services for biologic therapies and packaging services for oral solid dose products. We also utilize an outsourced network to manufacture our small molecule products.

We currently manufacture AVONEX drug substance at our RTP and Cambridge facilities and TYSABRI drug substance at our RTP facility, and plan to also manufacture TYSABRI drug substance in our Hillerød facility in 2013. Genentech is responsible for all worldwide manufacturing activities for bulk RITUXAN and has sourced the manufacture of certain bulk RITUXAN requirements to a third party. Acorda Therapeutics supplies FAMPYRA to us pursuant to its supply agreement with Alkermes, Inc. We use third parties to manufacture the active pharmaceutical ingredient and the final product for FUMADERM.

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. We have internal label and pack capability for clinical and commercial products at our Cambridge and Hillerød facilities. Raw materials and supplies required for the production of AVONEX, TYSABRI, FAMPYRA and FUMADERM are procured from various suppliers in quantities adequate to meet our needs. Continuity of supply of raw materials is assured using a strategy of dual sourcing where possible or by a risk-based inventory strategy. Our third party service providers, suppliers and manufacturers may be subject to routine cGMP inspections by the FDA or comparable agencies in other jurisdictions and undergo assessment and certification by our quality management group.

We believe that our manufacturing facilities represent sufficient capacity for our own growing pipeline of products, as well as the products of potential partners. In February 2012, we finalized an agreement with Samsung Biologics that established an entity based in Korea to develop, manufacture and market biosimilars. Samsung will take a leading role in the entity, which has contracted with us for technical development services and biologics manufacturing.

Important factors that could adversely affect our manufacturing operations are discussed in the “Risk Factors” section of this report.

Our Employees

As of December 31, 2012, we had approximately 5,950 employees worldwide.

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Our Executive Officers (as of February 5, 2013)

George A. Scangos, Ph.D., 64, is our Chief Executive Officer and has served in this position since July 2010. From 1996 to July 2010, Dr. Scangos served as President and Chief Executive Officer of Exelixis, Inc., a drug discovery and development company, where he continues to serve on the board. From 1993 to 1996, Dr. Scangos served as President of Bayer Biotechnology, where he was responsible for research, business development, process development, manufacturing, engineering and quality assurance of Bayer's biological products. Before joining Bayer in 1987, Dr. Scangos was a Professor of Biology at Johns Hopkins University for six years. Dr. Scangos served as non-executive Chairman of Anadys Pharmaceuticals, Inc., a biopharmaceutical company, from 2005 to July 2010 and was a director of the company from 2003 to July 2010. Dr. Scangos served as the Chair of the California Healthcare Institute in 2010 and was a member of the Board of the Global Alliance for TB Drug Developments until 2010. He is also a member of the Board of Visitors of the University of California, San Francisco School of Pharmacy, and the National Board of Visitors of the University of California, Davis School of Medicine. He is currently an Adjunct Professor of Biology at Johns Hopkins. Dr. Scangos received his B.A. in Biology from Cornell University and Ph.D. in Microbiology from the University of Massachusetts, and was a Jane Coffin Childs Post-Doctoral Fellow at Yale University.

Susan H. Alexander, 56, is our Executive Vice President, Chief Legal Officer and Corporate Secretary and has served in these positions since January 2006. From 2003 to January 2006, Ms. Alexander served as the Senior Vice President, General Counsel and Corporate Secretary of PAREXEL International Corporation, a biopharmaceutical services company. From 2001 to 2003, Ms. Alexander served as General Counsel of IONA Technologies, a software company. From 1995 to 2001, Ms. Alexander served as Counsel at Cabot Corporation, a specialty chemicals and performance materials company. Prior to that, Ms. Alexander was a partner at the law firms of Hinckley, Allen & Snyder and Fine & Ambrogne.

Paul J. Clancy, 51, is our Executive Vice President, Finance and Chief Financial Officer and has served in these positions since August 2007. Mr. Clancy joined Biogen, Inc. in 2001 and has held several senior executive positions with us, 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 that, he spent 13 years at PepsiCo, a food and beverage company, serving in a range of financial and general management positions. Mr. Clancy received his B.S. in Finance from Babson College and M.B.A. from Columbia University.

Gregory F. Covino, 47, is our Vice President, Finance and Chief Accounting Officer and has served in this position since April 2012. Prior to that, Mr. Covino served at Boston Scientific Corporation, a medical device company, as Vice President, Corporate Analysis and Control since March 2010, having responsibility for the company's internal audit function, and as Vice President, Finance, International from February 2008 to March 2010, having responsibility for the financial activities of the company's international division. Prior to that, Mr. Covino held several finance positions at Hubbell Incorporated, an electrical products company, including Vice President, Chief Accounting Officer and Controller from 2002 to January 2008, Interim Chief Financial Officer from 2004 to 2005, and Director, Corporate Accounting from 1999 to 2002.

John G. Cox, 50, is our Executive Vice President, Pharmaceutical Operations and Technology and has served in this position since June 2010. Mr. Cox joined Biogen, Inc. in 2003 and has held several senior executive positions with us, including Senior Vice President of Technical Operations, Senior Vice President of Global Manufacturing, and Vice President of Manufacturing and General Manager of Biogen Idec's operations in RTP. Prior to that, Mr. Cox held a number of senior operational roles at Diosynth, a life sciences manufacturing and services company, where he worked in technology transfer, validation and purification. Prior to that, Mr. Cox focused on the same areas at Wyeth Corporation, a life sciences company, from 1993 to 2000. Mr. Cox received his M.B.A. from the University of Michigan and M.S. in Cell Biology from California State University.

Kenneth Di Pietro, 54, is our Executive Vice President, Human Resources and has served in this position since January 2012. Mr. Di Pietro joined Biogen Idec from Lenovo Group, a technology company, where he served as Senior Vice President, Human Resources from 2005 to June 2011. From 2003 to 2005, he served as Corporate Vice President, Human Resources at Microsoft Corporation, a technology company. From 1999 to 2002, Mr. Di Pietro

worked as Vice President, Human Resources at Dell Inc., a technology company. Prior to that, he spent 17 years at PepsiCo, a food and beverage company, serving in a range of human resource and general management positions. Mr. Di Pietro received his B.S. in Industrial and Labor Relations from Cornell University.

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Steven H. Holtzman, 58, is our Executive Vice President, Corporate Development and has served in this position since January 2011. Prior to that, Mr. Holtzman was a founder of Infinity Pharmaceuticals, Inc., a drug discovery and development company, where he served as Chair of the Board of Directors from company inception in 2001 to November 2012, Executive Chair of the Board of Directors in 2010 and as Chief Executive Officer from 2001 to December 2009. From 1994 to 2001, Mr. Holtzman was Chief Business Officer at Millennium Pharmaceuticals Inc., a biopharmaceutical company. From 1986 to 1994, he was a founder, member of the Board of Directors and Executive Vice President of DNX Corporation, a biotechnology company. From 1996 to 2001, Mr. Holtzman served as presidential appointee to the national Bioethics Advisory Commission. Mr. Holtzman received his B.A. from Michigan State University and B.Phil. graduate degree from Oxford University which he attended as a Rhodes Scholar.

Tony Kingsley, 49, is our Executive Vice President, Global Commercial Operations and has served in this position since November 2011. From January 2010 to November 2011, Mr. Kingsley served as our Senior Vice President, U.S. Commercial Operations. Prior to that, he served as Senior Vice President and General Manager of the Gynecological Surgical Products business at Hologic, Inc., a provider of diagnostic and surgical products, from October 2007 to November 2009, and as Division President, Diagnostic Products at Cytyc Corp., a provider of diagnostic and medical device products, from July 2006 to October 2007. In those roles, Mr. Kingsley ran commercial, manufacturing and research and development functions. From 1991 to 2006, he was a Partner at McKinsey & Company focusing on the biotechnology, pharmaceutical and medical device industries. Mr. Kingsley received his B.A. in Government from Dartmouth College and M.B.A. from Harvard Graduate School of Business Administration.

Ray Pawlicki, 52, is our Senior Vice President and Chief Information Officer and has served in this position since September 2008. From 2004 to September 2008, Mr. Pawlicki served as the Chief Information Officer of Novartis Pharmaceuticals, a pharmaceutical company. From 2000 to 2004, he served as Vice President and Chief Information Officer for the U.S. affiliate of Novartis Pharmaceuticals. Prior to that, Mr. Pawlicki held several positions of increasing responsibility with PepsiCo, a food and beverage company, and CitiGroup Inc., a financial services company, where he focused on innovative uses of technology to help drive the business. Mr. Pawlicki received his B.S. in Computer Science from Montclair State University.

Douglas E. Williams, Ph.D., 54, is our Executive Vice President, Research and Development and has served in this position since January 2011. Prior to that, Dr. Williams held several senior executive positions at ZymoGenetics Inc., a biopharmaceutical company, including Chief Executive Officer and a director from January 2009 to October 2010, President and Chief Scientific Officer from July 2007 to January 2009, and Executive Vice President, Research and Development and Chief Scientific Officer from 2004 to July 2007. Prior to that, he held leadership positions within the biotechnology industry, including Chief Scientific Officer and Executive Vice President of Research and Development at Seattle Genetics Inc., a biotechnology company, from 2003 to 2004, and Senior Vice President and Washington Site Leader at Amgen Inc., a biotechnology company, in 2002. Dr. Williams also served in a series of scientific and senior leadership positions over a decade at Immunex Corp., a biopharmaceutical company, including Executive Vice President and Chief Technology Officer, Senior Vice President of Discovery Research, Vice President of Research and Development and as a director. Prior to that, Dr. Williams served on the faculty of the Indiana University School of Medicine and the Department of Laboratory Medicine at the Roswell Park Memorial Institute in Buffalo, New York.

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Item 1A. Risk Factors

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

Our current and future revenues depend upon continued sales of our three principal products, AVONEX, TYSABRI and RITUXAN, which represented substantially all of our total revenues during 2012. Although we have developed and continue to develop additional products for commercial introduction, we may be substantially dependent on sales from these three products for many years. Any negative developments relating to any of these products, such as safety or efficacy issues, the introduction or greater acceptance of competing products, including biosimilars, or adverse regulatory or legislative developments, may reduce our revenues and adversely affect our results of operations. We and our competitors are introducing additional multiple sclerosis products in an increasingly crowded market and if they have a similar or more attractive profile in terms of efficacy, convenience or safety, future sales of AVONEX, TYSABRI or both could be adversely affected.

TYSABRI's sales growth is important to our success.

We expect that our revenue growth over the next several years will be dependent in part upon sales of TYSABRI. If we are not successful in growing sales of TYSABRI, our future business plans, revenue growth and results of operations may be adversely affected.

TYSABRI's sales growth cannot be certain given the significant restrictions on use and the significant safety warnings in the label, including the risk of developing progressive multifocal leukoencephalopathy (PML), a serious brain infection. The risk of developing PML increases with prior immunosuppressant use, which may cause patients who have previously received immunosuppressants or their physicians to refrain from using or prescribing TYSABRI. The risk of developing PML also increases with longer treatment duration, which may cause prescribing physicians or patients to suspend treatment with TYSABRI. The risk of developing PML also increases with exposure to JC virus, which may be indicated by the presence of anti-JCV antibodies. Patients testing positive for anti-JCV antibodies or their physicians may refrain from using or prescribing TYSABRI. Increased incidences of PML could limit sales growth, prompt regulatory review, require significant changes to the label or result in market withdrawal. Additional regulatory restrictions on the use of TYSABRI or safety-related label changes, including enhanced risk management programs, whether as a result of additional cases of PML, changes to the criteria for confirming PML diagnosis or otherwise, may significantly reduce expected revenues and require significant expense and management time to address the associated legal and regulatory issues.

As we continue to research and develop protocols and therapies intended to reduce risk and improve outcomes of PML in patients, regulatory authorities may not agree with our perspective on such protocols and therapies. Our efforts at stratifying patients into groups with lower or higher risk for developing PML may not result in corresponding changes to the TYSABRI label. Furthermore, our risk stratification efforts may have an adverse impact on prescribing behavior and reduce sales of TYSABRI. The potential utility of the JC virus antibody assay as a risk stratification tool may be diminished as a result of both the assay's false negative rate as well as the possibility that a patient who initially tests negative for the JC virus antibody may acquire the JC virus after testing. An increase in the recommended frequency of retesting with the assay or in the assay's sensitivity may exacerbate these risks or otherwise adversely impact prescribing behavior. In addition, new data may challenge the assumptions or estimates underlying our risk stratification tools, including estimates of the prevalence of JC virus in the general population.

We may be unable to successfully commercialize new product candidates.

We have filed or are preparing to file applications for marketing approval for multiple product candidates. These late-stage product candidates will impact our prospects for additional revenue growth and will require significant pre-launch investments that may not be recovered if they do not receive marketing approval.

Our ability to successfully commercialize a product candidate that does receive marketing approval depends on a number of factors, including the medical community's acceptance of the product, the effectiveness of our sales force and marketing efforts, the size of the patient population and our ability to identify new patients, pricing and the extent of reimbursement from third party payors, the ability to obtain and maintain data or market exclusivity for our products in the relevant indication(s), the availability or introduction of competing treatments that are deemed more effective, safer, more convenient, or less expensive, manufacturing the product in a timely and cost-effective manner, and compliance with complex regulatory requirements.

We have filed applications for marketing approval for TECFIDERA, our investigational oral compound for the treatment of relapsing MS, based on positive results from two pivotal trials. In addition to the risks described above and throughout these “Risk Factors,” other factors that may prevent us from successfully commercializing TECFIDERA, if approved, include:

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- there is intense competition in the increasingly crowded MS market, including the possibility of future competition from generic versions of TECFIDERA or related prodrug derivatives;
- we largely rely on third parties to manufacture TECFIDERA and these third parties may not supply TECFIDERA in a timely and cost-effective manner or in compliance with applicable regulations; and
- our sales and marketing efforts may not result in product revenues that meet the investment community's high expectations for TECFIDERA.

In addition, we have filed or are preparing to file applications for marketing approval for our long-lasting blood clotting factor candidates for the treatment of hemophilia. In addition to the risks described above and throughout these "Risk Factors," other factors that may prevent us from successfully commercializing our long-lasting blood clotting factor candidates, if approved, include:

- the hemophilia treatment market is highly competitive, with current treatments marketed by companies that have substantially greater financial resources and marketing expertise, and we may have difficulty penetrating this highly competitive market unless our long-lasting blood clotting factor candidates are regarded as offering substantial benefits over current treatments;
- we do not have marketing experience within the hemophilia treatment market or well-established relationships with the associated medical and scientific community; and
- several companies are working to develop additional treatments for hemophilia and may file for or obtain marketing approval of their treatments before we do or may introduce longer-lasting or more efficacious, safer, cheaper or more convenient treatments than our long-lasting blood clotting factor candidates.

Our long-term success depends upon the successful development of other product candidates.

Our long-term viability and growth will depend upon the successful development of new products from our research and development activities, including products licensed from third parties. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. 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 Practices. We have opened clinical sites and are enrolling patients in a number of countries where our experience is more limited, and we are in most cases using the services of third party clinical trial providers. If we fail to adequately manage the design, execution and 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. Clinical trials may indicate that our product candidates have harmful side effects or raise other safety concerns that may significantly reduce the likelihood of regulatory approval, result in significant restrictions on use and safety warnings in any approved label, adversely affect placement within the treatment paradigm, or otherwise significantly diminish the commercial potential of the product candidate. Also, positive results in a registrational trial may not be replicated in any subsequent confirmatory trials. Even if later stage clinical trials are successful, regulatory authorities may disagree with our view of the data or require additional studies, and may fail to approve or delay approval of our product candidates or may grant marketing approval that is more restricted than anticipated, including indications for a narrower patient population than expected and the imposition of safety monitoring or educational requirements or risk evaluation and mitigation strategies. In addition, if another company is the first to file for marketing approval of a competing orphan drug candidate, that company may ultimately receive marketing exclusivity for its drug candidate, preventing us from commercializing our orphan drug candidate in the applicable market for several years.

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 and in the product pipeline, greater financial and other resources and other technological or competitive advantages. One or more of our competitors may benefit from significantly

greater sales and marketing capabilities, may develop products that are accepted more widely than ours and may receive patent protection that dominates, blocks or adversely affects our product development or business. In addition, healthcare reform legislation enacted in the U.S. in 2010 has created a pathway for the U.S. Food and Drug Administration (FDA) to approve biosimilars, which could compete on price and differentiation with products that we now or could in the future market. The introduction by our

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competitors of more efficacious, safer, cheaper, or more convenient alternatives to our products could reduce our revenues and the value of our product development efforts.

Adverse safety events can negatively affect our business and stock price.

Adverse safety events involving our marketed products may have a negative impact on our commercialization efforts. Discovery of safety issues with our products 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 material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations. Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products and public rumors about such events could cause our product sales or stock price to decline or experience periods of volatility.

We depend, to a significant extent, on reimbursement from third party payors and a reduction in the extent of reimbursement could reduce 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 addition, 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.

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. The 2010 Patient Protection and Affordable Care Act encourages the development of comparative effectiveness research and any adverse findings for our products from such research may reduce the extent of reimbursement for our products. In addition, the Budget Control Act of 2011 mandates, among other things, reductions in Medicare payment rates if a sufficient deficit reduction plan is not approved, and a reduction in funding for Medicare, Medicaid or similar government programs may adversely affect our future results. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. In recent years, some states have considered legislation that would control the prices of drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. 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.

In the European Union 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. Many countries are reducing their public expenditures and we expect to see strong efforts to reduce healthcare costs in our international markets, including patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases, and greater importation of drugs from lower-cost countries to higher-cost countries. These cost control measures likely would reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the marketing of our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third party cross border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

Adverse market and economic conditions may exacerbate certain risks affecting our business.

Sales of our products are dependent on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. These organizations may reduce the extent of reimbursements, increase their scrutiny of claims, delay payment or be unable to satisfy their reimbursement obligations due to deteriorating global economic conditions, uncertainty about the direction and relative strength of the U.S. economy and resolution of the U.S. budget deficit, the growing European financial crisis, volatility in the credit and financial markets, and other disruptions due to natural disasters, political instability or otherwise.

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The European market represents a major part of our business - approximately 39% of our 2012 product revenues were derived from Europe and most of our marketing efforts outside the U.S. are focused on Europe. Thus, the deterioration of the credit and economic conditions in certain European countries may have a significant adverse impact on our results of operations. Our accounts receivable in certain European countries are subject to significant payment delays due to government funding and reimbursement practices. European governments have announced or implemented austerity measures to constrain the overall level of government expenditures, including reforming health care coverage and reducing health care costs. These measures continue to exert pressure on product pricing and may encourage higher levels of third party cross border trade.

These adverse market and economic conditions could reduce our product sales and revenues, result in additional allowances or significant bad debts, or cause us to recognize revenue in certain countries on a cash basis.

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

We have a number of collaborators and partners, and have both in-licensed and out-licensed several products and programs. In addition to the factors described throughout these “Risk Factors,” these collaborations are subject to several other risks, including:

- Our RITUXAN revenues are dependent on the efforts of Genentech and the Roche Group. Their interests may not always be aligned with our interests and they may not market RITUXAN in the same manner or to the same extent that we would, which could adversely affect our RITUXAN revenues.
- Under our collaboration agreement with Genentech, the successful development and commercialization of GA101 and certain other anti-CD20 products will decrease our percentage of the collaboration's co-promotion profits.
- Any failure on the part of our collaborators to comply with applicable laws and regulatory requirements in the sale, marketing and maintenance of the market authorization of our products or to fulfill any responsibilities they may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings.
- 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 could adversely affect the clinical development or regulatory approvals of products under joint control.

In addition, we rely on third parties for several other aspects of our business. As a sponsor of clinical trials of our products, we rely on third party contract research organizations to carry out most of our clinical trial related activities and accurately report their results. These activities include initiating and monitoring the conduct of studies at clinical trial sites and identifying any noncompliance with the study protocol or current Good Clinical Practices. The failure of a contract research organization to conduct these activities with proper vigilance and competence and in accordance with current Good Clinical Practices can result in regulatory authorities rejecting our clinical trial data or, in some circumstances, the imposition of civil or criminal sanctions against us.

Manufacturing issues could substantially increase our costs and limit supply of our products.

The process of manufacturing our products is complex, highly regulated and subject to several risks:

- The process of manufacturing biologics, such as AVONEX, TYSABRI and RITUXAN, is extremely susceptible to product loss due to contamination, oxidation, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant.
- We rely on third party suppliers and manufacturers for, among other things, RITUXAN manufacturing, the majority of our clinical and commercial requirements for small molecule product candidates such as TECFIDERA, our fill-finish operations, the majority of our final product storage, and a substantial portion of our packaging operations. In addition, due to the unique manner in which our products are manufactured, we rely on single source providers of several raw materials and manufacturing supplies. These third parties are independent entities subject to their own unique operational and financial risks that are outside of our control. These third parties may not perform their obligations in a timely and cost-effective manner or in compliance with applicable regulations, and they may be

unable or unwilling to increase production capacity commensurate with demand for our existing or future products. Finding alternative providers could take a significant amount of time and involve significant expense due to the specialized nature of the services and the

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need to obtain regulatory approval of any significant changes to our suppliers or manufacturing methods. We cannot be certain that we could reach agreement with alternative providers or that the FDA or other regulatory authorities would approve our use of such alternatives.

- We rely on our manufacturing facility in Research Triangle Park, North Carolina for the production of TYSABRI. Our global bulk supply of TYSABRI depends on the uninterrupted and efficient operation of this facility, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. If we are unable to meet demand for TYSABRI for any reason, we would need to rely on a limited number of qualified third party contract manufacturers.
- We and our third party providers are generally required to maintain compliance with current Good Manufacturing Practices and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. 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. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

Any adverse developments affecting our manufacturing operations or the operations of our third-party suppliers and manufacturers may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the commercial supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish our profitability or damage our reputation.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care 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 U.S. and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place greater restrictions on the marketing practices of health care companies. Healthcare companies are facing heightened scrutiny of their relationships with healthcare providers from anti-corruption enforcement officials. In addition, 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 health care business, submission of false claims for government reimbursement, antitrust violations, or violations related to environmental matters. These risks may be heightened as we continue to expand our global operations and introduce additional products to the market.

Regulations governing the health care industry are subject to change, with possibly retroactive effect, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for health care products and services, compliance with data privacy laws and regulations, tracking payments and other transfers of value made to physicians and teaching hospitals, and extensive anti-bribery and anti-corruption prohibitions;
- 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; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise

adversely affect the market for our products.

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Examples of previously enacted and possible future changes in laws that could adversely affect our business include the enactment in the U.S. of health care reform, potential regulations easing the entry of competing biosimilars in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and enhanced penalties for and investigations into non-compliance with U.S. fraud and abuse laws.

Violations of governmental regulation may be punishable by criminal and civil sanctions against us, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. 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 are unable to adequately protect and enforce our intellectual property and other proprietary rights, our competitors may take advantage of our development efforts or our acquired technology.

We have filed numerous patent applications in the U.S. and various other countries seeking protection of the processes, products and other inventions originating from our research and development. 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 drug and biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. 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, court decisions or patent office regulations that place additional restrictions on patent claim scope or that facilitate patent challenges could also reduce our ability to protect our intellectual property rights. If we cannot prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect.

Our products may qualify for regulatory data protection, which provides to the holder of a marketing authorization, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it compiled at significant cost and submitted to the applicable regulatory authority to obtain approval of its product. Our products also may qualify for market protection from regulatory authorities, pursuant to which a regulatory authority may not permit, for a set period of time, the approval or commercialization of another product containing the same active ingredient(s) as our product. After the set period of time, third parties are then permitted to rely upon our data to obtain approval of their abbreviated applications to market generic drugs and biosimilars. Although the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS) requires signatory countries to provide regulatory data protection to innovative pharmaceutical products, implementation and enforcement varies widely from country to country and we may not experience the extent or duration of data protection that we expect in each of the markets for our products.

Our drugs and biologics are susceptible to competition from generics and biosimilars in many markets. The legal and regulatory pathways leading to approval of generics and biosimilars vary widely from country to country and are in a state of rapid flux. Manufacturers of generics and biosimilars may choose to launch or attempt to launch their products before the expiration of patent or regulatory data or market protection and to concurrently challenge the patent and regulatory protections covering our products. In the U.S., a high proportion of all approved innovative drugs are met with generic challenge as early as four years following approval. Generic versions of drugs and biosimilars are likely to be sold at substantially lower prices than branded products because the generic or biosimilar manufacturer would not have to recoup the research and development and marketing costs associated with the branded product. Accordingly, the introduction of generic or biosimilar versions of our marketed products likely would significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may have an adverse impact on our results of operations.

We also rely upon unpatented proprietary and confidential information and technology in the research, development and manufacture of our products. We cannot ensure that others will not independently develop substantially equivalent information and technology or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect such rights. We protect such information principally through confidentiality agreements with our employees, consultants, outside scientific collaborators, scientists whose research we sponsor and other advisers. These agreements may not provide meaningful protection or adequate remedies for our unpatented confidential information in the event of use or disclosure of such information.

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Uncertainty over intellectual property in the biotechnology industry has been the source of litigation and other disputes, 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 U.S. and in other countries claiming subject matter potentially useful to our business. Some of those patents and patent applications claim only specific products or methods of making such products, while others claim more general processes or techniques useful or now used in the biotechnology industry. There is considerable uncertainty within our industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world, and, to date, the law and practice remains in substantial flux both in the agencies that grant patents and in the courts. 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, services or technologies.

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, arbitrations, administrative proceedings and other legal actions with private parties and governmental authorities 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 non-infringement 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, hinder our ability to manufacture and market our products, or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements.

To the extent that valid present or future third party patent or other intellectual property rights cover our products, services or technologies, we or our strategic collaborators may seek licenses or other agreements from the holders of such rights in order to avoid or settle legal claims. Such licenses may not be available on acceptable terms, which may hinder our ability to manufacture and market our products and services. Payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

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:

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- fluctuations in currency exchange rates;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the emergence of far-reaching anti-bribery and anti-corruption legislation in the U.K., including passage of the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- restrictions on direct investments by foreign entities and trade restrictions;
- greater political or economic instability; and
- changes in tax laws and tariffs.

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In addition, our international operations are subject to regulation under U.S. law. For example, the Foreign Corrupt Practices Act 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 health care professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act. 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 or withdrawal of an approved product from the market, the imposition of civil or criminal sanctions and the prosecution of executives overseeing our international operations.

Our business may be adversely affected if we do not manage our current growth and do not successfully execute our growth initiatives.

We have experienced growth in our headcount and operations, which has placed, and will continue to place, significant demands on our management and our operational and financial infrastructure. We anticipate further growing through both internal development projects as well as external opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. The availability of high quality development opportunities is limited and we are not certain that we will be able to identify candidates that we and our shareholders consider suitable or complete transactions on terms that are acceptable to us and our shareholders. 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. 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.

To effectively manage our current and future potential growth, we will need to continue to enhance our operational, financial and management processes and to effectively expand, train and manage our employee base. Supporting our growth initiatives will require significant capital expenditures and management resources, including investments in research and development, sales and marketing, manufacturing and other areas of our business. If we do not successfully manage our current growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely affected and we may incur asset impairment or restructuring charges.

Our investments in properties, including our manufacturing facilities, may not be fully realizable.

We own or lease real estate primarily consisting of buildings that contain research laboratories, office space, and biologic manufacturing operations. For strategic or other operational reasons, we may decide to further consolidate or co-locate certain aspects of our business operations or dispose of one or more of our properties, some of which may be located in markets that are experiencing high vacancy rates and decreasing property values. If we determine that the fair value of any of our owned properties, including any properties we may classify as held for sale, is lower than their book value we may not realize the full investment in these properties and incur significant impairment charges. If we decide to fully or partially vacate a leased property, we may incur significant cost, including lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements. In addition, we may not fully utilize our manufacturing facilities, resulting in idle time at facilities or substantial excess manufacturing capacity, due to reduced expectations of product demand, improved yields on production and other factors. Any of these events may have an adverse impact on our results of operations.

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

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 places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Our effective tax rate, however, may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability from country to country, the results of audits of our tax filings, 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.

In addition, our inability to secure or sustain acceptable arrangements with tax authorities and previously enacted or future changes in the tax laws, among other things, may result in tax obligations in excess of amounts accrued in our financial statements.

In the U.S., there are several proposals under consideration to reform tax law, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, scrutinize certain transfer pricing structures, and reduce or eliminate certain foreign tax credits. Our future reported financial results may be adversely affected by tax law changes which restrict or eliminate certain foreign tax credits or our ability to deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

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The growth of our business depends on our ability to attract and retain qualified personnel and to develop and maintain key relationships.

The achievement of our commercial, research and development and external growth objectives depends upon our ability to attract and retain qualified scientific, manufacturing, sales and marketing and executive personnel and to develop and maintain relationships with qualified clinical researchers and key distributors. Competition for these people and relationships is intense and comes from a variety of sources, including pharmaceutical and biotechnology companies, universities and non-profit research organizations.

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 if in excess of our insurance coverage. 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.

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. We have recorded, or may be required to record, charges that include:

- the cost of restructurings;
- impairments with respect to investments, fixed assets, and in-process research and development and other long-lived assets;
- inventory write-downs for failed quality specifications, charges for excess or obsolete inventory and charges for inventory write downs relating to product suspensions;
- bad debt expenses and increased bad debt reserves;
- milestone payments under license and collaboration agreements; and
- payments in connection with acquisitions and other business development activity.

Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. We recognize foreign currency gains or losses arising from our operations in the period in which we incur those gains or losses. 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, currency fluctuations among our reporting currency, the U.S. dollar, and the currencies in which we do business will affect our operating results, often in unpredictable ways. Our net income may also 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 than expected charges from hedge ineffectiveness 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.

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

We maintain a significant portfolio of marketable securities. Changes in the value of this portfolio could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities 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 other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment

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portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks by investing in high quality securities and continuously monitoring our portfolio's overall risk profile, the value of our investments may nevertheless decline.

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. 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. 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.

Provisions in our most significant collaboration agreements may discourage a third party from attempting to acquire us.

Provisions in our collaboration agreements with Elan and Genentech might discourage a takeover attempt that could be viewed as beneficial to shareholders who wish to receive a premium for their shares from a potential bidder. Our collaboration agreements with Elan and Genentech respectively allow Elan to purchase our rights to TYSABRI and Genentech to purchase our rights to RITUXAN and certain anti-CD20 products developed under the agreement if we undergo a change of control and certain other conditions are met, which may limit our attractiveness to potential acquirers.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Below is a summary of our owned and leased properties as of December 31, 2012.

Massachusetts

In Cambridge, we own approximately 508,000 square feet of real estate space, consisting of a building that houses a research laboratory, office space and a cogeneration plant totaling approximately 263,000 square feet and a building that contains research, development and quality laboratories which total approximately 245,000 square feet.

In July 2011, we executed leases for two office buildings currently under construction in Cambridge, with a planned occupancy during the second half of 2013. Construction of these facilities began in late 2011. These buildings, totaling approximately 500,000 square feet, will serve as the future location of our corporate headquarters and will provide additional general and administrative and research and development office space.

In addition, we currently lease a total of approximately 648,000 square feet in Massachusetts, which is summarized as follows:

- 357,000 square feet of office space housing our corporate headquarters in Weston, which we expect will be reduced once we relocate our corporate headquarters to Cambridge;
- 220,000 square feet in Cambridge, which is comprised of a 67,000 square foot biologics manufacturing facility and office space of 153,000 square feet;
- 25,000 square feet of office and laboratory space in Waltham covered by a lease that will expire in 2013; and
- 46,000 square feet of warehouse space in Somerville.

Our Massachusetts lease agreements expire at various dates through the year 2028.

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North Carolina

We manufacture bulk AVONEX, TYSABRI and other products in our pipeline at our facilities located in Research Triangle Park, North Carolina, where we own approximately 740,000 square feet of real estate space, which is summarized as follows:

- 357,000 square feet of laboratory and office space;
- 175,000 square feet related to a large-scale biologics manufacturing facility;
- 105,000 square feet related to a biologics manufacturing facility;
- 60,000 square feet of warehouse space; and
- 43,000 square feet related to a large-scale purification facility.

In addition, we leased approximately 50,000 square feet of office space in Durham, North Carolina, which expired December 31, 2012.

Denmark

We own approximately 60 acres of land in Hillerød, Denmark, upon which we have completed construction of a large-scale biologics manufacturing facility totaling approximately 225,000 square feet. We began the process of manufacturing clinical products for sale to third parties during 2012. The facility is currently not licensed to produce commercial product, a process we expect to be completed in 2013.

We also own approximately 310,000 square feet of additional space, which is currently in use at this location and is summarized as follows:

- 140,000 square feet of warehouse, utilities and support space;
- 70,000 square feet related to a label and packaging facility;
- 50,000 square feet of administrative space; and
- 50,000 square feet related to a laboratory facility.

Other International

We lease office and laboratory space in Zug, Switzerland, our international headquarters, the United Kingdom, Germany, France, Denmark, and numerous other countries. Our international lease agreements expire at various dates through the year 2023.

Item 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2012, please read Note 22, Litigation to our consolidated financial statements included in this report, which is incorporated into this item by reference.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market and Stockholder 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, 2012 and 2011:

	Common Stock Price			
	2012		2011	
	High	Low	High	Low
First Quarter	$127.85	$111.44	$73.53	$64.28
Second Quarter	$144.38	$124.23	$109.63	$72.70
Third Quarter	$157.18	$137.88	$109.14	$83.83
Fourth Quarter	$155.30	$134.00	$120.66	$87.72

As of January 31, 2013, there were approximately 901 stockholders of record of our common stock.

In addition, as of January 31, 2013, 82 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 in November 2003.

Dividends

We have not paid cash dividends since our inception. We do not anticipate paying any cash dividends in the near term.

Issuer Purchases of Equity Securities

The following table summarizes our common stock repurchase activity during the fourth quarter of 2012:

Period	Total Number of Shares Purchased (#)	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Programs (#)	Maximum Number of Shares That May Yet Be Purchased Under Our Programs ($ in millions)
Oct-12	—	—	—	6,326,521
Nov-12	155,400	138.64	155,400	6,171,121
Dec-12	—	—	—	6,171,121
Total	155,400	138.64		

On February 11, 2011, we announced that our Board of Directors authorized the repurchase of up to 20.0 million shares of common stock. This authorization does not have an expiration date. As of December 31, 2012, approximately 13.8 million shares of our common stock at a cost of $1,482.7 million have been repurchased under this authorization. In 2012, approximately 7.8 million shares were repurchased at a cost of $984.7 million. Approximately 6.2 million shares of our common stock remain available for repurchase under the 2011 authorization.

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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, 2007 with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

	2007	2008	2009	2010	2011	2012
Biogen Idec Inc.	100.00	83.68	94.02	117.83	193.42	257.27
NASDAQ Pharmaceutical	100.00	93.04	104.54	113.33	121.32	161.39
S&P 500 Index	100.00	63.01	79.67	91.67	93.61	108.59

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Item 6. Selected Consolidated Financial Data

BIOGEN IDEC INC. AND SUBSIDIARIES
SELECTED FINANCIAL DATA

	For the Years Ended December 31,				
(In millions, except per share amounts)	2012 (10) (11) (12)	2011 (7) (8) (9)	2010 (4) (5) (6)	2009 (2) (3)	2008 (1)
Results of Operations					
Product revenues	$4,166.1	$3,836.1	$3,470.1	$3,152.9	$2,839.7
Revenues from unconsolidated joint business	1,137.9	996.6	1,077.2	1,094.9	1,128.2
Other revenues	212.5	215.9	169.1	129.5	129.6
Total revenues	5,516.5	5,048.6	4,716.4	4,377.3	4,097.5
Cost and expenses:					
Cost of sales, excluding amortization of acquired intangible assets	545.5	466.8	400.3	382.1	402.0
Research and development	1,334.9	1,219.6	1,248.6	1,283.1	1,072.1
Selling, general and administrative	1,277.5	1,056.1	1,031.5	911.0	925.3
Collaboration profit sharing	317.9	317.8	258.1	215.9	136.0
Amortization of acquired intangible assets	202.2	208.6	208.9	289.8	332.7
Fair value adjustment of contingent consideration	27.2	36.1	—	—	—
Restructuring charge	2.2	19.0	75.2	—	—
Acquired in-process research and development	—	—	245.0	—	25.0
Facility impairments and gain on dispositions, net	—	—	—	—	(9.2)
Total cost and expenses	3,707.4	3,323.9	3,467.5	3,081.9	2,883.9
Gain on sale of rights	46.8	—	—	—	—
Income from operations	1,855.9	1,724.7	1,248.9	1,295.4	1,213.6
Other income (expense), net	(0.7)	(13.5)	(19.0)	37.3	(57.7)
Income before income tax expense and equity in loss of investee, net of tax	1,855.1	1,711.2	1,229.9	1,332.7	1,155.9
Income tax expense	470.6	444.5	331.3	355.6	365.8
Equity in loss of investee, net of tax	4.5	—	—	—	—
Net income	1,380.0	1,266.7	898.6	977.1	790.1
Net income (loss) attributable to noncontrolling interests, net of tax	—	32.3	(106.7)	6.9	6.9
Net income attributable to Biogen Idec Inc.	$1,380.0	$1,234.4	$1,005.3	$970.1	$783.2
Diluted Earnings Per Share					
Diluted earnings per share attributable to Biogen Idec Inc.	$5.76	$5.04	$3.94	$3.35	$2.65
Weighted-average shares used in calculating diluted earnings per share attributable to Biogen Idec Inc.	239.7	245.0	254.9	289.5	295.0
Financial Condition					
Cash, cash equivalents and marketable securities	$3,742.4	$3,107.4	$1,950.8	$2,457.8	$2,262.8

Total assets	$10,130.1	$9,049.6	$8,092.5	$8,551.9	$8,479.0
Notes payable, line of credit and other financing arrangements, less current portion	$687.4	$1,060.8	$1,066.4	$1,080.2	$1,085.4
Total Biogen Idec Inc. shareholders' equity	$6,961.5	$6,425.5	$5,396.5	$6,221.5	$5,806.1

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In addition to the following notes, the financial data included within the tables above should be read in conjunction with our consolidated financial statements and related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this report and our previously filed Forms 10-K.

(1) Included in total 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 Therapeutics pursuant to the terms of our acquisition of Conforma Therapeutics in 2006.

(2) Total cost and expenses in 2009 includes the $110.0 million upfront payment made to Acorda Therapeutics, Inc. pursuant to our June 30, 2009 collaboration and license agreement to develop and commercialize products containing fampridine in markets outside the U.S.

(3) Changes in tax law in certain state jurisdictions in which we operate and the resolution of multiple federal, state and foreign tax audits, including the effective settlement of several uncertain tax positions resulted in a $58.3 million reduction to our 2009 income tax expense.

(4) Included in total cost and expenses in 2010 is a charge to acquired in-process research and development of $40.0 million related to the achievement of a milestone by Biogen Idec Hemophilia, Inc. (formerly Syntonix Pharmaceuticals, Inc.).

(5) Included in total cost and expenses in 2010 is a charge to acquired in-process research and development of $205.0 million incurred in connection with the license agreement entered into with Knopp Neurosciences Inc. (Knopp), which we consolidated as we determined that we are the primary beneficiary of the entity. The $205.0 million charge was partially offset by an attribution of $145.0 million to the noncontrolling interest.

(6) Net income attributable to noncontrolling interest also includes a charge of $25.0 million related to the payment made in 2010 to Cardiokine Biopharma LLC pursuant to the termination of our lixivaptan collaboration.

(7) In the second quarter of 2011 our share of RITUXAN revenues from unconsolidated joint business was reduced by approximately $50.0 million to reflect our share of the approximately $125.0 million compensatory damages and interest that Genentech estimated might be awarded to Hoechst GmbH (Hoechst), in relation to Genentech's ongoing arbitration with Hoechst.

(8) Biogen Idec Inc.'s shareholders' equity in 2011 reflects a reduction in additional paid in capital and noncontrolling interests totaling $187.3 million resulting from our purchase of the noncontrolling interest in our joint venture investments in Biogen Dompé SRL and Biogen Dompé Switzerland GmbH.

(9) Included in total cost and expenses in 2011 is a charge to research and development expense of $36.8 million related to an upfront payment made in connection with our collaboration and license agreement entered into with Portola Pharmaceuticals, Inc.

(10) Included in total cost and expenses in 2012 are charges to research and development expense of $71.0 million related to upfront payments made in connection with our collaboration agreements entered into with Isis Pharmaceuticals, Inc.

(11) Gain on sale of rights of $46.8 million relates to the sale of all of our rights, including rights to royalties, related to BENLYSTA.

(12) Equity in loss of investee, net of tax relates to our agreement with Samsung BioLogics Co. Ltd. that established an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. We recognize our share of the results of operations related to our investment in Samsung Bioepis one quarter in arrears.

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes beginning on page F-1 of this report. Certain totals may not sum due to rounding.

Executive Summary

Introduction

Biogen Idec is a global biotechnology company focused on discovering, developing, manufacturing and marketing therapies for the treatment of multiple sclerosis and other autoimmune disorders, neurodegenerative diseases and hemophilia. We also collaborate on the development and commercialization of RITUXAN and anti-CD20 product candidates for the treatment of non-Hodgkin's lymphoma and other conditions.

In the near term, our current and future revenues are dependent upon continued sales of our three principal products, AVONEX, TYSABRI, and RITUXAN as well as the potential approval of TECFIDERA, Factor VIII and Factor IX. In the longer term, our revenue growth will be dependent upon the successful clinical development, regulatory approval and launch of new commercial products, our ability to obtain and maintain patents and other rights related to our marketed products and assets originating from our research and development efforts, and successful execution of external business development opportunities. As part of our on-going research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

Financial Highlights

The following table is a summary of financial results achieved:

(In millions, except per share amounts and percentages)	For the Years Ended December 31, 2012 (4) (5)	2011 (1) (2) (3)	% Change 2012 compared to 2011	
Total revenues	$5,516.5	$5,048.6	9.3	%
Income from operations	$1,855.8	$1,724.7	7.6	%
Net income attributable to Biogen Idec Inc.	$1,380.0	$1,234.4	11.8	%
Diluted earnings per share attributable to Biogen Idec Inc.	$5.76	$5.04	14.3	%

(1) Income from operations, as well as net income attributable to Biogen Idec Inc. for 2011, was reduced by a charge of $36.8 million to research and development expense incurred in connection with the collaboration and license agreement entered into with Portola Pharmaceuticals, Inc. in October 2011.

(2) In the second quarter of 2011 our share of RITUXAN revenues from unconsolidated joint business was reduced by approximately $50.0 million to reflect our share of the approximately $125.0 million compensatory damages and interest that Genentech estimated might be awarded to Hoechst GmbH (Hoechst), in relation to Genentech's ongoing arbitration with Hoechst.

(3) Income from operations, as well as net income attributable to Biogen Idec Inc., for 2011 was reduced by $19.0 million resulting from charges associated with our restructuring initiative announced in November 2010.

(4) Income from operations, as well as net income attributable to Biogen Idec Inc. for 2012, was reduced by charges totaling $71.0 million to research and development expense incurred in connection with our collaboration agreements entered into with Isis Pharmaceuticals, Inc. in January, June and December 2012.

(5) Income from operations, as well as net income attributable to Biogen Idec Inc. for 2012, includes $46.8 million from the sale of all of our rights, including rights to royalties, related to BENLYSTA.

As described below under "Results of Operations," our operating results for the year ended December 31, 2012, reflect the following:

- Worldwide AVONEX revenues totaled $2,913.1 million for 2012, representing an increase of 8.4% over 2011.
- Our share of TYSABRI revenues totaled $1,135.9 million for 2012, representing an increase of 5.2% over 2011.

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- Our share of RITUXAN revenues totaled $1,137.9 million for 2012, representing an increase of 14.2% from 2011.
- Total cost and expenses increased 11.5% for 2012 compared to 2011. This increase was primarily the result of a 16.9% increase in cost of sales, a 9.5% increase in research and development expense, and a 21.0% increase in selling, general and administrative costs over the same period in 2011. These increases reflect an increase in manufacturing costs driven by higher sales, spending associated with licensing and development of our early stage product candidates and preparing for the potential launches of TECFIDERA, Factor VIII and Factor IX.
- We generated $1,879.9 million of net cash flows from operations for 2012, which were primarily driven by earnings.
- Cash, cash equivalents and marketable securities totaled approximately $3,742.4 million as of December 31, 2012.

Business Environment

We conduct our business within the biotechnology and pharmaceutical industries, which are highly competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing, including oral and other alternative formulations that may compete with AVONEX, TYSABRI or other products we are developing. In addition, the commercialization of certain of our own pipeline product candidates, such as TECFIDERA, may negatively impact future sales of AVONEX, TYSABRI or both. We may also face increased competitive pressures from the emergence of biosimilars. In the U.S., AVONEX, TYSABRI, and RITUXAN are licensed under the Public Health Service Act (PHSA) as biological products. In March 2010, U.S. healthcare reform legislation amended the PHSA to authorize the U.S. Food and Drug Administration (FDA) to approve biological products, known as biosimilars, that are similar to or interchangeable with previously approved biological products based upon potentially abbreviated data packages.

Global economic conditions continue to present challenges for our industry. Governments in many international markets where we operate have announced or implemented austerity measures to constrain the overall level of government expenditures. These measures, which include efforts aimed at reforming health care coverage and reducing health care costs, particularly in certain countries in Europe, continue to exert pressure on product pricing, have delayed reimbursement for our products, and have negatively impacted our revenues and results of operations. For additional information about certain risks that could negatively impact our financial position or future results of operations, please read the “Risk Factors” section of this report.

The Affordable Care Act

On June 28, 2012, the United States Supreme Court upheld the constitutionality of the 2010 Patient Protection and Affordable Care Act’s mandate to purchase health insurance but rejected specific funding provisions that incentivized states to expand their current Medicaid programs. As a result of this ruling, we currently expect implementation of most of the major provisions of the Act to continue. Changes to the Affordable Care Act, or other federal legislation regarding health care access, financing, or delivery and other actions taken by individual states concerning the possible expansion of Medicaid could impact our financial position or results of operations.

The American Taxpayer Relief Act of 2012

The American Taxpayer Relief Act of 2012 (the “TRA”) was passed by the House of Representatives and the Senate on January 1, 2013, and was signed into law by the President on January 2, 2013. The TRA, among other things, extends through 2013 an array of temporary business and individual tax provisions and temporarily delayed the implementation of certain spending reductions (known as “sequestration”). We do not expect that the TRA will have a material impact on our financial position or results of operation.

During 2013 we expect Congress to again consider sequestration and other means of reducing government expenditures, as well as an increase to the government's borrowing authority. Proposals that have been raised to address government finances include changes to the Medicare program, including increases to Part D rebates or co-payments or reductions in premium subsidies, increases to the pharmaceutical fee, changes to the coverage gap and reductions in physician payments for Part B drugs. If enacted, these changes to current policy could have a material impact on our financial position or results of operations.

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Key Pipeline Developments

Peginterferon beta-1a

In January 2013, we released the primary efficacy analysis and safety data from our Phase 3 study, ADVANCE. Results support Peginterferon as a potential treatment dosed every two weeks or every four weeks for relapsing-remitting MS. The primary endpoint of ADVANCE, annualized relapse rate at one year, was met for both the two-week and four-week dosing regimens. Results showed that Peginterferon also met the secondary endpoints of risk of 12-week confirmed disability progression, proportion of patients who relapsed and magnetic resonance imaging assessments for both dose regimens. We plan to submit marketing applications for Peginterferon in the U.S. and E.U. by mid - 2013.

Dexpramipexole

At the end of December 2012, we learned that a Phase 3 trial investigating dexpramipexole in people with amyotrophic lateral sclerosis (ALS) did not meet its primary endpoint, a joint rank analysis of function and survival, and no efficacy was seen in the individual components of function or survival. The trial also failed to show efficacy in its key secondary endpoints. Based on these results, we have discontinued development of dexpramipexole in ALS.

Long-Lasting Recombinant Factors VIII and IX

In October 2012, we announced positive top-line results from the Phase 3 study, known as A-LONG, investigating our long-lasting recombinant Factor VIII-Fc fusion protein in hemophilia A, a rare inherited disorder which inhibits blood coagulation. We plan to submit a Biologics License Application to the FDA for Factor VIII in the first half of 2013. We submitted a Biologics License Application to the FDA for marketing approval of our long-lasting recombinant Factor IX-Fc fusion protein in hemophilia B, a rare inherited disorder which inhibits blood coagulation, during the fourth quarter of 2012. The regulatory submission was based on the positive top-line results from the Phase 3 study known as B-LONG.

Pediatric data will be required as part of the Marketing Authorization Applications for Factor VIII and Factor IX that we plan to submit to the EMA, and we have initiated two global pediatric studies of Factor VIII and Factor IX.

We collaborate with Swedish Orphan Biovitrum AB on the commercialization of Factor VIII and Factor IX. For information about this collaboration, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

TECFIDERA

In February 2012, we submitted a New Drug Application to the FDA for marketing approval of TECFIDERA, our oral small molecule candidate for the treatment of MS. The regulatory submission was based on TECFIDERA's comprehensive development program, in which TECFIDERA demonstrated significant reductions in MS disease activity coupled with favorable safety and tolerability in the Phase 3 DEFINE and CONFIRM studies. The FDA accepted our application for TECFIDERA and granted us a standard review timeline. In October 2012, we announced that the FDA extended the initial PDUFA date for its review of our application by three months, which is a standard extension period. The extended PDUFA target date is in late March 2013. The FDA has indicated that the extension of the PDUFA date is needed to allow additional time for review of our application. The agency has not asked for additional studies.

In March 2012, we submitted a Marketing Authorisation Application for TECFIDERA to the European Medicines Agency (EMA). The EMA has validated our application for review of TECFIDERA in the E.U. We have submitted additional regulatory applications for TECFIDERA in Australia, Canada and Switzerland.

We acquired TECFIDERA as part of our acquisition of Fumapharm AG in 2006. For more information about this acquisition and associated milestone obligations, please read the subsection entitled “Contractual Obligations and Off-Balance Sheet Arrangements – Contingent Consideration” subsection of this “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

AVONEX PEN and Dose Titration

In February 2012, the FDA approved two separate dosing innovations designed to improve the treatment experience for patients receiving once-a-week AVONEX for relapsing forms of MS: AVONEX PEN and a new dose titration regimen. AVONEX PEN is the first intramuscular autoinjector approved for MS and is designed to enhance the self-injection process for patients receiving AVONEX therapy. A new dose titration regimen, facilitated by the

AVOSTARTGRIP titration devices, provides patients with the option to gradually increase the dose of AVONEX at treatment initiation to reduce the incidence and severity of flu-like symptoms that patients may experience with therapy. These AVONEX dosing innovations are commercially available in the E.U., U.S. and other countries.

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Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2012	2011	2010	% Change 2012 compared to 2011	2011 compared to 2010
Product Revenues:					
United States	$2,176.8	$1,954.8	$1,744.4	11.4 %	12.1 %
Rest of world	1,989.3	1,881.3	1,725.7	5.7 %	9.0 %
Total product revenues	4,166.1	3,836.1	3,470.1	8.6 %	10.5 %
Unconsolidated joint business revenues	1,137.9	996.6	1,077.2	14.2 %	(7.5)%
Other revenues	212.5	215.9	169.1	(1.6)%	27.7 %
Total revenues	$5,516.5	$5,048.6	$4,716.4	9.3 %	7.0 %

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2012	2011	2010	% Change 2012 compared to 2011	2011 compared to 2010
AVONEX	$2,913.1	$2,686.6	$2,518.4	8.4 %	6.7 %
TYSABRI	1,135.9	1,079.5	900.2	5.2 %	19.9 %
Other product revenues	117.1	70.0	51.5	67.3 %	35.9 %
Total product revenues	$4,166.1	$3,836.1	$3,470.1	8.6 %	10.5 %

AVONEX

Revenues from AVONEX are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2012	2011	2010	% Change 2012 compared to 2011	2011 compared to 2010
United States	$1,793.7	$1,628.3	$1,491.6	10.2 %	9.2 %
Rest of world	1,119.4	1,058.3	1,026.8	5.8 %	3.1 %
Total AVONEX revenues	$2,913.1	$2,686.6	$2,518.4	8.4 %	6.7 %

For 2012 compared to 2011, as well as for 2011 compared to 2010, the increase in U.S. AVONEX revenues was due to price increases offset by decreased unit sales volume. U.S. AVONEX unit sales volume decreased approximately 2% and 3% for 2012 and 2011, respectively, over the prior year comparative periods.

For 2012 compared to 2011, as well as for 2011 compared to 2010, the increase in rest of world AVONEX revenues was due to increased demand primarily in Europe driven by customer penetration attributable to the AVONEX PEN launch, offset by pricing reductions resulting from austerity measures enacted in some countries. Rest of world AVONEX unit volume primarily in Europe increased 8% and 6% for 2012 and 2011, respectively, over the prior year comparative periods. The increase in rest of world AVONEX revenues for 2012 compared to 2011 also reflects gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program, which partially offset negative impacts of foreign currency as those gains were less than the impacts of foreign currency exchange rates on sales. The increase in rest of world AVONEX revenues for 2011 compared to 2010 also reflects the favorable impact of foreign currency exchange rates offset by losses recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program.

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Gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program totaled $25.4 million in 2012, compared to losses recognized of $30.6 million for 2011 and gains recognized of $35.0 million in 2010.

We expect AVONEX to continue facing increased competition in the MS marketplace in both the U.S. and rest of world. We and a number of other companies are working to develop or have commercialized additional treatments for MS, including oral and other alternative formulations that may compete with AVONEX. In addition, the continued growth of TYSABRI and the commercialization of certain of our own pipeline product candidates, such as TECFIDERA, may negatively impact future sales of AVONEX. Increased competition also may lead to reduced unit sales of AVONEX, as well as increasing price pressures particularly in geographic markets outside the U.S.

TYSABRI

We collaborate with Elan Pharma International, Ltd (Elan) an affiliate of Elan Corporation, plc, on the development and commercialization of TYSABRI. For additional information about this collaboration, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Revenues from TYSABRI are summarized as follows:

	For the Years Ended December 31,			% Change			
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011		2011 compared to 2010	
United States	$383.1	$326.5	$252.8	17.3	%	29.2	%
Rest of world	752.8	753.0	647.4	—	%	16.3	%
Total TYSABRI revenues	$1,135.9	$1,079.5	$900.2	5.2	%	19.9	%

For 2012 compared to 2011, as well as for 2011 compared to 2010, the increase in U.S. TYSABRI revenues was due to increased unit sales volume and price increases. U.S. TYSABRI unit sales volume increased approximately 11% and 12% for 2012 and 2011, respectively, over the prior year comparative periods. Net sales of TYSABRI from our collaboration partner, Elan, to third-party customers in the U.S. for 2012, 2011, and 2010 totaled $886.0 million, $746.5 million, and $593.1 million, respectively.

For 2012 compared to 2011, the change in rest of world TYSABRI revenues reflects the deferral of a portion of our revenues recognized on sales of TYSABRI in Italy (as described below) and pricing reductions from austerity measures enacted in some countries offset by an increase in demand. Increased demand resulted in increases of approximately 14% and 19% in rest of world TYSABRI unit sales volume for 2012 and 2011, respectively, over the prior year comparative periods. For 2011 compared to 2010, the increase in rest of world TYSABRI revenues reflects an increase in demand offset by a deferral of a portion of our revenues recognized on sales of TYSABRI in Italy (as described below) and pricing reductions from austerity measures enacted in some countries. The decrease in rest of world TYSABRI revenues for 2012 compared to 2011 also reflects gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program, which only partially offset negative impacts of foreign currency on sales. The increase in rest of world TYSABRI revenues for 2011 compared to 2010 reflects the favorable impact of foreign currency exchange rates offset by losses recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program.

Gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program totaled $9.7 million in 2012, compared to losses recognized of $6.3 million for 2011 and gains recognized of $10.7 million in 2010.

In the fourth quarter of 2011, Biogen Idec SRL received a notice from the Italian National Medicines Agency (AIFA) stating that sales of TYSABRI for the period from February 2009 through February 2011 exceeded by EUR30.7 million a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in February 2007. In December 2011, we filed an appeal against AIFA in administrative court seeking a ruling that the reimbursement limit does not apply and that the position of AIFA is unenforceable. As a result of being notified that AIFA believes a reimbursement limit is in effect, we have deferred $62.7 million and $13.8 million of revenue of TYSABRI in Italy for 2012 and 2011, respectively. We expect to continue to defer a portion of our revenues on future sales of TYSABRI in Italy until this matter is resolved. For additional information, please read

Note 22, Litigation to our consolidated financial statements included within this report.

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We expect TYSABRI to continue facing increased competition in the MS marketplace in both the U.S. and rest of world. We and a number of other companies are working to develop or have commercialized additional treatments for MS, including oral and other alternative formulations that may compete with TYSABRI. The commercialization of certain of our own pipeline product candidates, such as TECFIDERA, also may negatively impact future sales of TYSABRI. Increased competition may also lead to reduced unit sales of TYSABRI, as well as increasing price pressure. In addition, safety warnings included in the TYSABRI label, such as the risk of progressive multifocal leukoencephalopathy (PML), and any future safety-related label changes, may limit the growth of TYSABRI unit sales. We continue to research and develop protocols and therapies that may reduce risk and improve outcomes of PML in patients. Our efforts to stratify patients into lower or higher risk for developing PML, including through the JCV antibody assay, and other on-going or future clinical trials involving TYSABRI may have a negative impact on prescribing behavior, which may result in decreased product revenues from sales of TYSABRI.

Other Product Revenues

Other product revenues are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011	2011 compared to 2010
FUMADERM	$59.7	$54.7	$51.2	9.1 %	6.8 %
FAMPYRA	57.4	13.6	—	**	**
Other	—	1.7	0.3	(100.0)%	**
Total other product revenues	$117.1	$70.0	$51.5	67.3 %	35.9 %

We have a license from Acorda Therapeutics, Inc. (Acorda) to develop and commercialize FAMPYRA in all markets outside the U.S. The European Commission previously granted a conditional marketing authorization for FAMPYRA in the E.U. in July 2011. A conditional marketing authorization is renewable annually and is granted to a medicinal product with a positive benefit-risk assessment that fulfills an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. To meet the conditions of this marketing authorization, we will provide additional data from on-going clinical studies regarding FAMPYRA's benefits and safety in the long term. This marketing authorization was renewed as of July 2012. FAMPYRA is the first treatment that addresses the unmet medical need of walking improvement in adult patients with MS who have walking disability. FAMPYRA is commercially available throughout the European Union and in Canada, Australia, New Zealand, Israel and South Korea, and we anticipate making FAMPYRA commercially available in additional markets in 2013.

In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product’s comparative efficacy. We launched FAMPYRA in Germany in August 2011. During the second quarter of 2012, the government agency completed its comparative efficacy assessment of FAMPYRA indicating a range of pricing below our initial launch price, which was unregulated for the first 12 months after launch consistent with German law. As of the third quarter of 2012, we have had pricing negotiations with the German authorities which were resolved in 2013. We recognized revenue during the fourth quarter of 2012 based on the lowest point of the initially indicated German pricing authority range. We will recognize revenue at the negotiated fixed price effective upon the signing of the new agreement in 2013.

For information about our relationship with Acorda, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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Unconsolidated Joint Business Revenues

We collaborate with Genentech on the development and commercialization of RITUXAN. For additional information related to this collaboration including information regarding the pre-tax co-promotion profit sharing formula for RITUXAN and its impact on future unconsolidated joint business revenues, please read Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Revenues from unconsolidated joint business are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011	2011 compared to 2010
Biogen Idec's share of pre-tax co-promotion profits in the U.S.	$1,031.7	$872.7	$848.0	18.2 %	2.9 %
Reimbursement of our selling and development expenses in the U.S.	1.6	6.1	58.3	(73.8)%	(89.5)%
Revenue on sales of RITUXAN in the rest of world	104.6	117.8	170.9	(11.2)%	(31.1)%
Total unconsolidated joint business revenues	$1,137.9	$996.6	$1,077.2	14.2 %	(7.5)%

Biogen Idec’s Share of Pre-tax Co-Promotion Profits in the U.S.

The following table provides a summary of amounts comprising our share of pre-tax co-promotion profits in the U.S.:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011	2011 compared to 2010
Product revenues, net	$3,131.8	$2,924.5	$2,759.2	7.1 %	6.0 %
Cost and expenses	543.7	730.8	626.8	(25.6)%	16.6 %
Pre-tax co-promotion profits in the U.S.	$2,588.1	$2,193.7	$2,132.4	18.0 %	2.9 %
Biogen Idec's share of pre-tax co-promotion profits in the U.S.	$1,031.7	$872.7	$848.0	18.2 %	2.9 %

For 2012 compared to 2011, as well as for 2011 compared to 2010, the increase in U.S. RITUXAN product revenues was primarily due to price increases and an increase in commercial demand. Increased commercial demand was approximately 3% and 4% in U.S. RITUXAN unit sales volume for 2012 and 2011, respectively, over the prior year comparative periods. The increase in demand was driven by numerous factors including a continued uptake in the rheumatoid arthritis and vasculitis indications.

Collaboration costs and expenses for 2012 compared to 2011 decreased primarily due to a decrease in sales and marketing expenses incurred by the collaboration and a decline in expenditures for the development of RITUXAN for use in other indications. For 2012 and 2011, we have increased our share of co-promotion profits in the U.S. by approximately $14.3 million and $12.0 million, respectively, to reflect our interpretation of a proposed rule within the 2010 healthcare reform legislation related to changes in the exclusion of orphan drugs under Section 340B of the Public Health Services Act. The cumulative amount of these adjustments is $26.3 million, which is reflected as an amount due from Genentech in our consolidated balance sheets and may be subject to adjustment when a final rule on the provisions of 340B is issued.

Collaboration cost and expenses for 2011 compared to 2010 were favorably impacted by Genentech assuming responsibility for the U.S. sales and marketing efforts for RITUXAN in the fourth quarter of 2010. The savings realized from the consolidation of the sales force in 2011 were offset by a charge of approximately $125.0 million recorded to the collaboration, representing Genentech's estimate of compensatory damages and interest that might be awarded to Hoechst GmbH (Hoechst), in relation to an intermediate decision by the arbitrator in Genentech’s ongoing arbitration with Hoechst. As a result of this charge to the collaboration, our share of RITUXAN revenues from

unconsolidated joint business was reduced by approximately $50.0 million in the second quarter of 2011. This $50.0 million amount reflects our share of the estimate of the loss that we may incur in the event of a final arbitration award unfavorable to Genentech. The actual amount of our share of any damages may vary from this estimate depending on the nature or amount of any damages awarded to Hoechst. For additional information related to this matter, please read Note 22, Litigation to our consolidated financial statements included within this report.

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In addition, total collaboration cost and expenses for 2011 was further negatively impacted by a fee which became payable in 2011 by all branded prescription drug manufacturers and importers. This fee is calculated based upon each organization's percentage share of total branded prescription drug sales to qualifying U.S. government programs (such as Medicare, Medicaid and Veterans Administration (VA) and Public Health Service (PHS) discount programs). We have reduced our share of pre-tax co-promotion profits in the U.S. by approximately $15.0 million in 2012 and 2011 based upon Genentech's estimate of the fee that will be assessed to Genentech on qualifying sales of RITUXAN.

Under our collaboration agreement, our current pre-tax co-promotion profit-sharing formula, which resets annually, provides for a 40% share of pre-tax co-promotion profits if co-promotion operating profits exceed $50.0 million. For 2012, 2011, and 2010, the 40% threshold was met during the first quarter.

Reimbursement of Selling and Development Expense in the U.S.

In the fourth quarter of 2010, we and Genentech made an operational decision under which we eliminated our RITUXAN oncology and rheumatology sales force, with Genentech assuming responsibility for the U.S. sales and marketing efforts related to RITUXAN. As a result of this change, selling and development expense incurred by us in the U.S. and reimbursed by Genentech decreased for 2011 in comparison to 2010. As discussed in Note 21, Collaborative and Other Relationships to our consolidated financial statements included in this report, Genentech incurs the majority of continuing development costs for RITUXAN. Expenses incurred by Genentech in the development of RITUXAN are not recorded as research and development expense, but rather reduce our share of pre-tax co-promotion profits recorded as a component of unconsolidated joint business revenues.

For 2012 and 2011, amounts received in reimbursement of selling and development expenses in the U.S. were insignificant.

Revenue on Sales of RITUXAN in the Rest of World

Revenue on sales of RITUXAN in the rest of world consists of our share of pre-tax co-promotion profits in Canada and royalty revenue on sales of RITUXAN outside the U.S. and Canada. For 2012 compared to 2011, revenue on sales of RITUXAN in the rest of world decreased due to the expirations of royalties on a country-by-country basis offset by a portion of the 2011 Hoechst charge, noted above, which was recorded as of June 30, 2011. For 2011 compared to 2010, revenue on sales of RITUXAN in the rest of world decreased due to the expirations of royalties on a country-by-country basis. In addition, revenue on sales of RITUXAN in the rest of world for 2010 were favorably impacted by receipt of $21.3 million representing the cumulative underpayment of past royalties owed to us on sales of RITUXAN in the rest of world.

The royalty period for sales in the rest of world with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis. The royalty periods for substantially all of the remaining royalty-bearing sales of RITUXAN in the rest of world markets expired during 2012. After 2012, we expect revenue on sales of RITUXAN in the rest of world will primarily be limited to our share of pre-tax co-promotion profits in Canada.

Other Revenues

Other revenues are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011	2011 compared to 2010
Royalty revenues	$168.7	$158.5	$137.4	6.4 %	15.4 %
Corporate partner revenues	43.8	57.4	31.7	(23.7)%	81.1 %
Total other revenues	$212.5	$215.9	$169.1	(1.6)%	27.7 %

Royalty Revenues

We receive royalties from net sales on products related to patents that we licensed. Our most significant source of royalty revenue is derived from net worldwide sales of ANGIOMAX, which is licensed to The Medicines Company (TMC). Royalty revenues from the net worldwide sales of ANGIOMAX are recognized in an amount equal to the level of net sales achieved during a calendar year multiplied by the royalty rate in effect for that tier under our agreement with TMC. The royalty rate increases based upon which tier of total net sales are earned in any calendar

year. For 2012 compared to 2011, as well as for 2011 compared to 2010, the increase in royalty revenues reflects an increase in the net worldwide sales of ANGIOMAX. The increase in royalty revenues related to the sale of ANGIOMAX for 2011 compared to 2010 also reflects a $14.7 million adjustment recorded in the fourth quarter of 2011, as net sales levels for 2011 achieved a new royalty tier.

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In March 2012, the U.S. Patent and Trademark Office granted the extension of the term of the principal U.S. patent that covers ANGIOMAX to December 15, 2014. Under the terms of our royalty arrangement for ANGIOMAX, TMC is obligated to pay us royalties earned, on a country-by-country basis, until the later of (1) twelve years from the date of the first commercial sale of ANGIOMAX in such country or (2) the date upon which the product is no longer covered by a licensed patent in such country. The annual royalty rate is reduced by a specified percentage in any country where the product is no longer covered by a licensed patent and where sales have been reduced to a certain volume-based market share. TMC began selling ANGIOMAX in the U.S. in January 2001.

Corporate Partner Revenues

Our corporate partner revenues include amounts earned upon delivery of product under contract manufacturing agreements, revenues related to our arrangement with Samsung BioLogics Co. Ltd. (Samsung Biologics) to develop, manufacture and market biosimilar pharmaceuticals and supply agreement revenues covering products previously included within our product line that we have sold or exclusively licensed to third parties.

The decrease in corporate partner revenues for 2012 compared to 2011, as well as the increase for 2011 compared to 2010, is primarily related to a one-time cash payment of approximately $11.0 million received in exchange for entering into an asset transfer agreement in March 2011.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of applicable allowances for trade term discounts, wholesaler incentives, Medicaid rebates, VA and PHS discounts, managed care rebates, product returns, and other governmental rebates or applicable allowances including those associated with the implementation of pricing actions in certain international markets where we operate.

Reserves established for these discounts and allowances are classified as reductions of accounts receivable (if the amount is payable to our direct customer) or a liability (if the amount is payable to a party other than our customer). These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment. The estimates we make with respect to these allowances represent the most significant judgments with regard to revenue recognition.

Reserves for discounts, contractual adjustments and returns that reduced gross product revenues are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011	2011 compared to 2010
Discounts	$113.5	$96.0	$77.9	18.2 %	23.2 %
Contractual adjustments	512.2	346.4	282.6	47.9 %	22.6 %
Returns	21.9	14.8	14.3	48.0 %	3.5 %
Total allowances	$647.6	$457.2	$374.8	41.6 %	22.0 %
Gross product revenues	$4,813.7	$4,293.3	$3,844.9	12.1 %	11.7 %
Percent of gross product revenues	13.5 %	10.6 %	9.7 %		

Discount reserves include trade term discounts and wholesaler incentives. For 2012 compared to 2011, the increase in discounts was primarily driven by wholesaler incentives as a result of price increases. For 2011 compared to 2010, the increase in discounts was primarily driven by increases in trade term and volume discounts and wholesaler incentives as a result of price increases.

Contractual adjustment reserves relate to Medicaid and managed care rebates, VA, PHS discounts and other government rebates or applicable allowances. For 2012 compared to 2011, as well as for 2011 compared to 2010, the increase in contractual adjustments was due to higher reserves for managed care and Medicaid and VA programs principally associated with higher rebates resulting from price increases as well as an increase in governmental rebates and allowances in certain of the international markets in which we operate. The amount of contractual adjustments as

of December 31, 2012 includes our price adjustments related to sales of FAMPYRA described above under the heading "Other Product Revenues".

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Product return reserves are established for returns made by wholesalers. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. The majority of wholesaler returns are due to product expiration. Reserves for product returns are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. For 2012 compared to 2011, return reserves increased primarily due to returns associated with a voluntary withdrawal of a limited amount of AVONEX product in the first quarter of 2012 that demonstrated a trend in oxidation that may have led to expiry earlier than stated on its label as well as price increases. For 2011 compared to 2010, return reserves remained relatively unchanged.

Cost and Expenses

A summary of total cost and expenses is as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2012	2011	2010	2012 compared to 2011	2011 compared to 2010
Cost of sales, excluding amortization of acquired intangible assets	$545.5	$466.8	$400.3	16.9 %	16.6 %
Research and development	1,334.9	1,219.6	1,248.6	9.5 %	(2.3)%
Selling, general and administrative	1,277.5	1,056.1	1,031.5	21.0 %	2.4 %
Collaboration profit sharing	317.9	317.8	258.1	— %	23.1 %
Amortization of acquired intangible assets	202.2	208.6	208.9	(3.1)%	(0.2)%
Fair value adjustment of contingent consideration	27.2	36.1	—	(24.7)%	**
Restructuring charge	2.2	19.0	75.2	(88.4)%	(74.7)%
Acquired in-process research and development	—	—	245.0	— %	(100.0)%
Total cost and expenses	$3,707.4	$3,323.9	$3,467.5	11.5 %	(4.1)%

Cost of Sales, Excluding Amortization of Acquired Intangible Assets (Cost of Sales)