BIOGEN IDEC INC.
Form 10-K
February 06, 2014
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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, 2013

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.)

225 Binney Street, Cambridge, Massachusetts 02142
(617) 679-2000
(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. þ

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 $51,089,367,313.

As of January 31, 2014, the registrant had 236,393,930 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2014 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. The following cautionary statements are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the "Act") with the intention of obtaining the benefits of the "Safe Harbor" provisions of the Act. 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, contingent payments, milestone, royalty and other payments under licensing, collaboration or acquisition agreements, tax positions and contingencies, doubtful accounts, pre-approval inventory, cost of sales, research and development costs, compensation and other expenses, amortization of intangible assets, and foreign currency forward contracts;
- the anticipated timing of commercial launches of TECFIDERA in European countries;
- anticipated regulatory filings and regulatory actions relating to, and commercial launch of, ELOCTATE and ALPROLIX;
- additional anticipated commercial launches of FAMPYRA and the timing thereof;
- patent terms, patent term extensions, patent office actions, and expected availability and period of data protection and market exclusivity rights;
- the potential impact of increased product competition in the multiple sclerosis (MS) market, including competition from and growth of our own products and the possibility of future competition from biosimilars, generic versions or related prodrug derivatives;
- the potential for increased competition between RITUXAN and GAZYVA in the oncology market;
- our plans to develop further risk stratification protocols and therapies for TYSABRI and the impact of such protocols;
- the timing, outcome and impact of administrative, regulatory, litigation and other proceedings related to patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, product liability and other matters;
- the impact of the commercial launch of TECFIDERA on sales and market share of our products;
- the expected timing and financial impact of the final approval of the settlement of our dispute with the Italian National Medicines Agency relating to sales of TYSABRI;
- the anticipated lifetime revenues of AVONEX and TYSABRI and amortization recorded in relation to their technology;
- the costs, timing, potential approval and therapeutic scope of the development and commercialization of our pipeline products;
- lease commitments and purchase obligations;
- the potential impact of budget cuts and other measures in the U.S. and worldwide designed to reduce healthcare costs to constrain the overall level of government expenditures, including the impact of pricing actions in Europe and elsewhere;
- the impact of the continued uncertainty and deterioration of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the impact of new laws and accounting standards;
- the expected timing of completion of our manufacturing obligation for Zevalin;
- manufacturing capacity and our intent to utilize third party contract manufacturing organizations to provide manufacturing services for our small molecule products; and
- the drivers for growing our business, including our plans to pursue business development and research opportunities, and competitive conditions.

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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.

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®, AVOSTARTGRIP®, RITUXAN®, TECFIDERA®, TYSABRI® and TOUCH® are registered trademarks of Biogen Idec. ALPROLIX™, ELOCTATE™, FUMADERM™ and PLEGRIDY™ are trademarks of Biogen Idec. 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® — GlaxoSmithKline Intellectual Property Limited; BETASERON® and BETAFERON® — Bayer Schering Pharma AG; 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.; GAZYVA™ — Genentech, Inc.; HUMIRA® — AbbVie Biotechnology Ltd.; ORENCIA® — Bristol-Myers Squibb Company; REBIF® — Ares Trading S.A.; REMICADE® — Janssen Biotech, Inc.; SIMPONI® and SIMPONI ARIA™ — Johnson & Johnson; TREANDA® — Cephalon, Inc.; and XELJANZ® — Pfizer 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 for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia and other conditions and share profits and losses for GAZYVA for the treatment of chronic lymphocytic leukemia. 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	2013	2012	2011
AVONEX (1)	Multiple sclerosis	None	$3,005.5	$2,913.1	$2,686.6
TYSABRI (2)	Multiple sclerosis Crohn’s disease	None	$1,526.5	$1,135.9	$1,079.5
TECFIDERA (3)	Multiple sclerosis	None	$876.1	$—	$—
FAMPYRA (4)	Multiple sclerosis (walking ability)	Acorda Therapeutics	$74.0	$57.4	$13.6
FUMADERM (5)	Psoriasis	None	$60.2	$59.7	$54.7
			Unconsolidated Joint Business Revenues to Biogen Idec (in millions)		
			2013	2012	2011
RITUXAN (6)	Non-Hodgkin’s lymphoma Rheumatoid arthritis Chronic lymphocytic leukemia ANCA-associated vasculitis	Genentech (Roche Group)	$1,126.0	$1,137.9	$996.6

(1) AVONEX (interferon beta-1a), injection for intramuscular use, 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), injection for intravenous infusion, is indicated (1) as a monotherapy for the treatment of patients with relapsing forms of MS 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.

We previously collaborated with Elan Pharma International, Ltd (Elan), an affiliate of Elan Corporation, plc. on the development, manufacture and commercialization of TYSABRI. On April 2, 2013, we acquired full ownership of, and strategic, commercial and decision-making rights to, TYSABRI. Upon the closing of the transaction, our collaboration agreement with Elan was terminated.

(3) TECFIDERA (dimethyl fumarate), delayed release capsules for oral use, is indicated for the treatment of patients with relapsing forms of MS. TECFIDERA was approved by the U.S. Food and Drug Administration (FDA) in March 2013. In February 2014, the European Commission (EC) approved the use of TECFIDERA in the European Union (E.U.) as a first-line oral treatment for people with relapsing-remitting MS.

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

(5) FUMADERM (fumaric acid esters), prolonged release tablets, 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.

(6)

RITUXAN (rituximab), injection for intravenous infusion, 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

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other anthracycline-based chemotherapy regimens, (2) patients with 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, significant customers and geographic areas in which we operate is set forth in our consolidated financial statements, in Note 25, Segment Information to our consolidated financial statements, and in Item 6. Selected Financial Data and in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations included in this report. A discussion of the risks attendant to our operations is set forth in the “Risk Factors” section of this report.

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

(In millions)	2013	2012	2011
Research and development	$1,444.1	$1,334.9	$1,219.6
Amortization of acquired intangible assets	$342.9	$202.2	$208.6
(Gain) loss on fair value remeasurement of contingent consideration	$(0.5)	$27.2	$36.1

Additional information about our research and development programs and business development activity during 2013 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 225 Binney Street, Cambridge, MA 02142 and our telephone number is (617) 679-2000. 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 report.

Marketed Products

MS Products

We develop, manufacture and market a number of products designed to treat patients with MS. MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis and, in some cases, death. Patients with active relapsing MS experience an uneven pattern of disease progression characterized by periods of stability that are interrupted by flare-ups of the disease after which the patient returns to a new baseline of functioning.

AVONEX

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. AVONEX is a recombinant form of the interferon beta protein produced in the body in response to viral infection. 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. The 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, and were recently approved for marketing in Japan.

TYSABRI

TYSABRI has advanced the treatment of relapsing MS 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.

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TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic infection of the brain by the JC virus (JCV) that usually leads to death or severe disability. Infection by the JC virus 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. 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.

In 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 and 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. A second generation assay capable of detecting JCV antibodies at lower concentrations than the original assay, known as STRATIFY DX SELECT JCV Antibody ELISA, has also been developed.

2013 Developments

- We previously collaborated with Elan on the development, manufacture and commercialization of TYSABRI. On April 2, 2013, we acquired full ownership of, and strategic, commercial and decision-making rights to, TYSABRI from Elan, for an upfront payment of $3.25 billion together with an agreement to make contingent payments to Elan. Upon the closing of the transaction, our collaboration agreement with Elan was terminated. For additional information related to this relationship, please read Note 2, Acquisitions and Note 20, Collaborative and Other Relationships to our consolidated financial statements included within this report.
- In 2013, the FDA and the European Medicines Agency (EMA) approved updates to the TYSABRI product labels. In July 2013, the EMA approved an expanded indication statement for TYSABRI to include glatiramer acetate (GA) treatment failures in the definition of non-responders eligible for TYSABRI, and in December 2013, the FDA approved a modification to the indication statement in the U.S. product label for TYSABRI clarifying the intended use of TYSABRI for people living with relapsing forms of MS, as well as updates to certain safety information. In May 2013, we withdrew the variation in our application we submitted to the EMA requesting to expand the indication statement to allow first-line use of TYSABRI for people living with certain relapsing forms of MS who have tested negative for antibodies to the JC virus.
- In 2013, we submitted an application for approval of TYSABRI in Japan.

TECFIDERA

TECFIDERA is our first-line oral treatment for people with relapsing forms of MS. TECFIDERA was approved by the FDA in March 2013 and by regulatory authorities in Canada and Australia in April 2013 and July 2013, respectively. In February 2014, the EC approved the use of TECFIDERA in the E.U. as a first-line oral treatment for people with relapsing-remitting MS. TECFIDERA is also currently under review by regulatory authorities in additional markets.

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 related to Business Combinations” of our “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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 has been approved in over 50 countries across Europe, Asia and the Americas, and we anticipate making FAMPYRA commercially available in additional markets in 2014.

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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 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

2013 Developments

- The EC 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 2013. To meet the conditions of this marketing authorization, we will continue to provide additional data from on-going clinical studies regarding FAMPYRA's benefits and safety.

Other Products

FUMADERM

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

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.

In the U.S., we collaborate with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, on the development and commercialization of RITUXAN. For information about this collaboration, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

GAZYVA

GAZYVA (obinutuzumab), injection for intravenous infusion, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia. The FDA granted GAZYVA breakthrough therapy designation due to the significance of the positive progression-free survival results from the Phase 3 CLL11 clinical trial and the serious and life threatening nature of CLL. GAZYVA, formerly known as GA101, was approved by the FDA in November 2013.

In the U.S., we share operating profits and losses relating to GAZYVA with Genentech. The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S. For information about our agreement with Genentech, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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)	2013	2012	2011
Royalty revenues	$185.7	$168.7	$158.5
Corporate partner revenues	$78.2	$43.8	$57.4

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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. 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. 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. We expect royalty revenue to decrease significantly when the term of the U.S. patent covering ANGIOMAX expires. For a further description of our royalty arrangement with TMC, 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.

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 and anti-sense 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. 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 that are in clinical trials. 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.

Therapeutic Area	Product Candidate	Targeted Indications	Collaborator	Status
Neurology	PLEGRIDY (peginterferon beta-1a)	MS	None	U.S. BLA and EMA marketing authorisation application submitted and under regulatory review
	Daclizumab High Yield Process (HYP)	MS	AbbVie Biotherapeutics	Phase 3
	TYSABRI	Secondary progressive MS	None	Phase 3
		Stroke	None	Phase 2
	Anti-LINGO	Optic Neuritis	None	Phase 2
		MS	None	Phase 2
	Neublastin	Neuropathic pain	None	Phase 2
	BIIB037	Alzheimer’s disease	None	Phase 1b
	ISIS - SMN_{Rx}	Spinal muscular atrophy	Isis Pharmaceuticals	Phase 1b/2a
	BIIB061	MS	None	Phase 1
Hemophilia	ALPROLIX [Coagulation Factor IX, Fc Fusion Protein (Recombinant)]	Hemophilia B	Swedish Orphan Biovitrum	U.S. BLA submitted and under regulatory review

	ELOCTATE [(Antihemophilic Factor, Fc Fusion Protein (Recombinant)]	Hemophilia A	Swedish Orphan Biovitrum	U.S. BLA submitted and under regulatory review
Immunology	STX-100	Idiopathic pulmonary fibrosis	None	Phase 2a
	Anti-TWEAK	Lupus nephritis	None	Phase 2
	Anti-CD40 Ligand	General lupus	UCB, Inc.	Phase 1
Other	GAZYVA (obinutuzumab)	Non-Hodgkin’s lymphoma	Genentech (Roche Group)	Phase 3

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Late Stage Product Candidates

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

PLEGRIDY (peginterferon beta-1a)

PLEGRIDY (peginterferon beta-1a) is designed to prolong the effects and reduce the dosing frequency of interferon beta-1a.

In January 2013, we released the top-line efficacy analysis and safety data from the first year of the two-year global Phase 3 study, ADVANCE. Results support PLEGRIDY 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 PLEGRIDY 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.

During the second quarter of 2013, we submitted a Biologics License Application (BLA) to the FDA and a Marketing Authorisation Application to the EMA, in each case for marketing approval of PLEGRIDY in relapsing forms of MS. The regulatory submission was based on the results from the first year of the two-year global Phase 3 ADVANCE study. The FDA accepted our application in July 2013, and granted us a standard review timeline. The EMA validated our application in June 2013. We have also submitted a regulatory application for PLEGRIDY in Japan.

Daclizumab High Yield Process (HYP)

Daclizumab HYP is a monoclonal antibody that is being tested in relapsing-remitting MS. In April 2012, we completed patient enrollment in a Phase 3 study of daclizumab in relapsing-remitting 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 involves approximately 1,800 patients.

In August 2011, we announced positive results from SELECT, a global, registrational Phase 2b study designed to evaluate Daclizumab HYP in relapsing-remitting MS over one year. Results showed that Daclizumab HYP, 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 HYP. For information about this collaboration, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

TYSABRI (SPMS)

In May 2013, we completed 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 involves approximately 875 patients. Secondary progressive MS is characterized by a steady progression of nerve damage, symptoms and disability.

Hemophilia Product Candidates

ELOCTATE [Antihemophilic Factor, Fc Fusion Protein (Recombinant)]

In October 2012, we announced positive top-line results from the Phase 3 study, known as A-LONG, investigating ELOCTATE in hemophilia A, a rare inherited disorder which inhibits blood coagulation. Top-line results from the A-LONG study showed that ELOCTATE was effective in the control and prevention of bleeding episodes, routine prophylaxis and perioperative management. Based on the results from the A-LONG clinical trial, we submitted a BLA to the FDA for marketing approval of ELOCTATE in the first quarter of 2013. In May 2013, the FDA accepted our application for ELOCTATE and granted us a standard review timeline. In October 2013, we announced that the FDA had requested additional information pertaining to the validation of certain steps in the manufacturing process for ELOCTATE. In December 2013, the FDA extended the initial Prescription Drug User Fee Act (PDUFA) date for the FDA’s review our application by three months, which is a standard extension period.

We have submitted additional regulatory applications for ELOCTATE in Australia, Canada and Japan.

Pediatric data will be required as part of the Marketing Authorisation Application for ELOCTATE that we plan to submit to the EMA, and we have initiated a global pediatric study of ELOCTATE.

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ALPROLIX [Coagulation Factor IX, Fc fusion protein (Recombinant)]

In September 2012, we announced positive top-line results from the Phase 3 study, known as B-LONG, investigating ALPROLIX in hemophilia B, a rare inherited disorder which inhibits blood coagulation. Top-line results from the B-LONG study showed that ALPROLIX was effective in the control and prevention of bleeding episodes, routine prophylaxis, and perioperative management. Based on this data, we submitted a BLA to the FDA for marketing approval of ALPROLIX in the fourth quarter of 2012. In March 2013, the FDA accepted our application for ALPROLIX and granted us a standard review timeline. In November 2013, in response to a request from FDA, we submitted additional information to the FDA related to the validation of a manufacturing step for ALPROLIX. Due to the timing of this submission, the FDA extended the initial PDUFA date for its review of our application by three months, which is a standard extension period.

We have submitted additional regulatory applications for ALPROLIX in Australia, Canada and Japan.

Pediatric data will be required as part of the Marketing Authorisation Application for ALPROLIX that we plan to submit to the EMA, and we have initiated a global pediatric study of ALPROLIX.

We collaborate with Swedish Orphan Biovitrum AB on the development and commercialization of ELOCATE and ALPROLIX. For information about this collaboration, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

GAZYVA

The Roche Group is managing the following Phase 3 studies of GAZYVA:

- GOYA: investigating the efficacy and safety of GAZYVA 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 GAZYVA in combination with chemotherapy followed by maintenance with GAZYVA 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 GAZYVA plus bendamustine compared with bendamustine alone in patients with RITUXAN-refractory, indolent non-Hodgkin's lymphoma.

For information about our agreement with Genentech, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Business Development

In January 2014, we entered into an exclusive worldwide collaboration and license agreement with Sangamo BioSciences, Inc. (Sangamo) focused on the development of therapeutics for hemoglobinopathies, inherited conditions that result from the abnormal structure or underproduction of hemoglobin. Under the terms of the agreement, Sangamo is responsible for all research and development activities through the first clinical proof of concept trial in beta-thalassemia, and both companies will perform activities to enable submission of an Investigational New Drug application for sickle cell disease. We will be responsible for subsequent worldwide clinical development, manufacturing and commercialization of products arising from the alliance. Sangamo retains an option to co-promote any licensed product to treat sickle cell disease and beta-thalassemia in the U.S. Completion of the transaction is subject to customary closing conditions, including antitrust clearance in the U.S. under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. For additional information about this transaction, please read Note 27, Subsequent Events to our consolidated financial statements included in this report.

In December 2013, pursuant to our joint venture agreement with Samsung Biologics, we exercised our right to enter into an agreement with Samsung Bioepis to commercialize anti-TNF biosimilar product candidates in Europe. Under the agreement, we will be responsible for commercialization of these product candidates across Europe. For additional information about this transaction and our joint venture agreement with Samsung Biologics, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

In December 2013, we entered into a collaborative research, development, commercialization and license agreement with Proteostasis Therapeutics, Inc. (Proteostasis) under which both companies will develop and commercialize small molecule therapeutics for the treatment of neurological diseases. For additional information about this transaction, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this

report.

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In September 2013, we entered into a six-year research collaboration with Isis Pharmaceuticals, Inc. (Isis) under which both companies will perform discovery level research and develop and commercialize antisense and other therapeutics for the treatment of neurological disorders. Under the collaboration, Isis will perform research on a set of neurological targets identified within the agreement. Once the research has reached a specific stage of development we will make the determination whether antisense is the preferred approach to develop a therapeutic candidate or whether another modality is preferred. If antisense is selected, Isis will continue development and identify a product candidate. If another modality is used, we will assume the responsibility for identifying a product candidate and developing it. For additional information about this transaction, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

In July 2013, we entered into a Platform Agreement with Adimab LLC (Adimab). Pursuant to the agreement, Adimab granted us a non-exclusive license to its proprietary antibody discovery platform that enables our researchers to utilize the Adimab technology for the discovery and optimization of all antibody formats, including bispecific antibodies.

In April 2013, we acquired full ownership of, and strategic, commercial and decision-making rights to, TYSABRI from Elan. Upon the closing of the transaction, our collaboration agreement with Elan was terminated. For additional information about this transaction, please read Note 2, Acquisitions to our consolidated financial statements included in this report.

Patents and Other Proprietary Rights

Patents are important to developing and protecting exclusive rights in our drugs and drug candidates. 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.

U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest 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 exclusivity, which may consist of regulatory data protection and market 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 created 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 that 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 exclusivity 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 AVONEX, RITUXAN, TECFIDERA and TYSABRI, 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 trademark FAMPYRA which we license from Acorda Therapeutics. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark 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.

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AVONEX and PLEGRIDY (peginterferon beta-1a)

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 the treatment of MS with our product AVONEX, as well as the treatment of MS with our product candidate PLEGRIDY. A discussion of legal proceedings related to this patent is set forth in Note 21, Litigation to our consolidated financial statements included in this report.

Additionally, we and another party each own a pending U.S. patent application related to recombinant interferon-beta protein. 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 is a pending interference proceeding in the USPTO involving these applications. We do not know whether either of these applications will mature into patents with claims relevant to AVONEX or to PLEGRIDY.

Additional protection for PLEGRIDY 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 that PLEGRIDY, if approved, will be granted regulatory exclusivity for 12 years from approval in the U.S. and 10 years from approval in the E.U.

TYSABRI

We 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. The principal patents covering the product and use of the product to treat MS are U.S. patent nos. 5,840,299 and 6,602,503 and European patent no. (EP) 0804237, which expire between 2015 and 2020. Additional U.S. patents and applications covering methods of treatment using the product and methods of manufacturing the product generally expire between 2014 and 2023. In other countries, additional patents and patent applications covering methods of treatment using the product and methods of manufacturing the product expire between 2014 and 2023, subject to any supplemental protection (i.e., patent term extension) certificates that may be obtained.

TECFIDERA

We have several U.S. patents and patent applications, and a number of corresponding foreign counterparts, related to TECFIDERA.

Our principal U.S. patents and expiration dates, subject to any available patent term extension following product approval, are:

- U.S. patent no. 6,509,376, having claims to formulations of dimethyl fumarate for use in the treatment of autoimmune diseases including MS, expiring in 2019;
- U.S. patent no. 7,320,999, having claims to a method of treating MS using dimethyl fumarate, expiring in 2020;
- U.S. patent no. 7,619,001, having claims to a method of treating MS using dimethyl fumarate, monomethyl fumarate, or a combination thereof, expiring in 2018;
- U.S. patent no. 7,803,840, having claims to a method of treating an autoimmune disease selected from autoimmune polyarthritis and MS using dimethyl fumarate, expiring in 2018;
- U.S. patent no. 8,399,514, covering the dosing regimen of 240 mg of TECFIDERA administered twice a day, expiring in 2028; and
- U.S. patent no. 8,524,773, having claims to a method of treating MS using monomethyl fumarate, expiring in 2018.

Our principal European patents expiration dates, subject to any potential supplemental patent certificates that may be available, are:

- EP 1131065, directed to formulations of dimethyl fumarate and to uses thereof for treating autoimmune diseases, including MS, expiring in 2019; and
- EP 2137537, the counterpart patent to our U.S. patent covering the dosing regimen of 240 mg of TECFIDERA administered twice a day, expiring in 2028.

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In addition to patent protection, in the U.S. TECFIDERA is entitled to regulatory exclusivity afforded to new chemical entities until 2018. In the E.U., the EMA has determined that dimethyl fumurate in TECFIDERA qualifies as a new active substance (NAS). TECFIDERA is entitled to regulatory exclusivity in the E.U., which is expected to provide 8 years of data protection plus two years of market exclusivity from the date of notification of approval of our marketing application by the EC in February 2014.

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 expired 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 rheumatoid arthritis, was revoked by the European Patent Office.

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 have expired or will 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 EP 0484186B1 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 EP 1732548B1, which claims sustained-release aminopyridine compositions for increasing walking speed in patients with MS, and EP 2377536B1, which claims sustained-release aminopyridine compositions for treating multiple sclerosis both expire in 2025 but are subject to pending and granted supplemental protection certificates which, if granted, will extend one of the patents' term to 2026 on a country-by-country basis. In addition to these patent rights, FAMPYRA is covered by regulatory exclusivity in Europe expected until 2021.

ELOCTATE [Antihemophilic Factor, Fc Fusion Protein (Recombinant)] and ALPROLIX [Coagulation Factor IX, Fc fusion protein (Recombinant)]

We have several U.S. patents and patent applications, and a number of corresponding foreign counterparts, related to ELOCTATE and ALPROLIX, our long-lasting recombinant Factor VIII and Factor IX product candidates and their use, including U.S. patents nos. 7,404,956, 8,329,182, 7,348,004 and 7,862,820. These patents will expire between 2024 and 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. Related European patents EP 1624891 and EP 1625208 expire 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, including from our own products and products of our competitors. 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. Following the completion of our acquisition of 100% of the rights to TYSABRI from Elan in April 2013, we are solely responsible for the marketing and sale of TYSABRI for MS in the U.S. and the rest of world. We use a combination of our own sales force and marketing group and third party service providers for our marketing and distribution of TYSABRI.

TECFIDERA

The principal market for TECFIDERA is the U.S. and the E.U. In the U.S., E.U., Canada and Australia, we market and sell TECFIDERA through our own sales forces and marketing groups and distribute TECFIDERA principally through wholesale distributors of pharmaceutical products, mail order specialty distributors or shipping service providers.

RITUXAN and GAZYVA

The Roche Group and its sub-licensees market and sell RITUXAN worldwide. In the U.S., we collaborate with Genentech 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.

Pursuant to our agreement with Genentech, the Roche Group and its sub-licensees will maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S.

FAMPYRA

We market and sell FAMPYRA in major markets outside the U.S., such as France, Germany, Spain and Canada, through our own sales forces and marketing groups and distribute FAMPYRA in those markets principally through wholesale distributors of pharmaceutical products. In other countries outside the U.S., we sell FAMPYRA to distribution partners who are then responsible for most marketing and distribution activities. Our 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 excellence and innovation as well as 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., a number 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, TYSABRI and TECFIDERA

Each of AVONEX, TYSABRI and TECFIDERA competes with the following products:

- COPAXONE (glatiramer acetate), which is marketed by Teva Pharmaceutical Industries Ltd. COPAXONE generated worldwide revenues of approximately $4.0 billion in 2012.
- 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 $2.5 billion in 2012.
- BETASERON/BETAFERON (interferon-beta-1b), which is marketed by the Bayer Group. BETASERON/BETAFERON generated worldwide revenues of approximately $1.6 billion in 2012.
- EXTAVIA (interferon-beta-1b), which is marketed by Novartis AG. EXTAVIA generated worldwide revenues of approximately $159.0 million in 2012.
- GILENYA (fingolimod), which is marketed by Novartis AG. GILENYA generated worldwide revenues of approximately $1.2 billion in 2012.
- AUBAGIO (teriflunomide), which is marketed by Sanofi. AUBAGIO generated worldwide revenues of approximately $9.2 million in 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, TECFIDERA or all of them. For example, a marketing application for LEMTRADA (alemtuzumab) (developed by Sanofi) has been approved in the E.U. as a treatment for MS in September 2013. In addition, the commercialization of our own products, such as TECFIDERA, may negatively impact future sales of AVONEX, TYSABRI or both. Further, following the expected expiration of Teva Pharmaceutical's patent protection for COPAXONE (May 2014 for its U.S. patents and in May 2015 for its European patents), we anticipate that additional companies will introduce similar versions of COPAXONE that may also create further competition in the MS market.

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. FAMPYRA is currently the only therapy approved to improve walking in patients with MS, and benefits from exclusivity rights that prohibit generic versions from being marketed.

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

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We also expect that over time GAZYVA will compete with RITUXAN, TREANDA AND ARZERRA in the oncology market. In addition, we are aware of other anti-CD20 molecules, including biosimilars, in development that, if successfully developed and registered, may compete with RITUXAN and GAZYVA in the oncology market.

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 and SIMPONI ARIA (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).
- XELJANZ (tofacitinib) (marketed by Pfizer).

We are also aware of other products, including biosimilars, 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 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.

Product development and receipt of regulatory approval 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.

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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.

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.

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, 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.

We monitor information on side effects and adverse events reported during clinical studies and after marketing approval and report such information and events to regulatory agencies. 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.

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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 EC. The CHMP opinion is not binding, 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.

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Orphan Drug Act

Under the U.S. Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics 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 payors, 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.

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. For most brand name drugs, the amount of the basic rebate for each product is set by law as the greater of 23.1% (17.1% for clotting factors and certain other products) 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). This adjustment can cause the total rebate amount to exceed the minimum 23.1% (or 17.1%) basic 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%. 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.

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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 covered entities that purchase products under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics, hemophilia treatment centers and other entities that receive health services grants from the PHS.

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). Budgetary pressures in many E.U. countries are continuing to cause 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.

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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.

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 Research Triangle Park (RTP), North Carolina and are required to operate pursuant to certain permits.

Other Laws

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, 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 three licensed biologics manufacturing facilities, which are located in RTP, North Carolina, Cambridge, Massachusetts, and Hillerød, Denmark. The RTP site includes a 105,000 square foot manufacturing plant, which contains 6,000 (3 x 2,000) liters of bioreactor capacity, as well as a 218,000 square foot Large-Scale Manufacturing (LSM) plant which contains 90,000 (6 x 15,000) liters of bioreactor capacity. The Cambridge site is a 67,000 square foot facility that contains 10,000 (5 x 2,000) liters of bioreactor capacity. The Hillerød site is an LSM plant that contains 90,000 (6 x 15,000) liters of bioreactor capacity. Our Hillerød facility was approved by the FDA and EMA

for the manufacture of commercial TYSABRI in July 2013.

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We currently manufacture AVONEX, PLEGRIDY and ELOCTATE drug substance at our RTP and Cambridge facilities, ALPROLIX drug substance at our RTP facility and TYSABRI drug substance at our RTP and Hillerød facilities. Genentech is responsible for all worldwide manufacturing activities for bulk RITUXAN and GAZYVA and has sourced the manufacture of certain bulk RITUXAN and GAZYVA 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 (API) and the final product for TECFIDERA and FUMADERM. In December 2012, we entered into an arrangement with Eisai, Inc. (Eisai) to lease a portion of their facility in RTP to manufacture oral solid dose products supplementing our outsourced small molecule manufacturing capabilities. That facility also manufactures oral solid dose products for Eisai. As part of that arrangement, Eisai also provides us with vial-filling services for biologic therapies and packaging services for oral solid dose products. We intend to continue to utilize third party contract manufacturing organizations to manufacture the API and final product for our small molecule products, which we intend to supplement through our internal oral solid dose manufacturing capabilities.

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 our products and product candidates 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 provide sufficient capacity for our products. In February 2012, we finalized an agreement with Samsung Biologics that established an entity based in South Korea to develop, manufacture and market biosimilars. Under the agreement, Samsung takes a leading role in the entity, which has contracted with us for technical development services and biologics manufacturing. In December 2013, pursuant to our joint venture agreement with Samsung Biologics, we exercised our right to enter into an agreement with Samsung Bioepis to commercialize anti-TNF biosimilar product candidates in Europe.

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, 2013, we had approximately 6,850 employees worldwide.

Our Executive Officers (as of February 6, 2014)

George A. Scangos, Ph.D., 65, 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 Trustees of the Boston Museum of Science and the Biomedical Sciences Career Program, and a member of 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, 57, is our Executive Vice President, Chief Legal Officer and Corporate Secretary and has served in these positions since December 2011. Prior to that, from 2006 to December 2011, Ms. Alexander served as our Executive Vice President, General Counsel and Corporate Secretary. 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. Ms. Alexander received her B.A. from Wellesley College and her J.D. from Boston University School of Law.

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Spyros Artavanis-Tsakonas, Ph.D., 67, is our Senior Vice President, Chief Scientific Officer and has served in this position since May 2013. Prior to his appointment in May 2013, Dr. Artavanis-Tsakonas served as our interim Chief Scientific Officer while on sabbatical from Harvard Medical School from March 2012 to May 2013. Dr. Artavanis-Tsakonas has been a Professor of Cell Biology at the Harvard Medical School since 1999. Prior to that, from 1999 through 2012, he was Professor, Collège de France, serving as Chair of Biology and Genetics of Development, and from 1999 to 2007, he was also the K.J. Isselbacher- P. Schwartz Professor at the Massachusetts General Hospital Cancer Center and Director of Developmental Biology and Cancer at the Harvard Medical School. Dr. Artavanis-Tsakonas is the scientific co-founder of Exelixis Pharmaceuticals, Inc., a drug discovery and development company, Cellzome, a drug discovery and development company, and Anadys Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Artavanis-Tsakonas obtained his M.Sc. in Chemistry from the Federal Institute of Technology, Zurich and a Ph.D. in Molecular Biology from the University of Cambridge, England. His postdoctoral research was completed at Biozentrum, University of Basel and Stanford University.

Paul J. Clancy, 52, 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 serves on the board of directors of Agios Pharmaceuticals, Inc., a biopharmaceutical company. Mr. Clancy received his B.S. in Finance from Babson College and M.B.A. from Columbia University.

Gregory F. Covino, 48, 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. Mr. Covino received his B.S. in Business Administration from Bryant University.

John G. Cox, 51, 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 Inc., 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 serves on the board of directors of Repligen Corporation, a life sciences company. Mr. Cox received his B.S. in Biology from Arizona State University, M.B.A. from the University of Michigan and M.S. in Cell Biology from California State University.

Kenneth Di Pietro, 55, 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. DiPietro serves on the board of directors of InVivo Therapeutics Corporation, a medical device company. Mr. Di Pietro received his B.S. in Industrial and Labor Relations from Cornell University.

Steven H. Holtzman, 59, 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.

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Tony Kingsley, 50, 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.

Alfred W. Sandrock, Jr., M.D., Ph.D., 56, is our Group Senior Vice President, Chief Medical Officer and has served in this position since May 2013. From February 2012 to April 2013, Dr. Sandrock served as our Senior Vice President, Chief Medical Officer. Prior to that, Dr. Sandrock held several senior executive positions since joining us in 1998, including Senior Vice President of Development Sciences, Senior Vice President of Neurology Research and Development and Vice President of Clinical Development, Neurology. Dr. Sandrock received his B.A. in Human Biology from Stanford University, an M.D. from Harvard Medical School, and a Ph.D. in Neurobiology from Harvard University. He completed an internship in Medicine, a residency and chief residency in Neurology, and a Clinical Fellowship in Neuromuscular Disease and Clinical Neurophysiology (electromyography) at Massachusetts General Hospital.

Douglas E. Williams, Ph.D., 55, 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. Dr. Williams serves on the board of directors of Regulus Therapeutics Inc., a life sciences company. Dr. Williams received his B.S. in Biological Sciences from the University of Massachusetts, Lowell and Ph.D. in Physiology from the State University of New York at Buffalo, Roswell Park Memorial Institute Division.

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Item 1A. Risk Factors

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

Our current and future revenues depend upon continued sales of our four principal products, AVONEX, TYSABRI, TECFIDERA and RITUXAN. Although we have developed and continue to develop additional products for commercial introduction, we may be substantially dependent on sales from these 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, generics or related prodrug derivatives, constraints on product pricing or price increases, changes in reimbursement policies of third parties 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 those products have a similar or more attractive profile in terms of efficacy, convenience or safety, future sales of AVONEX, TYSABRI or TECFIDERA could be adversely affected. Sales of RITUXAN may be adversely affected by commercialized products such as GAZYVA, TREANDA and ARZERRA, and potentially other anti-CD20 and other molecules in development to treat the indications approved for RITUXAN.

If we fail to successfully execute on our commercialization efforts for TECFIDERA, our future revenue growth and results of operations may be adversely affected, and our stock price may decline.

We remain in the early stages of our commercial launch of TECFIDERA. If we are unable to successfully execute on our commercialization plans for TECFIDERA, our future revenue growth and results of operations may be adversely affected, and could cause a decline in our stock price. Factors that may prevent us from successfully commercializing TECFIDERA include:

- intense competition in the increasingly crowded MS market, including the possibility of future competition from generic versions of TECFIDERA or related prodrug derivatives or from off-label use by physicians of therapies indicated for other conditions to treat MS patients;
- our significant reliance on third parties to manufacture TECFIDERA, including the risks these third parties may not be able to supply TECFIDERA in a timely and cost-effective manner or in compliance with applicable regulations or otherwise fail to have sufficient aggregate manufacturing capacity to satisfy demand;
- our sales and marketing efforts may not result in product revenues that meet the investment community's expectations for TECFIDERA;
- additional risks associated with our anticipated launches of TECFIDERA in the E.U., including the impact of delays and the effects of a slower rollout of TECFIDERA across European countries over an extended number of months, the impact of competitive oral MS therapies approved in the E.U. prior to TECFIDERA, and our ability to obtain appropriate pricing and reimbursement for TECFIDERA in countries throughout the E.U.;
- damage to our sales and reputation, and physician and patient confidence in TECFIDERA relating to any adverse experiences or events that may occur with patients treated with TECFIDERA, including any PML cases that may develop in patients previously treated with TYSABRI that switch to therapy with TECFIDERA; and
- the other risks related to commercialization of new products described throughout these “Risk Factors”.

We remain in the early stages of our commercial launch of TECFIDERA and there is a limited amount of prescription, patient compliance and retention and other data available to date. These limited results may not be indicative of future performance or trends or the impact of TECFIDERA on our other products or the products of our competitors.

If we are unable to adequately protect and enforce our data, 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 or licensed 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

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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 exclusivity, which may consist of regulatory data protection and market protection. Although the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS) requires signatory countries to provide regulatory exclusivity to innovative pharmaceutical products, implementation and enforcement varies widely from country to country. Failure to qualify for regulatory data or market protection, or failure to obtain or maintain the extent or duration of such protections that we expect in each of the markets for our products, could affect our revenue for our products or our decision on whether to market our products in a particular country or countries or could otherwise have an adverse impact on our results of operations.

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 in some cases are not well defined. 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. In the E.U., drugs that do not have regulatory exclusivity may face immediate generic competition. 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.

Sales of TYSABRI are uncertain due to restrictions on use and safety warnings.

Sales of TYSABRI are uncertain 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. Increased competition, including competition from our own products, could also negatively impact future sales.

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.

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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 for the treatment of MS and the treatment of hemophilia. 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 receives marketing approval depends on a number of factors, including:

- the medical community's acceptance of the product and the confidence of patients in 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);
- our ability to offer products that have convenient dosing and delivery methods;
- 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.

Our ability to successfully commercialize ELOCTATE and ALPROLIX, our long-lasting blood clotting factor candidates, may also be impacted by additional factors such as:

- 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;
- filing of our planned marketing authorization applications with the EMA requires the submission of positive pediatric data from our ongoing global pediatric studies with our applications, and there can be no assurance that we will receive such positive data; and
- several companies are working to develop additional treatments for hemophilia and may obtain marketing approval of their treatments before we do, which has the potential to bar our application with the EMA under operation of the EMA’s Orphan Medicines Regulation; and
- other companies may introduce longer-lasting or more efficacious, safer, cheaper or more convenient treatments than our long-lasting blood clotting factor candidates.

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, as well as pressure by employers on private health insurance plans to reduce costs, 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.

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In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals and enactments to reform health care insurance programs could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the 2010 Patient Protection and Affordable Care Act (PPACA) have resulted in changes in the way health care is paid for by both governmental and private insurers, which has had and is expected to continue to have a significant impact on our business. These changes include, among other things, increased Medicare rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts. The U.S. federal government has also implemented spending cuts under the Budget Control Act of 2011, known as “sequestration”, which included a 2% reduction in Medicare reimbursements rates to providers such as physicians, hospitals and drug plans. These cuts, which reduce payments to health care providers for Medicare Part B drugs, could affect decisions regarding prescribing patterns or site of care, which could adversely impact sales of our products such as TYSABRI and RITUXAN, which are administered by infusion. In addition, Medicare Part D plans managing outpatient prescription drugs that are receiving less reimbursement from the government could seek further discounts from manufacturers, which could adversely affect our sales of our Part D drugs, such as AVONEX and TECFIDERA. It is possible that additional federal health care reform measures will be adopted in the future, including as a result of ongoing discussions to reduce the U.S. federal budget deficit to address government finances, any of which could result in increased pricing pressure and reduced reimbursement for our products and otherwise have an adverse impact on our financial position or results of operations.

There is also significant economic pressure on state budgets that 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, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. 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 addition, under the PPACA, as states implement their health care marketplaces or operate under the federal exchange, the impact on drug manufacturers, including us, will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in these programs. It is possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our products for this patient population, which could have an adverse impact on our sales and results of operations.

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 have announced or implemented measures to reduce health care costs to constrain their overall level of government expenditures. These measures vary by country and may include, among other things, 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 measures have negatively impacted our revenues, and may continue to adversely affect our revenues and results of operations in the future. 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 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 or products similar to ours and public rumors about such events could cause our product sales or stock price to decline or experience periods of volatility.

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Our long-term success depends upon the successful development of 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, patient enrollment rates, 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 which may impact our ability to control the timing, conduct, expense and quality of our clinical trials. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and diverse clinical trials, our studies and any potential regulatory approvals may be delayed, or we may fail to gain approvals for our product candidates. Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects or raise safety or other concerns that may significantly reduce the likelihood of regulatory approval, result in significant restrictions on use and safety warnings in the 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, may disagree with the endpoints employed in the trials, may fail to approve the facilities or the processes used to manufacture a product candidate, and may fail to approve or delay approval of our product candidates, dosing or delivery methods, or may otherwise grant marketing approval that is more restricted than anticipated, including indications covering narrow patient populations and the imposition of safety monitoring or educational requirements or risk evaluation and mitigation strategies. The occurrence of any such events could result in the incurrence of significant costs and expenses and could otherwise have an adverse effect on our business, including our financial condition and results of operations.

Even if we are able to successfully develop new products, we may make a strategic decision to discontinue development of a product candidate if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. Similarly, if we successfully develop a new product, but 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. We also expect increased competition in the MS market through the introduction of generic versions of COPAXONE following the expected expiration of Teva Pharmaceutical’s patent protection for COPAXONE.

In addition, health care reform legislation enacted in the U.S. in 2010 has created a pathway for the FDA to approve biosimilars or follow-on products, which could compete on price and differentiation with a number of our existing products, including AVONEX, TYSABRI and RITUXAN, or products we may market in the future. 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. The introduction by our competitors of more

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

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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 continuing European financial crisis, volatility in the credit and financial markets, and other disruptions due to natural disasters, political instability or otherwise.

The European market represents a major part of our business and most of our marketing efforts outside the U.S. are focused on Europe. Thus, the continued uncertainty of the credit and economic conditions in Italy, Spain and Portugal, among other members of the European Union, subjects us to credit risk from accounts receivable related to our product sales in these countries, which may have a significant adverse impact on our results of operations. Our accounts receivable in certain European countries, such as Spain, Italy and Portugal, are subject to significant payment delays due to government funding and reimbursement practices. Continued adverse market and economic conditions in the European market could result in further reimbursement delays, 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, the clinical development of future products and commercialization, marketing and manufacturing of certain 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, as well as any future revenues related to GAZYVA, 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 or GAZYVA in the same manner or to the same extent that we would, which could adversely affect our RITUXAN or GAZYVA revenues.
- Under our collaboration agreement with Genentech, the successful development and commercialization of GAZYVA 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, identifying any noncompliance with the study protocol or current Good Clinical Practices and interfacing with regulators throughout the process. 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 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.

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- We rely on third party suppliers and manufacturers for, among other things, manufacturing of RITUXAN and GAZYVA, the majority of our clinical and commercial requirements for TECFIDERA and other small molecule products and product candidates, raw materials and supplies for production of products we manufacture, 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 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 facilities in Research Triangle Park, North Carolina (RTP) and Hillerød, Denmark for the production of TYSABRI and our manufacturing facilities in RTP and Cambridge, Massachusetts for the production of AVONEX. Our global bulk supply of TYSABRI and AVONEX depends on the uninterrupted and efficient operation of these facilities, 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 or AVONEX 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.
- 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.

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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.

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, distributors and other 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. Health care companies are facing heightened scrutiny of their relationships with health care 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 health information and data privacy and security laws and regulations, tracking and reporting 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.

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, enhanced penalties for and investigations into non-compliance with

U.S. fraud and abuse laws, and compliance with the Physician Payment Sunshine Act in the U.S. and similar foreign rules and regulations that require collection and reporting of payments or other transfers of value made to physicians and teaching hospitals.

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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.

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 that could adversely affect our business, such as:

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- collectability of accounts receivable;
- 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;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and trade restrictions;
- greater political or economic instability; and
- changes in tax laws and tariffs.

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 and other strategic alliances and collaborations, we may not be able to integrate them or take full advantage of them and therefore may not realize the benefits that we expect.

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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 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, such as we did in connection with our recent relocation of our corporate headquarters from Weston, Massachusetts to Cambridge, Massachusetts, 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 examinations and audits of our tax filings, adjustments to the value of our uncertain tax positions, including those relating to our manufacturing deduction, 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, penalize certain transfer pricing structures, and reduce or eliminate certain foreign or domestic tax credits or deductions. 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.

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.

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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 risks described in these "Risk Factors" as well as 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 long-lived assets, including in-process research and development and other intangible assets;
- inventory write-downs for failed quality specifications, charges for excess or obsolete inventory and charges for inventory write downs relating to product suspensions, expirations or recalls;
- bad debt expenses and increased bad debt reserves;
- outcomes of litigation and other legal proceedings, regulatory matters and tax matters;
- 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.

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 subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities for investment of our cash. Changes in the value of our portfolio of marketable securities 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 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 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.

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A breakdown or breach of our information technology systems could subject us to liability or interrupt the operation of our business.

Many of our key business processes are facilitated by information technology systems. Information technology systems are potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, individuals authorized to access our information technology systems may pose a risk by exposing private or confidential data to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to minimize these risks to our data and information technology systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

Provisions in our Genentech collaboration agreement may discourage a third party from attempting to acquire us.

Provisions in our collaboration agreement with 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 agreement with Genentech allows 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, 2013.

Massachusetts

In Cambridge, Massachusetts, 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 addition, we lease a total of approximately 1,132,000 square feet in Massachusetts, which is summarized as follows:

- 729,000 square feet in Cambridge, Massachusetts, which is comprised of a 67,000 square foot biologics manufacturing facility and 662,000 square feet for our corporate headquarters, laboratory and additional office space;
- 357,000 square feet of office space in Weston, Massachusetts, of which 175,000 square feet has been subleased for a term which started in January 2014 and will continue through the remaining term of our lease agreement; and
- 46,000 square feet of warehouse space in Somerville, Massachusetts.

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

North Carolina

We manufacture bulk AVONEX and TYSABRI and other products in our pipeline at our facilities located in RTP, 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 lease 48,000 square feet of a facility in RTP, North Carolina from Eisai to manufacture our and Eisai's oral solid dose products.

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Denmark

We have a large-scale biologics manufacturing facility totaling approximately 225,000 square feet located in Hillerød, Denmark. In July 2013, the facility was approved by the FDA and EMA for the manufacture of commercial TYSABRI.

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 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, 2013, please read Note 21, 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, 2013 and 2012:

	Common Stock Price			
	2013		2012	
	High	Low	High	Low
First Quarter	$192.92	$139.72	$127.85	$111.44
Second Quarter	$242.64	$191.80	$144.38	$124.23
Third Quarter	$248.95	$203.55	$157.18	$137.88
Fourth Quarter	$298.82	$221.07	$155.30	$134.00

As of January 31, 2014, there were approximately 867 stockholders of record of our common stock.

In addition, as of January 31, 2014, 47 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 2013:

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-13	—	—	—	4,185,526
Nov-13	—	—	—	4,185,526
Dec-13	—	—	—	4,185,526
Total	—	—		

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, 2013, approximately 15.8 million shares of our common stock at a cost of $1,883.0 million have been repurchased under this authorization. In 2013, approximately 2.0 million shares were repurchased at a cost of $400.3 million. Approximately 4.2 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, the Nasdaq Pharmaceutical Index and the Nasdaq Biotechnology Index assuming the investment of $100.00 on December 31, 2008 with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

	2008	2009	2010	2011	2012	2013
Biogen Idec Inc.	100.00	112.32	140.77	231.05	307.31	586.96
NASDAQ Pharmaceutical	100.00	112.36	121.80	130.37	173.45	285.96
S&P 500 Index	100.00	126.46	145.51	148.59	172.37	228.19
NASDAQ Biotechnology	100.00	115.96	134.58	150.85	200.25	332.45

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Item 6. Selected Financial Data

BIOGEN IDEC INC. AND SUBSIDIARIES
SELECTED FINANCIAL DATA

	For the Years Ended December 31,				
(In millions, except per share amounts)	2013 (5) (7) (9) (10)	2012 (7) (8)	2011 (5) (6)	2010 (3) (4)	2009 (1) (2)
Results of Operations					
Product revenues	$5,542.3	$4,166.1	$3,836.1	$3,470.1	$3,152.9
Revenues from unconsolidated joint business	1,126.0	1,137.9	996.6	1,077.2	1,094.9
Other revenues	263.9	212.5	215.9	169.1	129.5
Total revenues	6,932.2	5,516.5	5,048.6	4,716.4	4,377.3
Cost and expenses:					
Cost of sales, excluding amortization of acquired intangible assets	857.7	545.5	466.8	400.3	382.1
Research and development	1,444.1	1,334.9	1,219.6	1,248.6	1,283.1
Selling, general and administrative	1,712.1	1,277.5	1,056.1	1,031.5	911.0
Amortization of acquired intangible assets	342.9	202.2	208.6	208.9	289.8
Collaboration profit sharing	85.4	317.9	317.8	258.1	215.9
(Gain) loss on fair value remeasurement of contingent consideration	(0.5)	27.2	36.1	—	—
Restructuring charges	—	2.2	19.0	75.2	—
Acquired in-process research and development	—	—	—	245.0	—
Total cost and expenses	4,441.6	3,707.4	3,323.9	3,467.5	3,081.9
Gain on sale of rights	24.9	46.8	—	—	—
Income from operations	2,515.5	1,855.9	1,724.7	1,248.9	1,295.4
Other income (expense), net	(34.9)	(0.7)	(13.5)	(19.0)	37.3
Income before income tax expense and equity in loss of investee, net of tax	2,480.6	1,855.1	1,711.2	1,229.9	1,332.7
Income tax expense	601.0	470.6	444.5	331.3	355.6
Equity in loss of investee, net of tax	17.2	4.5	—	—	—
Net income	1,862.3	1,380.0	1,266.7	898.6	977.1
Net income (loss) attributable to noncontrolling interests, net of tax	—	—	32.3	(106.7)	6.9
Net income attributable to Biogen Idec Inc.	$1,862.3	$1,380.0	$1,234.4	$1,005.2	$970.1
Diluted Earnings Per Share					
Diluted earnings per share attributable to Biogen Idec Inc.	$7.81	$5.76	$5.04	$3.94	$3.35
Weighted-average shares used in calculating diluted earnings per share attributable to Biogen Idec Inc.	238.3	239.7	245.0	254.9	289.5
Financial Condition					
Cash, cash equivalents and marketable securities	$1,848.5	$3,742.4	$3,107.4	$1,950.8	$2,457.8
Total assets	$11,863.3	$10,130.1	$9,049.6	$8,092.5	$8,551.9

Notes payable, line of credit and other financing arrangements, less current portion	$592.4	$687.4	$1,060.8	$1,066.4	$1,080.2
Total Biogen Idec Inc. shareholders' equity	$8,620.2	$6,961.5	$6,425.5	$5,396.5	$6,221.5

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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 Form 10-Ks.

(1) Total cost and expenses 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.

(2) 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 income tax expense.

(3) Included in total cost and expenses 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.).

(4) Included in total cost and expenses 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 were 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.

(5) Our share of revenues from unconsolidated joint business reflects charges of $50.0 million in 2011 and $49.7 million in 2013 for damages and interest awarded to Hoechst in Genentech's arbitration with Hoechst for RITUXAN.

(6) Biogen Idec Inc.'s shareholders' equity 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.

(7) Gain on sale of rights relates to the sale of all of our rights, including rights to royalties, related to BENLYSTA.

(8) Equity in loss of investee, net of tax relates to our ownership interest in Samsung Bioepis to develop, manufacture and market biosimilar pharmaceuticals.

(9) Commencing in the second quarter of 2013, product revenues and total revenues includes 100% of net revenues related to sales of TYSABRI as a result of our acquisition of TYSABRI rights from Elan and net revenues related to sales of TECFIDERA, our new oral first-line treatment for people with relapsing forms of multiple sclerosis (MS), which was approved by the FDA and commenced commercial sales. In addition, upon the closing of our acquisition of TYSABRI rights, our collaboration agreement was terminated, and we no longer record collaboration profit sharing.

(10) Included in net income is a $38.5 million benefit, net of ancillary federal and state income and non-income tax effects, related to years 2005 through 2012 as a result of receiving updated technical guidance from the IRS concerning our current and prior year filings and calculation of our U.S. federal manufacturing deduction and overall tax classification of our unconsolidated joint business.

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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 (MS) and other autoimmune disorders, neurodegenerative diseases and hemophilia. We also collaborate on the development and commercialization of RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia and other conditions and share profits and losses for GAZYVA for the treatment of chronic lymphocytic leukemia.

In the near term, our revenues are dependent upon continued sales of our four principal products, AVONEX, TYSABRI, TECFIDERA and RITUXAN. 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 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.

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, 2013 (1) (2)	2012	% Change 2013 compared to 2012	
Total revenues	$6,932.2	$5,516.5	25.7	%
Income from operations	$2,515.5	$1,855.8	35.5	%
Net income attributable to Biogen Idec Inc.	$1,862.3	$1,380.0	34.9	%
Diluted earnings per share attributable to Biogen Idec Inc.	$7.81	$5.76	35.8	%

(1) Commencing in the second quarter of 2013, product revenues and total revenues includes 100% of net revenues related to sales of TYSABRI as a result of our acquisition of TYSABRI rights from Elan and net revenues related to sales of TECFIDERA, our new oral first-line treatment for people with relapsing forms of MS, which was approved by the FDA and commenced commercial sales.

(2) Our share of revenues from unconsolidated joint business reflects a charge of $49.7 million for damages and interest awarded to Hoechst in Genentech's arbitration with Hoechst for RITUXAN.

As described below under "Results of Operations," our operating results for the year ended December 31, 2013, reflect the following:

- Worldwide AVONEX revenues totaled $3,005.5 million for 2013, representing an increase of 3.2% over 2012.
- Worldwide TYSABRI revenues totaled $1,526.5 million for 2013, representing an increase of 34.4% over 2012. The increase in revenue is primarily due to 100% of net U.S. revenue being recognized starting in April 2013 as a result of our acquisition of TYSABRI rights.
- Worldwide TECFIDERA revenues totaled $876.1 million for 2013. Approximately $134.0 million of U.S. TECFIDERA revenues in 2013 represent inventory in the channel.
- Our share of revenues from unconsolidated joint business totaled $1,126.0 million for 2013, representing a decrease of 1.0% from 2012.
- Total cost and expenses increased 19.8% for 2013 compared to 2012. This increase resulted from a 69.6% increase in the amortization of acquired intangible assets, a 57.2% increase in cost of sales, a 34.0% increase in selling, general and administrative expense and an 8.2% increase in research and development expense, partially offset by a 73.1% decrease in collaboration profit sharing compared with the same period in 2012.

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The increases in cost of sales and the amortization of acquired intangibles are a result of both our 2013 acquisition of the TYSABRI rights and higher amortization recorded on our AVONEX intangible asset. Our increase in research and development expense was primarily attributable to the upfront payment we made to Isis Pharmaceuticals, Inc. (Isis) upon entering into a six year research collaboration and the upfront and milestone payments made to Samsung Bioepis upon entering into a development and commercialization agreement. Higher selling, general and administrative expense resulted from increased costs incurred in connection with our product launch of TECFIDERA in the U.S. and our development of commercial capabilities for potential product launches of ELOCTATE and ALPROLIX, respectively.

We generated $2,345.1 million of net cash flows from operations for 2013, which were primarily driven by earnings. In addition, we used $3.25 billion of our cash, cash equivalents and marketable securities for our acquisition of TYSABRI rights from Elan. Cash, cash equivalents and marketable securities totaled approximately $1,848.5 million as of December 31, 2013.

Acquisitions

On April 2, 2013, we acquired full ownership of, and strategic, commercial and decision-making rights to TYSABRI from Elan. Upon the closing of the transaction, our collaboration agreement with Elan was terminated. For additional information related to this transaction, please read Note 2, Acquisitions to our consolidated financial statements included within this report.

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, TECFIDERA or other products we are developing. In addition, the commercialization of certain of our own approved products and pipeline product candidates may negatively impact future sales of AVONEX, TYSABRI, TECFIDERA or all three. We may also face increased competitive pressures from the emergence of biosimilars, generic versions of TECFIDERA or related prodrug derivatives. 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 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 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. It is possible that additional U.S. federal health care reform measures will be adopted in the future, including as a result of ongoing discussions to reduce the U.S. federal budget deficit to address government finances, any of which could result in increased pricing pressure and reduced reimbursement for our products and otherwise have an adverse impact on our financial position or 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 Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA) included a significant expansion of the Medicaid program, as well as the creation of new state-based health benefit exchanges, or marketplaces, through which individuals and small businesses may purchase health insurance. Premium and cost-sharing credits and subsidies are available to those who qualify based on income. Marketplace plans began to enroll new members in October 2013, and coverage began on January 1, 2014. Although the effects of the legislation are still unclear, PPACA could result in a greater number of individuals with health insurance under Medicaid and the marketplace health plans. The impact on manufacturers, including us, will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in the programs. It is possible that individuals who were previously unable to access insurance may now become insured, thus increasing coverage for our products. This potential increase in coverage, however, may be offset by the added discounts that could be required in these channels as well as the number of patients who over time

move from commercial insurance to the health insurance marketplaces. It is also possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our products for this patient population, which could have an adverse impact on our sales and results of operations.

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Key Pipeline Developments

TECFIDERA

In March 2013, the FDA approved TECFIDERA, our first-line oral treatment for people with relapsing forms of MS. The FDA approval 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. We commenced our commercial launch of TECFIDERA in the U.S. in April 2013. In February 2014, the European Commission (EC) approved the use of TECFIDERA in the European Union (E.U.) as a first-line oral treatment for people with relapsing-remitting MS.

TECFIDERA was approved in Canada in April 2013 and Australia in July 2013.

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 related to Business Combinations” of this “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

ELOCTATE and ALPROLIX

In October 2012, we announced positive top-line results from the Phase 3 study, known as A-LONG, investigating ELOCTATE in hemophilia A, a rare inherited disorder which inhibits blood coagulation. Top-line results from the A-LONG study showed that ELOCTATE was effective in the control and prevention of bleeding episodes, routine prophylaxis and perioperative management. Based on the results from the A-LONG clinical trial, we submitted a Biologics License Application (BLA) to the FDA for marketing approval of ELOCTATE in the first quarter of 2013. In May 2013, the FDA accepted our application for ELOCTATE and granted us a standard review timeline. In October 2013, we announced that the FDA had requested additional information pertaining to the validation of certain steps in the manufacturing process for ELOCTATE. In December 2013, the FDA extended the initial Prescription Drug User Fee Act (PDUFA) date for the FDA’s review our application by three months, which is a standard extension period.

In September 2012, we announced positive top-line results from the Phase 3 study, known as B-LONG, investigating ALPROLIX in hemophilia B, a rare inherited disorder which inhibits blood coagulation. Top-line results from the B-LONG study showed that ALPROLIX was effective in the control and prevention of bleeding episodes, routine prophylaxis, and perioperative management. Based on this data, we submitted a BLA to the FDA for marketing approval of ALPROLIX in the fourth quarter of 2012. In March 2013, the FDA accepted our application for ALPROLIX and granted us a standard review timeline. In November 2013, in response to a request from FDA, we submitted additional information to the FDA related to the validation of a manufacturing step for ALPROLIX. Due to the timing of this submission, the FDA extended the initial PDUFA date for its review of our application by three months, which is a standard extension period.

We have submitted additional regulatory applications for ELOCTATE and ALPROLIX in Australia, Canada and Japan.

Pediatric data will be required as part of the Marketing Authorisation Applications for ELOCTATE and ALPROLIX that we plan to submit to the EMA, and we have initiated global pediatric studies of ELOCTATE and ALPROLIX.

We collaborate with Swedish Orphan Biovitrum AB on the development and commercialization of ELOCTATE and ALPROLIX. For information about this collaboration, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included within this report.

PLEGRIDY (Peginterferon beta-1a)

During the second quarter of 2013, we submitted a BLA to the FDA and a Marketing Authorisation Application to the EMA, in each case for marketing approval of PLEGRIDY in relapsing forms of MS. The regulatory submission was based on the results from the first year of the two-year global Phase 3 ADVANCE study. The FDA accepted our application in July 2013, and granted us a standard review timeline. The EMA validated our application in June 2013.

GAZYVA

GAZYVA, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia. The FDA granted GAZYVA breakthrough therapy designation due to the significance of the positive progression-free survival results from the Phase 3 CLL11 clinical trial and the serious and life

threatening nature of CLL. GAZYVA, formerly known as GA101, was approved by the FDA and commenced commercial sales in November 2013.

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In the U.S., we share operating profits and losses relating to GAZYVA with Genentech. The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S. For information about our agreement with Genentech, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Product Revenues:					
United States	$3,581.0	$2,176.8	$1,954.8	64.5 %	11.4 %
Rest of world	1,961.3	1,989.3	1,881.3	(1.4)%	5.7 %
Total product revenues	5,542.3	4,166.1	3,836.1	33.0 %	8.6 %
Unconsolidated joint business revenues	1,126.0	1,137.9	996.6	(1.0)%	14.2 %
Other revenues	263.9	212.5	215.9	24.2 %	(1.6)%
Total revenues	$6,932.2	$5,516.5	$5,048.6	25.7 %	9.3 %

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
AVONEX	$3,005.5	$2,913.1	$2,686.6	3.2 %	8.4 %
TYSABRI	1,526.5	1,135.9	1,079.5	34.4 %	5.2 %
TECFIDERA	876.1	—	—	**	**
Other product revenues	134.2	117.1	70.0	14.6 %	67.3 %
Total product revenues	$5,542.3	$4,166.1	$3,836.1	33.0 %	8.6 %

AVONEX

Revenues from AVONEX are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
United States	$1,902.4	$1,793.7	$1,628.3	6.1 %	10.2 %
Rest of world	1,103.1	1,119.4	1,058.3	(1.5)%	5.8 %
Total AVONEX revenues	$3,005.5	$2,913.1	$2,686.6	3.2 %	8.4 %

For 2013 compared to 2012, the increase in U.S. AVONEX revenues was primarily due to price increases partially offset by an 8% decrease in unit sales volume, which was attributable in part to patients transitioning to TECFIDERA. For 2012 compared to 2011, the increase in U.S. AVONEX revenues was due to price increases partially offset by a 2% decrease in unit sales volume.

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For 2013 compared to 2012, the decrease in rest of world AVONEX revenues was primarily due to pricing reductions resulting from austerity measures enacted in some countries, partially offset by increased unit demand primarily in Europe. For 2012 compared to 2011, 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, partially offset by pricing reductions resulting from austerity measures enacted in some countries. Rest of world AVONEX unit volume primarily in Europe increased 2% and 8% for 2013 and 2012, respectively, over the prior year comparative periods. Rest of world AVONEX revenue for 2013 compared to 2012 also reflects the positive impact of foreign currency exchange rates, partially offset by losses recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program. Rest of world AVONEX revenues for 2012 compared to 2011 also reflects the negative impact of foreign currency exchange rates, partially offset by gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program. Losses recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program for AVONEX totaled $9.3 million in 2013, compared to gains recognized of $25.4 million for 2012 and losses recognized of $30.6 million in 2011.

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 have commercialized or are working to develop additional treatments for MS, including oral and other alternative formulations that may compete with AVONEX. The launch and growth of TECFIDERA and the commercialization of certain of our own potential products, such as PLEGRIDY, may also 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

Revenues from TYSABRI are summarized as follows:

	For the Years Ended December 31,			% Change			
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012		2012 compared to 2011	
United States	$814.2	$383.1	$326.5	112.5	%	17.3	%
Rest of world	712.3	752.8	753.0	(5.4	)%	—	%
Total TYSABRI revenues	$1,526.5	$1,135.9	$1,079.5	34.4	%	5.2	%

For 2013 compared to 2012, the increase in U.S. TYSABRI revenues was primarily due to our recognition, starting in April 2013, of 100% of net revenues on TYSABRI in-market sales due to our acquisition of the remaining TYSABRI rights from Elan, price increases and a 1% increase in unit sales volume, which includes the impact of patients transitioning to TECFIDERA. For 2012 compared to 2011, the increase in U.S. TYSABRI revenues was due to an 11% increase in unit sales volume and price increases.

Based on data reported by Elan and our sales to third party customers, total U.S. TYSABRI in-market sales were $958.3 million, $886.0 million and $746.5 million for 2013, 2012, and 2011, respectively. For 2013 compared to 2012, the increase in in-market sales was due to price increases. For 2012 compared to 2011, the increase in in-market sales was due to increased unit sales volume and price increases.

For 2013 compared to 2012, the decrease in rest of world TYSABRI revenues was primarily due to pricing reductions from austerity measures enacted in some countries, a decrease in unit demand primarily in Europe and the net impact of a EUR15.4 million ($20.0 million) reduction in revenues recorded for a probable settlement of outstanding claims with the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) relating to sales of TYSABRI in Italy in excess of a reimbursement limit for the periods between February 2009 and February 2011. 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 and pricing reductions from austerity measures enacted in some countries offset by an increase in demand. The change in demand resulted in a decrease of approximately 1% in rest of world TYSABRI unit sales volume for 2013 compared with 2012 versus an increase of 14% in rest of world TYSABRI unit sales volume for 2012 compared with 2011. Rest of world TYSABRI revenue for 2013 compared to 2012 also reflects the positive impact of foreign currency exchange rates, partially offset by losses recognized in relation to the

settlement of certain cash flow hedge instruments under our foreign currency hedging program. Rest of world TYSABRI revenues for 2012 compared to 2011 also reflects the negative impact of foreign currency exchange rates, partially offset by gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program.

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Losses recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program for TYSABRI totaled $3.8 million in 2013, compared to gains recognized of $9.7 million for 2012 and losses recognized of $6.3 million in 2011.

For information relating to our agreement in principle with AIFA relating to sales of TYSABRI in Italy, please read Note 4, Accounts Receivable to our consolidated financial statements included in this report. As described in Note 4, the settlement with AIFA is pending approval by Italian regulatory authorities. Upon approval of the settlement, any deferred revenue related to the periods subsequent to February 2011 that is in excess of the settlement will be recognized as revenue. Currently, we expect to record approximately $105.0 million of incremental revenue based on amounts deferred through December 31, 2013.

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 have commercialized or are working to develop additional treatments for MS, including oral and other alternative formulations that may compete with TYSABRI. In addition, the launch and growth of TECFIDERA and the commercialization of certain of our own products 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.

TECFIDERA

Revenues from TECFIDERA are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
United States	$864.4	$—	$—	**	**
Rest of world	11.7	—	—	**	**
Total TECFIDERA revenues	$876.1	$—	$—	**	**

During 2013, we received marketing approval for TECFIDERA in the U.S., Canada and Australia. U.S. sales began in April 2013. Approximately $134.0 million of U.S. TECFIDERA revenues in 2013 represent inventory in the channel at December 31, 2013.

In the first three quarters subsequent to its commercial launch in the United States, approximately 70% of new patients taking TECFIDERA have switched from a different MS therapy, including our products AVONEX and TYSABRI. We believe that the previous therapies from which these patients switched to TECFIDERA is roughly proportionate to the current market share distribution of all products currently approved to treat relapsing remitting MS. As TECFIDERA has only been approved for nine months, we have limited product history and it is difficult to estimate trends of future product sales of TECFIDERA and the resulting impact on sales and market share of our other therapies and other competing MS therapies.

Other Product Revenues

Other product revenues are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
FAMPYRA	$74.0	$57.4	$13.6	28.9 %	322.1 %
FUMADERM	60.2	59.7	54.7	0.8 %	9.1 %
Other	—	—	1.7	**	(100.0)%
Total other product revenues	$134.2	$117.1	$70.0	14.6 %	67.3 %

We have a license from Acorda Therapeutics, Inc. (Acorda) to develop and commercialize FAMPYRA in all markets outside the U.S. For information about our relationship with Acorda, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included within this report.

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For 2013 compared to 2012, the increase in FAMPYRA revenue was due to the recognition of previously deferred revenue and increased demand in Germany and France. FAMPYRA revenue for 2013 includes the recognition of revenues previously deferred in Germany as a result of finalizing the contract that included the final negotiated fixed price, which was favorable to the initial range cited by the German pricing authority.

Unconsolidated Joint Business Revenues

We collaborate with Genentech, Inc., a wholly-owned member of the Roche Group, on the development and commercialization of RITUXAN. In addition, in the U.S. we share operating profits and losses relating to GAZYVA with Genentech. The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S. For additional information related to this collaboration, including information regarding the pre-tax profit sharing formula and its impact on future unconsolidated joint business revenues, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included within this report.

Revenues from unconsolidated joint business are summarized as follows:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Biogen Idec's share of profits in the U.S. for RITUXAN and GAZYVA (1)	$1,085.2	$1,031.7	$872.7	5.2 %	18.2 %
Reimbursement of selling and development expenses in the U.S. for RITUXAN	2.1	1.6	6.1	31.3 %	(73.8)%
Revenue on sales in the rest of world for RITUXAN	38.7	104.6	117.8	(63.0)%	(11.2)%
Total unconsolidated joint business revenues	$1,126.0	$1,137.9	$996.6	(1.0)%	14.2 %

(1) GAZYVA was approved by the FDA in November 2013.

For 2013 compared to 2012, our share of revenues from unconsolidated joint business reflects a charge for damages and interest awarded to Hoechst in Genentech's arbitration with Hoechst. As disclosed in Note 21, Litigation to our consolidated financial statements included within this report, Genentech and Hoechst have completed the arbitration relating to Hoechst's claims under a license agreement between Hoechst's predecessor and Genentech that was terminated in October 2008. The license agreement provided for royalty payments of 0.5% on net sales of certain products defined by the agreement.

Although we were not a party to the arbitration, we reduced our share of RITUXAN revenues from unconsolidated joint business by $49.7 million during 2013 to reflect our share of the royalties and interest awarded to Hoechst, of which revenue on sales in the rest of world for RITUXAN was reduced by $41.2 million and pre-tax profits in the U.S. were reduced by $8.5 million. In 2011, we reduced our share of RITUXAN revenues from unconsolidated joint business by $50.0 million for our share of the estimate of the loss that we expected to be incurred upon completion of the arbitration award unfavorable to Genentech.

Biogen Idec’s Share of Pre-tax Profits in the U.S. for RITUXAN and GAZYVA

The following table provides a summary of amounts comprising our share of pre-tax profits on RITUXAN and GAZYVA in the U.S.:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Product revenues, net	$3,425.8	$3,131.8	$2,924.5	9.4 %	7.1 %
Cost and expenses	615.9	543.7	730.8	13.3 %	(25.6)%
	$2,809.9	$2,588.1	$2,193.7	8.6 %	18.0 %

Pre-tax profits in the U.S. for RITUXAN and GAZYVA							
Biogen Idec's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$1,085.2	$1,031.7	$872.7	5.2	%	18.2	%

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For 2013 compared to 2012, the increase in U.S. product revenues was due to price increases, an increase in commercial demand and the recognition of $94.9 million in net revenues resulting from the July 2013 issuance by the Department of Health and Human Services of its final rule on the Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program. The issuance of the final rule by the Department of Health and Human Services did not have an impact on the amount we recorded as revenues from unconsolidated joint business in our consolidated statements of income because, through June 30, 2013, we had been increasing our share of profits in the U.S. to reflect our interpretation of the proposed 340B rule. The final rule was consistent with our prior interpretation.

For 2012 compared to 2011, the increase in U.S. product revenues was primarily due to price increases and an increase in commercial demand. Increased commercial demand was approximately 4% and 3% in U.S. unit sales volume for 2013 and 2012, respectively, over the prior year comparative periods.

Collaboration costs and expenses for 2013 compared to 2012 increased primarily due to a higher cost of goods sold resulting from an increased volume in RITUXAN sales and higher associated third party royalties. In addition, upon the first marketing approval of GAZYVA by the FDA, we began recognizing all activity, including sales and marketing and research and development expenses, related to the GAZYVA program in unconsolidated joint business within our consolidated statements of income. Prior to its first regulatory approval, we recognized our share of GAZYVA development and commercialization expenses as research and development expense and selling, general and administrative expense, respectively, within our consolidated statements of income.

Collaboration costs and expenses for 2012 compared to 2011 decreased primarily due to lower sales and marketing expenses incurred by the collaboration and a decline in expenditures for the development of RITUXAN for use in other indications. The efficiencies and lower costs realized from the consolidation of the sales force in 2011 were offset by a 2011 charge of approximately $125.0 million recorded to the collaboration, representing Genentech's estimate of the compensatory damages and interest that may be awarded to Hoechst GmbH (Hoechst) resulting from an intermediate adverse decision by the arbitrator in Genentech’s ongoing arbitration with Hoechst. As a result of this charge to the collaboration, our share of revenues from unconsolidated joint business was reduced by $50.0 million in the second quarter of 2011. This $50.0 million amount reflected our share of the estimate of the loss that we expect to incur upon completion of the arbitration award unfavorable to Genentech.

Revenue on Sales in the Rest of World for RITUXAN

Revenue on sales in the rest of world for RITUXAN consists of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenue on sales outside the U.S. and Canada. For 2013 compared to 2012, revenue on sales in the rest of world for RITUXAN decreased as a result of a $41.2 million charge for damages and interest awarded to Hoechst, as discussed above, as well as the expirations of royalties on a country-by-country basis. For 2012 compared to 2011, revenue on sales in the rest of world for RITUXAN 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.

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 a substantial portion of the remaining royalty-bearing sales in the rest of world markets expired during 2012 and 2013. We expect future revenue on sales of RITUXAN in the rest of world will be limited to our share of pre-tax co-promotion profits in Canada.

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Other Revenues

Other revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Royalty revenues	$185.7	$168.7	$158.5	10.1 %	6.4 %
Corporate partner revenues	78.2	43.8	57.4	78.5 %	(23.7)%
Total other revenues	$263.9	$212.5	$215.9	24.2 %	(1.6)%

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. During 2012, we amended our agreement with TMC for the period from January 1, 2013 to December 15, 2014 to modestly increase the royalty rate in effect for all tiers. For 2013 compared to 2012, the increase in royalty revenues is primarily related to the increase in the royalty rate as well as an increase in the net worldwide sales of ANGIOMAX. For 2012 compared to 2011, the increase in royalty revenues reflects an increase in the net worldwide sales of ANGIOMAX.

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. We expect royalty revenue to decrease significantly when the term of the U.S. patent covering ANGIOMAX expires.

Corporate Partner Revenues

Our corporate partner revenues include amounts earned upon delivery of product under contract manufacturing agreements, revenues related to our arrangements with Samsung Bioepis and Eisai, Inc., and supply agreement revenues covering products previously included within our product line that we have sold or exclusively licensed to third parties.

For 2013 compared to 2012 the increase in corporate partner revenues was primarily due to increased revenue from our biosimilar arrangements and an amendment to our Zevalin supply agreement, which resulted in the delivery of our remaining Zevalin inventory and the recognition of a previously deferred amount. Zevalin is a program we sold in 2007 but have continued to manufacture. As part of the amendment, we have committed to one additional Zevalin manufacturing campaign, which we expect to complete in 2014. For 2012 compared to 2011, the decrease in corporate partner revenues was 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.

For additional information on our relationship with Samsung Bioepis, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included within this report. For additional information on our relationship with Eisai, please read Note 11, Property, Plant and Equipment to our consolidated financial statements included within this report.

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Reserves for Discounts and Allowances

Revenues from product sales are recorded net of applicable allowances for trade term discounts, wholesaler incentives, Medicaid rebates, Veterans Administration (VA) and Public Health Service (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 will have an effect on earnings in the period of adjustment. To date, such adjustments have not been significant.

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)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Discounts	$235.6	$96.2	$84.3	144.9 %	14.1 %
Contractual adjustments	835.0	529.5	358.1	57.7 %	47.9 %
Returns	24.0	21.9	14.8	9.6 %	48.0 %
Total allowances	$1,094.6	$647.6	$457.2	69.0 %	41.6 %
Gross product revenues	$6,636.9	$4,813.7	$4,293.3	37.9 %	12.1 %
Percent of gross product revenues	16.5 %	13.5 %	10.6 %		

During 2013, we reclassified prior year amounts related to our AVONEX co-pay programs from discounts to contractual adjustments. For the years ended December 31, 2012 and 2011, we reclassified $17.3 million and $11.7 million, respectively. For additional information related to our reserves, please read Note 5, Reserves for Discounts and Allowances to our consolidated financial statements included in this report.

As a result of our acquisition of TYSABRI rights from Elan, we began recognizing reserves for discounts and allowances for U.S. TYSABRI revenue in the second quarter of 2013. Prior periods included reserves for discounts and allowances for rest of world TYSABRI revenue and worldwide AVONEX revenue. In addition, following our commercial launch of TECFIDERA in the second quarter of 2013, we began recognizing reserves for discounts and allowances related to TECFIDERA revenue. Gross product revenues for 2012 and 2011 include sales of TYSABRI to Elan under our collaboration agreement, which did not have any corresponding reserves for discounts and allowances.

Discounts include trade term discounts and wholesaler incentives. For 2013 compared to 2012, the increase in discounts was primarily driven by the above noted additions of TECFIDERA and U.S. TYSABRI amounts. For 2012 compared to 2011, the increase in discounts was primarily driven by wholesaler incentives as a result of price increases.

Contractual adjustments relate to Medicaid and managed care rebates, VA, PHS discounts and other government rebates or applicable allowances. In addition to the above noted additions of TECFIDERA and U.S. TYSABRI amounts, for 2013 compared to 2012, the increase in contractual adjustments was primarily due to an increase in U.S. governmental rebates and allowances as a result of price increases. For 2012 compared to 2011, 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.

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 2013 compared to 2012, return reserves increased

primarily due to our acquisition of TYSABRI rights and the FDA approval and start of commercial sales of TECFIDERA, as discussed above. For 2012 compared to 2011, return reserves increased primarily due to returns associated with a voluntary withdrawal of a limited amount of AVONEX product as well as price increases.

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Cost and Expenses

A summary of total cost and expenses is as follows:

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Cost of sales, excluding amortization of acquired intangible assets	$857.7	$545.5	$466.8	57.2 %	16.9 %
Research and development	1,444.1	1,334.9	1,219.6	8.2 %	9.5 %
Selling, general and administrative	1,712.1	1,277.5	1,056.1	34.0 %	21.0 %
Amortization of acquired intangible assets	342.9	202.2	208.6	69.6 %	(3.1)%
Collaboration profit sharing	85.4	317.9	317.8	(73.1)%	— %
(Gain) loss on fair value remeasurement of contingent consideration	(0.5)	27.2	36.1	(102.0)%	(24.6)%
Restructuring charges	—	2.2	19.0	(100.0)%	(88.3)%
Total cost and expenses	$4,441.6	$3,707.4	$3,323.9	19.8 %	11.5 %

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

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Product cost of sales	$427.6	$365.9	$307.3	16.9 %	19.1 %
Royalty cost of sales	430.1	179.6	159.5	139.5 %	12.6 %
Total cost of sales	$857.7	$545.5	$466.8	57.2 %	16.9 %

For 2013 compared to 2012, the increase in royalty cost of sales was primarily driven by our acquisition of TYSABRI rights, partially offset by the expiration of a third party royalty related to AVONEX. Commencing in the second quarter of 2013, we began recording 100% of cost of sales and third party royalties of TYSABRI, which previously were shared with Elan. Our contingent payments due to Elan are also recorded as a component of royalty cost of sales. For additional information on the contingent payments due to Elan, please read Note 2, Acquisitions to our consolidated financial statements included within this report.

For 2013 compared to 2012, the increase in product cost of sales was driven by higher unit sales volume, our product launch of TECFIDERA in the U.S. and our biosimilars manufacturing arrangement with Samsung Bioepis. In addition, for 2013 compared to 2012, the increase in product cost of sales was driven by an increase in charges related to excess, obsolete, unmarketable or other inventory due in part to the implementation of our plans to supply rest of world markets with TYSABRI manufactured at our Hillerød, Denmark facility, which was approved by the FDA and EMA in July 2013.

For 2012 compared to 2011, the increase in cost of sales was primarily driven by higher revenue from our core products, higher costs of the AVONEX PEN and increased funding related to the JCV antibody assay, nurse training fees, and our arrangement with Samsung Biologics.

Our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. Periodically, certain batches or units of product may no longer meet quality specifications or may expire. The expiry associated with our inventory is generally between 6 months and 5 years, depending on the product. Inventory amounts written down related to excess, obsolete, unmarketable, or other inventory totaled $47.3 million, $24.8 million, and $25.4 million for the years ended December 31, 2013, 2012, and 2011, respectively.

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Research and Development

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Marketed products	$252.1	$128.2	$111.0	96.6 %	15.5 %
Late stage programs	272.8	467.0	428.1	(41.6)%	9.1 %
Early stage programs	130.8	90.7	72.5	44.2 %	25.1 %
Research and discovery	97.6	94.6	97.3	3.2 %	(2.8)%
Other research and development costs	552.7	479.0	465.6	15.4 %	2.9 %
Milestone and upfront payments	138.1	75.4	45.1	83.2 %	67.2 %
Total research and development	$1,444.1	$1,334.9	$1,219.6	8.2 %	9.5 %

Research and development expense incurred in support of our marketed products includes costs associated with product lifecycle management activities including, if applicable, costs associated with the development of new indications for existing products. Late stage programs are programs in Phase 3 development or in registration stage. Early stage programs are programs in Phase 1 or Phase 2 development. Research and discovery represents costs incurred to support our discovery research and translational science efforts. Other research and development costs consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as management costs as well as depreciation and other facility-based expenses.

For 2013 compared to 2012, the increase in research and development expense was primarily related to an increase in costs incurred in connection with our marketed products, early stage programs and upfront and milestone payments partially offset by a decrease in costs incurred in connection with our late stage programs. The increase in spending associated with marketed products is related to TECFIDERA, which is now recorded in this caption, and costs associated with TYSABRI, which previously were shared with Elan. Research and development expense related to our early stage programs increased over the prior year primarily due to costs incurred in the advancement of our Anti-LINGO program in multiple sclerosis, our BIIB037 program for Alzheimer's disease, our anti-TWEAK program for lupus nephritis, and an increase in spending incurred in connection with our development of STX-100 for the treatment of idiopathic pulmonary fibrosis.

The decrease in spending associated with our late stage product candidates was driven by the discontinuation of dexpramipexole (as described below), decreased clinical trial activity associated with our ELOCTATE and ALPROLIX product candidates, as these clinical trials concluded in 2012, and the FDA approval of TECFIDERA in the U.S. during the first quarter of 2013.

For 2012 compared to 2011, the increase in research and development expense includes costs incurred in connection with our late and early stage programs, additional investments in our marketed products, an increase in upfront and milestone payments, and costs related to reorganizing a group in our research and development function. The increase in spending associated with our late stage product candidates was driven by increased clinical trial activity associated with our ELOCTATE, dexpramipexole, and Daclizumab HYP product candidates as well as costs incurred in support of commercial preparatory capabilities related to ELOCTATE.

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 and failed to show efficacy in its key secondary endpoints. Based on these results, we discontinued development of dexpramipexole in ALS. Prior to our decision to discontinue dexpramipexole, we had started the R&D extension program, ENVISION, and had entered into arrangements with certain suppliers for the purchase of raw materials and the supply of drug product. These arrangements were canceled. We accrued approximately $12.3 million of research and development expense, as of December 31, 2012, related to these firm commitments to purchase R&D services and inventory or to pay cancellation charges.

Research and development expense related to our early stage programs in 2012 increased over 2011 compared to 2012 primarily due to costs incurred in the advancement of our Anti-TWEAK program in lupus nephritis, our BIIB037

program for Alzheimer's disease, our Neublastin program for neuropathic pain, an increase in spending incurred in connection with our collaboration and license agreement with Portola Pharmaceuticals, Inc. for the development of the Syk inhibitor molecule and development of STX-100 for the treatment of idiopathic pulmonary fibrosis.

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We intend to continue committing significant resources to targeted research and development opportunities where there is a significant unmet need and where the drug candidate has the potential to be highly differentiated. Specifically, we intend to continue to invest in bringing forward our MS pipeline and in pursuing additional therapies for autoimmune disorders, neurodegenerative diseases and hemophilia.

Milestone and Upfront Payments included in Research and Development Expense

Included in total research and development expense in 2013 were charges of $75.0 million related to an upfront payment made to Isis in September 2013 upon entering into a six year research collaboration with Isis under which both companies will perform research and then seek to develop and commercialize antisense or other therapeutics for the treatment of neurological disorders, $36.0 million related to upfront and milestone payments made to Samsung Bioepis in December 2013 upon entering into a development and commercialization agreement and a $10.0 million milestone payment made to Isis related to the selection and advancement of ISIS-DMPKRx to treat DM1. These payments are classified as research and development expense as the programs they relate to have not achieved regulatory approval. Research and development expense in 2012 included charges totaling $71.0 million related to upfront payments made to Isis in January, June and December 2012 upon entering into three separate agreements for the development of Isis' antisense investigational drug ISIS-SMNRx for the treatment of spinal muscular atrophy (SMA), product candidates related to the treatment of mytonic dystrophy (DM1), and antisense therapeutics for up to three gene targets, respectively. Research and development expense in 2011 included a charge of $36.8 million related to an upfront payment made in connection with our collaboration and license agreement entered into with Portola Pharmaceuticals, Inc.

Selling, General and Administrative

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Selling, general and administrative	$1,712.1	$1,277.5	$1,056.1	34.0 %	21.0 %

For 2013 compared to 2012, the increase in selling, general and administrative expense was primarily driven by costs associated with developing commercial capabilities for the product launch of TECFIDERA and the potential product launches of ELOCTATE and ALPROLIX, an increase in sales and marketing activities in support of AVONEX and TYSABRI and the $27.2 million charge recognized in relation to our exiting the Weston facility. For additional information related to this charge, please read Note 11, Property, Plant and Equipment to our consolidated financial statements included in this report. The increase in sales and marketing activities in support of TYSABRI were primarily driven by assuming 100% responsibility of activities as a result of the acquisition of TYSABRI rights. The successful commercialization of potential new products requires significant investments, such as sales force build and development, training, and other related activities. In addition, the increase in selling, general, and administrative expense was driven by an increase in share-based compensation expense, partially offset by a reduction in grant and sponsorship activity.

For 2012 compared to 2011, the increase in selling, general and administrative expense was primarily driven by costs associated with developing commercial capabilities in preparation for the potential product launches of TECFIDERA, ELOCTATE and ALPROLIX, an increase in costs associated with the development of our sales force and promotional spending in support of FAMPYRA, an increase in sales and marketing activities in support of AVONEX and TYSABRI, and an increase in grant and sponsorship activity. The increase in selling, general and administrative expense was offset by the positive impact of foreign currency exchange rates.

We remain focused on preparing for multiple potential product launches in the coming years. As discussed above, we continue to invest in the development of commercial capabilities in support of our TECFIDERA program, which was recently approved by the FDA and the EC and is in the early stages of commercial launch. We also have continued to make investments in the development of commercial capabilities for our hemophilia franchise.

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Amortization of Acquired Intangible Assets

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Amortization of acquired intangible assets	$342.9	$202.2	$208.6	69.6 %	(3.1)%

For 2013 compared to 2012, the change in amortization of acquired intangible assets was primarily driven by our acquisition of the TYSABRI rights from Elan and an increase in the amount of amortization recorded in relation to our AVONEX intangible asset. For 2012 compared to 2011, the change in amortization of acquired intangible assets was primarily driven by the decrease in the amount of amortization recorded in relation to our AVONEX intangible asset.

We amortize the intangible assets related to TYSABRI and AVONEX using the economic consumption method based on revenue generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenues of TYSABRI and AVONEX is performed annually during our long range planning cycle, which is generally updated in the third quarter of each year, and whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of TYSABRI or AVONEX. This analysis serves as the basis for the calculation of our economic consumption models used for these products. This analysis is based upon certain assumptions that we evaluate on a periodic basis, such as the anticipated product sales of AVONEX and TYSABRI, the expected impact of competitor products and our own commercial and pipeline product candidates, including TECFIDERA and PLEGRIDY, and the issuance of new patents or the extension of existing patents.

Our most recent long range planning cycle was updated in the third quarter of 2013, and included the impact of our acquisition of TYSABRI rights from Elan and a decrease in the expected future product revenues of AVONEX, resulting in an increase in amortization expense as compared to prior quarters. The results of our analysis were impacted by changes in the estimated impact of TECFIDERA, as well as other existing and potential oral and alternative MS formulations, including PLEGRIDY, that may compete with AVONEX and TYSABRI. Based upon this more recent analysis, the estimated future amortization for acquired intangible assets is expected to be as follows:

(In millions)	As of December 31, 2013
2014	$426.3
2015	336.4
2016	322.7
2017	327.5
2018	330.2
Total	$1,743.1

We monitor events and expectations regarding product performance. If there are any indications that the assumptions underlying our most recent analysis would be different than those utilized within our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenues of AVONEX and TYSABRI. The occurrence of an adverse event could substantially increase the amount of amortization expense associated with our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

Collaboration Profit Sharing

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Collaboration profit sharing	$85.4	$317.9	$317.8	(73.1)%	— %

Upon the closing of our acquisition of TYSABRI rights, our collaboration agreement was terminated, and we no longer record collaboration profit sharing. Collaboration profit sharing previously included the portion of rest of world net operating profits to be shared with Elan under the terms of our collaboration agreement for the development,

manufacture and commercialization of TYSABRI. The amount also included the reimbursement for our portion of third-party royalties paid by Elan on behalf of the collaboration relating to rest of world sales. For 2012 compared to 2011, collaboration profit sharing expense was consistent as a portion of our revenues recognized on sales of TYSABRI in Italy were deferred, as discussed under

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the heading Product Revenues - TYSABRI, resulting in rest of world net operating profits being lower, offset by unit volume revenue growth. For 2012 and 2011, our collaboration profit sharing expense included $53.2 million and $55.5 million, respectively, related to the reimbursement of third-party royalty payments made by Elan, which started to expire in 2013. For additional information about this collaboration, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
(Gain) loss on fair value remeasurement of contingent consideration	$(0.5)	$27.2	$36.1	(102.0)%	(24.6)%

The consideration for certain of our business combinations includes future payments that are contingent upon the occurrence of a particular factor or factors. For business combinations completed after January 1, 2009, we record an obligation for such contingent consideration payments at its fair value on the acquisition date. We revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration within our consolidated statements of income.

In connection with our acquisition of Stromedix, Inc. in March 2012, we recorded a contingent consideration obligation of $122.2 million. The fair value of this contingent consideration obligation as of December 31, 2013 and 2012 was $140.7 million and $135.3 million, respectively. For 2013 compared to 2012, the net increase in the fair value of this obligation was primarily due to changes in the discount rate and in the probability and expected timing related to the achievement of certain developmental milestones.

Upon completion of our purchase of the noncontrolling interest in our joint venture investments in Biogen Dompé SRL and Biogen Dompé Switzerland GmbH in September 2011, we recorded a contingent consideration obligation of $38.8 million. The fair value of this contingent consideration obligation as of December 31, 2013 and 2012 was $31.6 million and $29.8 million, respectively. For 2013 compared to 2012, the net increase in the fair value of this obligation was primarily due to changes in the probability and expected timing related to the achievement of certain cumulative sales-based and developmental milestones and in the discount rate. For 2012 compared to 2011, the net decrease in the fair value of this obligation was primarily due to changes in the probability and expected timing related to the achievement of certain cumulative sales-based and developmental milestones and in the discount rate as well as the payment of a $4.0 million regulatory approval milestone.

In connection with our acquisition of Biogen Idec International Neuroscience GmbH (BIN), formerly Panima Pharmaceuticals AG (Panima), in December 2010, we recorded a contingent consideration obligation of $81.2 million. The fair value of this contingent consideration obligation as of December 31, 2013 and 2012 was $108.6 million and $128.8 million, respectively. For 2013 compared to 2012, the net decrease in the fair value of this obligation was primarily due to changes in the probability and expected timing related to the achievement of certain remaining developmental milestones and in the discount rate as well as payments of $12.5 million in developmental milestones. For 2012 compared to 2011, the net increase in the fair value of this obligation was primarily due to changes in the discount rate and in the probability and expected timing related to the achievement of certain remaining developmental milestones, offset by a payment of a $2.5 million developmental milestone.

Restructuring Charges

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Restructuring charges	$—	$2.2	$19.0	(100.0)%	(88.3)%

For 2012 and 2011, restructuring charges were related to our 2010 restructuring initiative. In 2010 we announced a number of strategic, operational, and organizational initiatives designed to provide a framework for the future growth of our business and realign our overall structure to become a more efficient and cost effective organization. As part of this initiative:

- We out-licensed or terminated certain research and development programs, including those in oncology and cardiovascular medicine, that were no longer a strategic fit for us.

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- We completed a 13% reduction in workforce spanning our sales, research and development, and administrative functions.
- We vacated and recognized the sale of the San Diego, California facility as well as consolidated certain of our Massachusetts facilities.

As of December 31, 2012, all restructuring charges related to our 2010 initiative had been incurred and paid.

Gain on Sale of Rights

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Gain on sale of rights	$24.9	$46.8	$—	(46.8)%	**

During the third quarter of 2012, we sold all of our rights, including rights to royalties, related to BENLYSTA (belimumab). We were entitled to these rights pursuant to a license agreement with Human Genome Sciences, Inc. and GlaxoSmithKline plc (collectively the Licensees). Under the terms of the BENLYSTA sale agreement, we will receive payments equal to a multiple of royalties payable by the Licensees for the period covering October 2011 to September 2014 and a one-time contingency payment that could be paid to us if the cumulative royalties over the full royalty term exceed an agreed amount.

For 2013 compared to 2012, we recognized lower payments from the sale of our rights to BENLYSTA resulting from a lower multiple of sales being applied in 2013 as compared to 2012. The payments received during 2013 and 2012 covered the royalty period from October 1 to September 30. The remaining payments, which are contingent upon BENLYSTA sales over the period ending September 2014, will be recognized as the payments become due. For additional information related to this transaction, please read Note 3, Gain on Sale of Rights to our consolidated financial statements included in this report.

Other Income (Expense), Net

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Other income (expense), net	$(34.9)	$(0.7)	$(13.5)	**	(94.5)%

For 2013 compared to 2012, the change in other income (expense), net was due to a decrease in interest income due to lower average cash, cash equivalent and marketable securities balances primarily related to the use of cash in connection with our acquisition of TYSABRI rights from Elan and the repayment of our 6.0% Senior Notes, a decrease in other, net primarily related to higher non-income based state taxes and higher foreign exchange losses. For 2012 compared to 2011, the change in other income (expense), net was primarily due to an increase in interest income from the acceleration of interest imputed on originally discounted accounts receivables during the second quarter of 2012, which were collected in Spain in advance of original estimates, offset by an increase in interest expense due to a decrease in the amount of capitalized interest. Other income (expense), net in 2012 includes a gain of $9.0 million recognized upon our acquisition of Stromedix in March 2012, which was based on the value derived from the purchase price of our equity interest held in Stromedix prior to the acquisition. The amount in 2011 includes a gain of $13.8 million on the sale of stock from our strategic investments portfolio that was deemed no longer strategic.

For additional information related to our strategic investments, please read Note 9, Financial Instruments to our consolidated financial statements included in this report.

Income Tax Provision

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Effective tax rate on pre-tax income	24.2%	25.4%	26.0%	(4.7)%	(2.3)%
Income tax expense	$601.0	$470.6	$444.5	27.7%	5.9%

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Our effective tax rate fluctuates from year to year due to the global nature of our operations. The factors that most significantly impact our effective tax rate include variability in the allocation of our taxable earnings among multiple jurisdictions, changes in tax laws, the amount and characterization of our research and development expenses, the levels of certain deductions and credits, acquisitions, and licensing transactions.

Our effective tax rate for 2013 compared to 2012 decreased primarily as a result of a change in our uncertain tax position related to our U.S. federal manufacturing deduction and our unconsolidated joint business, described below under "Accounting for Uncertainty in Income Taxes", lower intercompany royalties owed by a foreign wholly owned subsidiary to a U.S. wholly owned subsidiary on the international sales of one of our products, the reinstatement of the federal research and development tax credit and the 2012 correction of an error in our deferred tax accounting, which increased our rate in the prior year. These favorable items were partially offset by higher relative earnings in the U.S. from the commercial launch of TECFIDERA, lower orphan drug credits due to reduced expenditures in eligible clinical trials and higher state taxes.

During 2013, we recorded a deferred charge of $203.7 million in connection with an intercompany transfer of the intellectual property for Daclizumab HYP. The deferred charge will be amortized to income tax expense over the economic life of the Daclizumab HYP program. If the Daclizumab HYP program were to be discontinued, we will accelerate the amortization of this deferred charge and record an expense equal to its remaining net book value.

Our effective tax rate for 2012 compared to 2011 decreased primarily as a result of higher orphan drug credits for our ELOCTATE, STX-100, dexpramipexole and other orphan credit eligible clinical trials, lower intercompany royalties owed by a foreign wholly owned subsidiary to a U.S. wholly owned subsidiary on the international sales of one of our products and higher deductions related to our manufacturing activities. These decreases were partially offset by the correction of an error which had accumulated over several years in our deferred tax accounting for capitalized interest which resulted in an expense of $29.0 million.

Accounting for Uncertainty in Income Taxes

During 2013, we received updated technical guidance from the IRS concerning our current and prior year filings and calculation of our U.S. federal manufacturing deduction and overall tax classification of our unconsolidated joint business. Based on this guidance we reevaluated the level of our unrecognized benefits related to uncertain tax positions, and recorded a $49.8 million income tax benefit. This benefit is for a previously unrecognized position and relates to years 2005 through 2012. We recorded an offsetting expense of $11.3 million for non-income based state taxes, which is recorded in other income (expense) within our consolidated statements of income.

For information on our state tax matter and additional information related to income taxes for 2013, 2012 and 2011, please read Note 17, Income Taxes to our consolidated financial statements included in this report.

Equity in Loss of Investee, Net of Tax

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Equity in loss of investee, net of tax	$17.2	$4.5	$—	281.2 %	**

In February 2012, we finalized an agreement with Samsung BioLogics Co. Ltd. that established an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. We account for this investment under the equity method of accounting. We recognize our share of the results of operations related to our investment in Samsung Bioepis one quarter in arrears. For 2013 compared to 2012, the increase in equity in loss of investee, net of tax was due to increased clinical trial activity. For additional information related to this transaction, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

On December 17, 2013, pursuant to our joint venture agreement with Samsung Biologics, we exercised our right to enter into an agreement with Samsung Bioepis to commercialize anti-TNF biosimilar product candidates in Europe. Under the terms of this agreement, we paid $21.0 million and accrued $15.0 million, which was recorded as research and development expense within our consolidated statements of income.

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Noncontrolling Interest

(In millions, except percentages)	For the Years Ended December 31, 2013	2012	2011	% Change 2013 compared to 2012	2012 compared to 2011
Net income attributable to noncontrolling interests, net of tax	$—	$—	$32.3	**	(100.0)%

For 2012 compared to 2011, the change in net income attributable to noncontrolling interests, net of tax, reflects a reduction in earnings from our foreign joint ventures due to our purchase of the noncontrolling interest in our joint venture investments described below. Amounts recognized during 2011 also reflect the attribution of a $10.0 million milestone payment to Knopp upon dosing the first patient in a registrational study for dexpramipexole as well as the attribution of a $15.0 million milestone payment to Neurimmune upon our submission of an IND application for BIIB037.

On September 6, 2011, we completed the purchase of the noncontrolling interest in our joint venture investments in Biogen Dompé SRL and Biogen Dompé Switzerland GmbH, our respective sales affiliates in Italy and Switzerland. Prior to this transaction, our consolidated financial statements reflected 100% of the operations of these joint venture investments and we recorded net income (loss) attributable to noncontrolling interests in our consolidated statements of income based on the percentage of ownership interest retained by our joint venture partners. We have continued to consolidate the operations of these entities following our purchase of the noncontrolling interest; however, as of September 6, 2011, we no longer allocate 50% of the earnings of these ventures to net income (loss) attributable to noncontrolling interests as Biogen Dompé SRL and Biogen Dompé Switzerland GmbH became wholly-owned subsidiaries of ours.

Market Risk

We conduct business globally. As a result, our international operations are subject to certain risks which may affect our results of operations, including volatility in foreign currency exchange rates or weak economic conditions in the foreign markets in which we operate.

Foreign Currency Exchange Risk

Our results of operations are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. While the financial results of our global activities are reported in U.S. dollars, the functional currency for most of our foreign subsidiaries is their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. Our net income may also fluctuate due to the impact of our foreign currency hedging program, which is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenues. We use foreign currency forward contracts to manage foreign currency risk with the majority of our forward contracts used to hedge certain forecasted revenue transactions denominated in foreign currencies in the next 18 months. For a more detailed disclosure of our hedges outstanding, please read Note 10, Derivative Instruments to our consolidated financial statements included in this report. Our ability to mitigate the impact of exchange rate changes on revenues and net income diminishes as significant exchange rate fluctuations are sustained over extended periods of time. Other foreign currency gains or losses arising from our operations are recognized in the period in which we incur those gains or losses.

Pricing Pressure

Governments in a number of international markets in which we operate, including Germany, France, Italy, the United Kingdom, Portugal and Spain, have implemented measures aimed at reducing healthcare costs to constrain the overall level of government expenditures. These implemented measures vary by country and include, among other things, mandatory rebates and discounts, prospective and possible retroactive price reductions and suspensions on pricing increases on pharmaceuticals. Certain implemented measures negatively impacted our revenues in 2012 and 2013. We expect to see continued efforts to achieve additional reductions in public expenditures and consequently our revenues and results of operations may be further negatively impacted if these, similar or more extensive measures are, or continue to be, implemented in these and other countries in which we operate.

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 impair our ability to obtain acceptable prices in existing and potential new markets and limit market growth. The continued implementation of pricing actions throughout Europe may also lead to higher levels of parallel trade.

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In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals and enactments to reform health care insurance programs could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the 2010 Patient Protection and Affordable Care Act (PPACA) have resulted in changes in the way health care is paid for by both governmental and private insurers, which has had and is expected to continue to have a significant impact on our business. These changes include, among other things, increased Medicare rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts. The U.S. federal government has also implemented spending cuts under the Budget Control Act of 2011, known as “sequestration”, which included a 2% reduction in Medicare reimbursement rates to providers such as physicians, hospitals and drug plans. These cuts, which reduce payments to health care providers for Medicare Part B drugs, could affect decisions regarding prescribing patterns or site of care, which could adversely impact sales of our products such as TYSABRI and RITUXAN, which are administered by infusion. In addition, Medicare Part D plans managing outpatient prescription drugs that are receiving less reimbursement from the government could seek further discounts from manufacturers, which could adversely affect our sales of our Part D drugs, such as AVONEX and TECFIDERA. It is possible that additional federal health care reform measures will be adopted in the future, including as a result of ongoing discussions to reduce the U.S. federal budget deficit to address government finances, any of which could result in increased pricing pressure and reduced reimbursement for our products and otherwise have an adverse impact on our financial position or results of operations.

There is also significant economic pressure on state budgets that 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 addition, under the PPACA, as states implement their health care marketplaces or operate under the federal exchange, the impact on drug manufacturers, including us, will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in these programs. It is possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our products for this patient population, which could have an adverse impact on our sales and results of operations.

Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance and credit worthiness of our large customers so that we can properly assess and respond to changes in their credit profile. We operate in certain countries where weakness in economic conditions has resulted in extended collection periods. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. Our historical write-offs of accounts receivable have not been significant.

Although our contractual payment terms have not changed, we noted greater volatility in the amount and timing of collections of accounts receivable balances in certain countries. In countries where we have experienced a pattern of payments extending beyond our contractual payment term and we expect to collect receivables greater than one year from the time of sale, we have discounted our receivables and reduced related revenues over the period of time that we estimate those amounts will be paid using the country’s market-based borrowing rate for such period. The related

receivables are classified at the time of sale as non-current assets.

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Within the European Union, our accounts receivable in Spain, Italy and Portugal continue to be subject to significant payment delays due to government funding and reimbursement practices. Uncertain credit and economic conditions have generally led to a lengthening of time to collect our accounts receivable in these countries, although these countries have introduced programs to pay down significantly overdue payables. Specifically during the fourth quarter of 2013, Portugal remitted approximately $10.0 million of funds against receivables aged greater than 2 years. Our net accounts receivable balances from product sales in Italy, Portugal and Spain totaled $217.2 million and $207.5 million as of December 31, 2013 and 2012, respectively, of which $17.4 million and $17.6 million were classified as non-current and included within investments and other assets within our consolidated balance sheets as of those dates. Approximately $45.9 million and $11.8 million of the aggregated balances for these three countries were overdue more than one year as of December 31, 2013 and 2012, respectively.

We believe that our allowance for doubtful accounts was adequate as of December 31, 2013 and 2012, respectively. However, if significant changes occur in the availability of government funding or the reimbursement practices of these or other governments, we may not be able to collect on amounts due to us from customers in such countries and our results of operations could be adversely affected.

Financial Condition and Liquidity

Our financial condition is summarized as follows:

	As of December 31,		% Change
(In millions, except percentages)	2013	2012	2013 compared to 2012
Financial assets:			
Cash and cash equivalents	$602.6	$570.7	5.6 %
Marketable securities — current	620.2	1,135.0	(45.4)%
Marketable securities — non-current	625.8	2,036.7	(69.3)%
Total cash, cash equivalents and marketable securities	$1,848.5	$3,742.4	(50.6)%
Borrowings:			
Current portion of notes payable and line of credit	$3.5	$453.4	(99.2)%
Notes payable and other financing arrangements	592.4	687.4	(13.8)%
Total borrowings	$595.9	$1,140.8	(47.8)%
Working Capital:			
Current assets	$3,184.9	$3,244.3	(1.8)%
Current liabilities	(1,758.3)	(1,657.4)	6.1 %
Total working capital	$1,426.6	$1,586.9	(10.1)%

For the year ended December 31, 2013, certain significant cash flows were as follows:

- $3.25 billion used for our acquisition of TYSABRI rights from Elan;
- $643.2 million in total payments for income taxes;
- $450.0 million used for the repayment of principal of our 6.0% Senior Notes;
- $400.3 million used for share repurchases;
- $246.3 million used for purchases of property, plant and equipment; and
- $100.0 million upfront payment made to Isis pursuant to our collaboration agreement dated September 2013.

For the year ended December 31, 2012, certain significant cash flows were as follows:

- $133.2 million in cash collections on accounts receivable balances in Spain and Portugal as part of new programs to resolve outstanding amounts long overdue;
- $67.5 million in proceeds from the issuance of stock for share-based compensation arrangements;
- $46.8 million in proceeds from the sale of our royalty and other rights to BENLYSTA;

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- $984.7 million used for share repurchases;
- $526.6 million in total payments for income taxes;
- $254.5 million used for purchases of property, plant and equipment;
- $72.4 million of net cash paid for the acquisition of Stromedix, Inc.;
- $71.0 million in upfront payments made to Isis, recognized as research and development expense, pursuant to our collaboration agreements dated January, June, and December 2012; and
- $32.1 million in contributions made to Samsung Bioepis.

We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. We expect to continue funding our current and planned operating requirements principally through our cash flows from operations, as well as our existing cash resources. We believe that our existing funds, when combined with cash generated from operations and our access to additional financing resources, if needed, are sufficient to satisfy our operating, working capital, strategic alliance, milestone payment, capital expenditure and debt service requirements for the foreseeable future. In addition, we may choose to opportunistically return cash to shareholders and pursue other business initiatives, including acquisition and licensing activities. We may, from time to time, also seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources should we identify a significant new opportunity.

The undistributed cumulative foreign earnings of certain of our foreign subsidiaries, exclusive of earnings that would result in little or no net income tax expense under current U.S. tax law or which has already been subject to tax under U.S. tax law, are invested indefinitely outside the U.S. During 2013, we completed our acquisition of TYSABRI rights using cash primarily located outside the U.S. Of the total cash, cash equivalents and marketable securities at December 31, 2013, approximately $300 million was generated from operations in foreign jurisdictions and is intended for use in our foreign operations or in connection with business development transactions outside of the U.S. In managing our day-to-day liquidity in the U.S., we do not rely on the unrepatriated earnings as a source of funds and we have not provided for U.S. federal or state income taxes on these undistributed foreign earnings. The residual U.S. tax liability, if cumulative amounts were repatriated, would be between $900 million to $1 billion as of December 31, 2013.

For additional information related to certain risks that could negatively impact our financial position or future results of operations, please read the “Risk Factors” and “Quantitative and Qualitative Disclosures About Market Risk” sections of this report.

Share Repurchase Programs

In February 2011, 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. In 2013, approximately 2.0 million shares were repurchased at a cost of $400.3 million.

We repurchased approximately 7.8 million shares at a cost of approximately $984.7 million under the 2011 authorization in 2012.

Approximately 4.2 million shares of our common stock remain available for repurchase under the 2011 authorization.

Cash, Cash Equivalents and Marketable Securities

Until required for another use in our business, we typically invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments and other interest bearing marketable debt instruments in accordance with our investment policy. It is our policy to mitigate credit risk in our cash reserves and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity, and investment type. We also limit our exposure to European sovereign debt securities and maintain no holdings with respect to certain euro-zone states, such as Portugal, Italy and Spain. The value of our investments, however, may be adversely affected by increases in interest rates, downgrades in the credit rating of the corporate bonds included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, and by other factors which may result in declines in the value of the investments. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio if the declines are other-than-temporary or sell investments for less than our acquisition cost which could adversely impact our financial position and our overall liquidity.

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The decrease in cash, cash equivalents and marketable securities from December 31, 2012 is primarily due to our acquisition of TYSABRI rights from Elan and the repayment of principal of our 6.0% Senior Notes, partially offset by net proceeds from sales and maturities of marketable securities and net cash flows provided by operating activities.

Borrowings

In March 2013, we entered into a $750.0 million senior unsecured revolving credit facility, which we may choose to use for working capital and general corporate purposes. The terms of this revolving credit facility include a financial covenant that requires us to not exceed a maximum debt to EBITDA ratio. This facility terminates in March 2014. As of December 31, 2013, we had no outstanding borrowings and were in compliance with all covenants under this facility.

On March 1, 2013, we repaid the $450.0 million principal amount of our 6.0% Senior Notes.

We have $550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 that were originally priced at 99.184% of par. The discount is amortized as additional interest expense over the period from issuance through maturity.

In connection with our 2006 distribution agreement with Fumedica, we issued notes totaling 61.4 million Swiss Francs which were payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica had a present value of 14.0 million Swiss Francs ($15.8 million) and 16.4 million Swiss Franc ($17.9 million) as of December 31, 2013 and 2012, respectively.

For a summary of the fair and carrying values of our outstanding borrowings as of December 31, 2013 and 2012, please read Note 8, Fair Value Measurements to our consolidated financial statements included in this report.

Working Capital

We define working capital as current assets less current liabilities. The decrease in working capital from December 31, 2012 reflects a decrease in total current assets of $59.4 million and an increase in total current liabilities of $100.9 million. The decrease in total current assets was primarily driven by our acquisition of TYSABRI rights from Elan, partially offset by an increase in inventory related to our AVONEX, TYSABRI and ELOCTATE programs and accounts receivable resulting from increased product revenue. The increase in total current liabilities primarily resulted from an increase in taxes payable and accrued expenses and other partially offset by the repayment of our 6.0% Senior Notes on March 1, 2013.

Cash Flows

The following table summarizes our cash flow activity:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2013	2012	2011	2013 compared to 2012	2012 compared to 2011
Net cash flows provided by operating activities	$2,345.1	$1,879.9	$1,727.7	24.7 %	8.8 %
Net cash flows used in by investing activities	$(1,604.7)	$(950.3)	$(1,650.3)	68.9 %	(42.4)%
Net cash flows used in financing activities	$(716.5)	$(877.5)	$(319.9)	(18.3)%	174.3 %

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures for the foreseeable future.

Operating cash flow is derived by adjusting our net income for:

- Non-cash operating items such as depreciation and amortization, impairment charges and share-based compensation charges;
- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
-

Changes associated with the fair value of contingent milestones associated with our acquisitions of businesses and payments related to collaborations.

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For 2013 compared to 2012, the increase in cash provided by operating activities is primarily driven by an increase in net income and taxes payable, partially offset by an increase in inventory related to our AVONEX, TYSABRI and ELOCTATE programs and accounts receivable resulting from increased product revenue.

For 2012 compared to 2011, the increase in cash provided by operating activities was driven by an increase in net income, primarily resulting from increased product revenue, and higher accrued balances offset by an increase in deferred income taxes and inventory balances.

Investing Activities

For 2013 compared to 2012, the increase in net cash flows used in investing activities is primarily due to $3,262.7 million used for our acquisition of TYSABRI rights from Elan, partially offset by net proceeds from sales and maturities of marketable securities.

For 2012 compared to 2011, the decrease in net cash flows used in investing activities is primarily due to a decrease in the net purchases of marketable securities offset by the net cash paid for the acquisition of Stromedix. Net purchases of marketable securities totaled $584.8 million in 2012, compared to $1,420.3 million in 2011.

Financing Activities

For 2013 compared to 2012, the decrease in net cash flows used in financing activities is primarily due to a decrease in the amount of our common stock we repurchased partially offset by the repayment of principal of our 6.0% Senior Notes.

For 2012 compared to 2011, the increase in net cash flows used in financing activities is due primarily to an increase in the amounts of our common stock we repurchased as well as a decrease in proceeds from the issuance of stock for share-based compensation arrangements. We received $67.5 million in 2012, compared to $314.7 million in 2011, related to stock option exercises and stock issuances under our employee stock purchase plan.

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2013, excluding amounts related to uncertain tax positions, amounts payable to tax authorities, funding commitments, contingent milestone payments, contingent payments, contingent consideration and our financing arrangements, as described below.

	Payments Due by Period				
(In millions)	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Non-cancellable operating leases (1), (2)	$611.7	$66.8	$109.6	$92.4	$342.9
Notes payable (3)	723.4	41.3	82.0	81.6	518.5
Purchase and other obligations (4)	188.7	165.2	22.1	1.4	—
Defined benefit obligation	42.6	—	—	—	42.6
Total contractual obligations	$1,566.4	$273.3	$213.7	$175.4	$904.0

(1) We lease properties and equipment for use in our operations. In addition to rent, the leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses. Amounts reflected within the table, detail future minimum rental commitments under non-cancelable operating leases as of December 31 for each of the periods presented.

(2) Includes future minimum rental commitments related to leases executed for two office buildings in Cambridge, Massachusetts, which completed construction in July and November 2013, net of sublease income expected to be received for the vacated portion of our Weston, MA facility. For additional information related to our leases, please read Note 11, Property, Plant and Equipment to our consolidated financial statements included in this report.

(3) Notes payable includes principal and interest payments.

(4) Purchase and other obligations include our obligations of approximately $23.5 million related to the fair value of net liabilities on derivative contracts, approximately $5.0 million related to fixed obligations for the purchase of natural gas and approximately $24.7 million related to obligations for communication services.

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Tax Related Obligations

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of December 31, 2013, we have approximately $99.4 million of liabilities associated with uncertain tax positions.

Other Funding Commitments

During the year ended December 31, 2013, we contributed the remaining 13.5 billion South Korean won (approximately $12.4 million) to Samsung Bioepis to complete our obligation to contribute an aggregate of approximately 49.5 billion South Korean won (approximately $45.0 million) for our 15 percent ownership interest of Samsung Bioepis. For additional information related to our relationship with Samsung Bioepis, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in this report.

As of December 31, 2013, we have funding commitments of up to approximately $14.0 million as part of our investment in biotechnology oriented companies and venture capital funds.

As of December 31, 2013, we have several on-going clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to clinical research organizations (CROs). The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses of approximately $28.2 million on our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2013. We have approximately $424.1 million in cancellable future commitments based on existing CRO contracts as of December 31, 2013.

Contingent Development and Commercial Milestone Payments

Based on our development plans as of December 31, 2013, we have committed to make potential future milestone payments to third parties of up to approximately $2.0 billion as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2013, such contingencies have not been recorded in our financial statements.

We anticipate that we may pay approximately $169.6 million of milestone payments in 2014, provided various development, regulatory or commercial milestones are achieved. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones. These milestones may not be achieved.

TYSABRI Contingent Payments

On April 2, 2013, we acquired full ownership of, and strategic, commercial and decision-making rights to, TYSABRI from Elan. Under the terms of the acquisition agreement, we continued to share TYSABRI profits with Elan on an equal basis until April 30, 2013. We recorded the profit split for the month ended April 30, 2013, as cost of sales within our consolidated statements of income as we controlled TYSABRI effective April 2, 2013. Commencing May 1, 2013 and for the first twelve months thereafter, we will make contingent payments to Elan of 12% on worldwide net sales of TYSABRI and, thereafter, 18% on annual worldwide net sales up to $2.0 billion and 25% on annual worldwide net sales that exceed $2.0 billion. In 2014, the $2.0 billion threshold will be pro-rated for the portion of 2014 remaining after the first 12 months expires. Royalty payments to Elan and other third parties are recognized as cost of sales within our consolidated statements of income.

Contingent Consideration related to Business Combinations

In connection with our purchase of the noncontrolling interests in our joint venture investments in Biogen Dompé SRL and Biogen Dompé Switzerland GmbH and our acquisitions of Stromedix, Biogen Idec International Neuroscience GmbH and Biogen Idec Hemophilia Inc., we agreed to make additional payments of up to approximately $1.0 billion based upon the achievement of certain milestone events. These milestones may not be achieved.

As the acquisitions of the noncontrolling interests in our joint venture investments and our acquisitions of Stromedix and Biogen Idec International Neuroscience GmbH, formerly Panima Pharmaceuticals AG, occurred after January 1, 2009, we record contingent consideration liabilities at their fair value on the acquisition date and revalue these obligations each reporting period. For additional information related to the acquisitions of the noncontrolling interests

in our joint venture investments and our acquisition of Stromedix please read Note 2, Acquisitions, to our consolidated financial statements included in this report.

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In connection with our acquisition of Biogen Idec Hemophilia Inc. (BIH), formerly Syntonix, in January 2007, we agreed to pay up to an additional $80.0 million if certain milestone events associated with the development of BIH's lead product, ALPROLIX are achieved. The first $40.0 million contingent payment was achieved in the first quarter of 2010. An additional $20.0 million contingent payment will occur if prior to the tenth anniversary of the closing date, the FDA grants approval of a Biologic License Application for ALPROLIX. A second $20.0 million contingent payment will occur if prior to the tenth anniversary of the closing date, a marketing authorization is granted by the EMA for ALPROLIX. For additional information related to our acquisition of BIH, please read Note 2, Acquisitions to our consolidated financial statements included in this report.

In 2006, we acquired Fumapharm AG. As part of this acquisition we acquired FUMADERM and TECFIDERA (together, Fumapharm Products). We paid $220.0 million upon closing of the transaction and agreed to pay an additional $15.0 million if a Fumapharm Product is approved for MS in the U.S. or E.U. In the second quarter of 2013, we paid this $15.0 million contingent payment as TECFIDERA was approved in the U.S. for MS by the FDA. We are also required to make the following additional contingent payments to former shareholders of Fumapharm AG based on the attainment of certain cumulative sales levels of Fumapharm Products and the level of total net sales of Fumapharm Products in the prior twelve month period, as defined in the acquisition agreement:

	Cumulative Sales Level				
Prior 12 Month Sales	$500M	$1.0B	$2.0B	$3.0B	Each additional $1.0B up to $20.0B
	Payment Amount (In millions)				
< $500 million	$—	$—	$—	$—	$—
$500 million - $1.0 billion	22.0	25.0	50.0	50.0	50.0
$1.0 billion - $1.5 billion	—	50.0	100.0	100.0	100.0
$1.5 billion - $2.0 billion	—	—	150.0	150.0	150.0
$2.0 billion - $2.5 billion	—	—	200.0	200.0	200.0
$2.5 billion - $3.0 billion	—	—	—	250.0	250.0
> $3.0 billion	—	—	—	—	300.0

For example, if we reach the $2.0 billion cumulative sales level related to the Fumapharm Products and our prior twelve month sales of the related products were between $1.0 million and $1.5 billion, then we will owe a $100.0 million contingent payment, and no further contingent payments will be required to be paid until such time as cumulative sales reach the next applicable cumulative sales level, or $3.0 billion in this example. These payments will be accounted for as an increase to goodwill as incurred, in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm. Any portion of the payment which is tax deductible will be recorded as a reduction to goodwill. Payments are due within 60 days following the end of the quarter in which the applicable cumulative sales level has been reached. During 2013, we accrued the $25.0 million contingent payment as we reached the $1.0 billion cumulative sales level related to the Fumapharm Products.

Financing Arrangement

In July 2011, we executed leases for two office buildings to be constructed in Cambridge, Massachusetts. Construction of these facilities began in late 2011. In accordance with accounting guidance applicable to entities involved with the construction of an asset that will be leased when the construction is completed, we were considered the owner of these properties during the construction period. Accordingly, we recorded an asset and a corresponding financing obligation on our consolidated balance sheet for the amount of costs incurred related to the construction for these buildings.

In July and November 2013, the construction of the two office buildings was completed and we started leasing the facilities. Upon completion of the construction of the buildings, we determined that we are no longer considered the owner of the buildings because we do not have any unusual or significant continuing involvement. Consequently, we derecognized the buildings and their associated financing obligation of approximately $161.5 million from our consolidated balance sheet. As of December 31, 2012, the amount recorded within our consolidated balance sheet as

property, plant and equipment and financing obligation totaled approximately $86.5 million.

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Other Off-Balance Sheet Arrangements

We do not have any relationships with entities often referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We consolidate variable interest entities if we are the primary beneficiary.

Legal Matters

For a discussion of legal matters as of December 31, 2013, please read Note 21, Litigation to our consolidated financial statements included in this report.

Critical Accounting Estimates

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP), requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. We evaluate our estimates, judgments and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition and Related Allowances

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; our price to the customer is fixed or determinable; and collectability is reasonably assured.

Product Revenues

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon delivery. Sales of TYSABRI in the U.S. were previously recognized on the “sell-through” model, upon shipment of the product by Elan to its third party distributor rather than upon shipment to Elan. As a result of our acquisition of TYSABRI rights from Elan on April 2, 2013, we began recognizing sales of TYSABRI in the U.S. when title and risk of loss passed to the same third party distributor. The timing of distributor orders and shipments can cause variability in earnings.

Revenues from Unconsolidated Joint Business

We collaborate with Genentech on the development and commercialization of RITUXAN. In addition, in the U.S. we share operating profits and losses relating to GAZYVA with Genentech. The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S. Revenues from unconsolidated joint business consists of (1) our share of pre-tax profits in the U.S. for RITUXAN and GAZYVA; (2) reimbursement of our selling and development expenses in the U.S. for RITUXAN; and (3) revenue on sales in the rest of world for RITUXAN, which consist of our share of pre-tax co-promotion profits in Canada and royalty revenue on sales outside the U.S. and Canada by F. Hoffmann-La Roche Ltd. (Roche) and its sublicensees. Pre-tax co-promotion profits on RITUXAN are calculated and paid to us by Genentech in the U.S. and by Roche in Canada. Pre-tax co-promotion profits consist of U.S. and Canadian net sales to third-party customers less the cost to manufacture, third-party royalty expenses, distribution, selling, and marketing expenses, and joint development expenses incurred by Genentech, Roche and us. We record our share of the pretax co-promotion profits on RITUXAN in Canada and royalty revenues on sales outside the U.S. on a cash basis as we do not have access to the information or ability to estimate these profits or royalty revenue in the period incurred. Additionally, our share of the pre-tax profits on RITUXAN and GAZYVA in the U.S. includes estimates made by Genentech and those estimates are subject to change. Actual results may ultimately differ from our estimates.

Reserves for Discounts and Allowances

We establish reserves for trade term discounts, wholesaler incentives, Medicaid and managed care rebates, VA and PHS discounts, product returns and other governmental discounts or applicable allowances associated with the implementation of pricing actions in certain of international markets in which we operate. 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,

industry data and forecasted customer buying patterns. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

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In addition to the discounts and rebates described above and classified as a reduction of revenue, we also maintain certain customer service contracts with distributors and other customers in the distribution channel that provide us with inventory management, data and distribution services. To the extent we can demonstrate a separable benefit and fair value for these services, we classify these payments within selling, general and administrative expenses.

Bad Debt Reserves

Bad debt reserves are based on our estimated uncollectible accounts receivable. Given our historical experience with bad debts, combined with our credit management policies and practices, we do not presently maintain significant bad debt reserves. However certain of our customers are based in countries where the economic conditions continue to present challenges. We continue to monitor these conditions and associated impacts on the financial performance and credit worthiness of our large customers so that we can properly assess and respond to changes in their credit profile.

Concentrations of Credit Risk

The majority of our receivables arise from product sales in the United States and Europe and are primarily due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance and credit worthiness of our large customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. The credit and economic conditions within many of the international markets in which we operate, particularly in certain countries throughout Europe, such as Italy, Spain and Portugal, remain uncertain. These conditions have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect on our accounts receivable outstanding in these countries.

In Portugal and select regions in Spain and Italy where our collections have slowed and a significant portion of these receivables are routinely being collected beyond our contractual payment terms and over periods in excess of one year, we have discounted our receivables and reduced related revenues based on the period of time that we estimate those amounts will be paid, to the extent such period exceeds one year, using the country’s market-based borrowing rate for such period. The related receivables are classified at the time of sale as non-current assets.

To date, we have not experienced any significant losses with respect to the collection of our accounts receivable. If economic conditions worsen and/or the financial condition of our customers were to further deteriorate, our risk of collectability may increase, which may result in additional allowances and/or significant bad debts.

For additional information related to our concentration of credit risk associated with our accounts receivable balances, please read the subsection above entitled “Credit Risk” in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Royalty Revenues

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

Clinical Trial Expenses

Clinical trial expenses include expenses associated with CROs. The invoicing from CROs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO activities based on our estimate of site management, monitoring costs, and project management costs. We maintain regular communication with our CROs to gauge the reasonableness of our estimates. Differences between actual clinical trial expenses and estimated clinical trial expenses recorded have not been material and are adjusted for in the period in which they become known.

We also accrue the costs of ongoing clinical trials associated with programs that have been terminated or discontinued for which there is no future economic benefit at the time the decision is made to terminate or discontinue the program.

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Consolidation of Variable Interest Entities

We consolidate variable interest entities in which we are the primary beneficiary. For such consolidated entities where we own or are exposed to less than 100% of the economics, we record noncontrolling interest in our statement of income for the current results allocated to the third party equity interests.

In determining whether we are the primary beneficiary of a variable interest entity, we consider a number of factors, including our ability to direct the activities that most significantly affect the entity's economic success, our contractual rights and responsibilities under the arrangement and the significance of the arrangement to each party. These considerations impact the way we account for our existing collaborative and joint venture relationships and may result in the future consolidation of companies or entities with which we have collaborative or other arrangements.

Inventory

Inventories are stated at the lower of cost or market with cost determined in a manner that approximates the first-in, first-out (FIFO) method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when selected for use in a clinical manufacturing campaign.

Capitalization of Inventory Costs

Our policy is to capitalize inventory costs associated with our products prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We consider numerous attributes in evaluating whether the costs to manufacture a particular product should be capitalized as an asset. We assess the regulatory approval process and where the particular product stands in relation to that approval process, including any known safety or efficacy concerns, potential labeling restrictions and other impediments to approval. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication in which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or delay commercialization. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize.

We expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or significant delay of approval by necessary regulatory bodies. There is a risk inherent in these judgments and any changes we make in these judgments may have a material impact on our results in future periods.

Obsolescence and Unmarketable Inventory

We periodically review our inventories for excess or obsolescence and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated by us, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Additionally, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. In the event that certain batches or units of product no longer meet quality specifications, we will record a charge to cost of sales to write-down any unmarketable inventory to its estimated net realizable value. In all cases, product inventory is carried at the lower of cost or its estimated net realizable value.

Acquired Intangible Assets, including In-process Research and Development (IPR&D)

Effective January 1, 2009, when we purchase a business, the acquired IPR&D is measured at fair value, capitalized as an intangible asset and tested for impairment at least annually until commercialization, after which time the IPR&D is amortized over its estimated useful life. If we acquire an asset or group of assets that do not meet the definition of a business under applicable accounting standards, the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

We have acquired, and expect to continue to acquire, intangible assets through the acquisition of biotechnology companies or through the consolidation of variable interest entities. These intangible assets primarily consist of technology associated with human therapeutic products and in-process research and development product candidates. When significant identifiable intangible assets are acquired, we generally engage an independent third-party valuation

firm to assist in determining the fair values of these assets as of the acquisition date. Management will determine the fair value of less significant identifiable intangible assets acquired. Discounted cash flow models are typically used in these valuations, and these models require the use of significant estimates and assumptions including but not limited to:

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

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

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

If these projects are not successfully developed, the sales and profitability of the company may be adversely affected in future periods. Additionally, the value of the acquired intangible assets may become impaired. We believe that the foregoing assumptions used in the IPR&D analysis were reasonable at the time of the respective acquisition. No assurance can be given, however, that the underlying assumptions used to estimate expected project sales, development costs or profitability, or the events associated with such projects, will transpire as estimated.

Impairment and Amortization of Long-lived Assets and Accounting for Goodwill

Long-lived Assets Other than Goodwill

Long-lived assets to be held and used, including property, plant and equipment as well as intangible assets, including IPR&D and trademarks, totaled approximately $6,225.4 million as of December 31, 2013. Property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. We review our intangible assets with indefinite lives for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

When performing our impairment assessment, we have the option to first assess qualitative factors to determine whether it is necessary to recalculate the fair value of our intangible assets with indefinite lives. If we elect this option and believe, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of our intangible assets with indefinite lives is less than its carrying amount, we calculate the fair value using the same methodology as described above. If the carrying value of our intangible assets with indefinite lives exceeds its fair value, then the intangible asset is written-down to its fair values. Alternatively, we may elect to not first assess qualitative factors and immediately recalculate the fair value of our intangible assets with indefinite lives.

Our most significant intangible assets are our acquired and in-licensed rights and patents and developed technology. Acquired and in-licensed rights and patents primarily relates to our acquisition of TYSABRI rights from Elan. Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. We amortize the intangible assets related to TYSABRI and AVONEX using the economic consumption method based on revenue generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenues of TYSABRI and AVONEX is performed annually during our long range planning cycle, which is generally updated in the third quarter of each year, and whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of TYSABRI or AVONEX. This analysis serves as the basis for the calculation of our economic consumption models used for these products. This analysis is based upon certain assumptions that we evaluate on a periodic basis, such as the anticipated product sales of AVONEX and TYSABRI, the expected impact of competitor products and our own commercial and pipeline product candidates, including TECFIDERA and PLEGRIDY, and the issuance of new patents or the extension of existing patents.

We monitor events and expectations regarding product performance. If there are any indications that the assumptions underlying our most recent analysis would be different than those utilized within our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenues of AVONEX and TYSABRI. The occurrence of an adverse event could substantially increase the amount of amortization expense associated with our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

Impairment charges related to our long-lived assets during 2013, 2012 and 2011 were immaterial.

Goodwill

Goodwill totaled approximately $1,232.9 million as of December 31, 2013, and relates largely to amounts that arose in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation. Our goodwill balances represent the difference between the purchase price and the fair value of the identifiable tangible and intangible net

assets when accounted for using the purchase method of accounting.

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We assess our goodwill balance within our single reporting unit annually, as of October 31, and whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. We have the option to first assess qualitative factors to determine whether it is necessary to perform the two-step impairment test. If we elect this option and believe, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of our reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. Alternatively, we may elect to not first assess qualitative factors and immediately perform the quantitative two-step impairment test. In the first step, we compare the fair value of our reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of our reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of our reporting unit's goodwill. If the carrying value of our reporting unit's goodwill exceeds its implied fair value, then we would record an impairment loss equal to the difference.

We completed our required annual impairment test in the fourth quarter of 2013, 2012 and 2011 and determined in each of those periods that the carrying value of goodwill was not impaired. In each year, the fair value of our reporting unit, which includes goodwill, was significantly in excess of the carry value of our reporting unit.

Investments, including Fair Value Measures and Impairments

We invest in various types of securities, including short-term and long-term marketable securities, principally corporate notes, government securities including government sponsored enterprise mortgage-backed securities and credit card and auto loan asset-backed securities, in which our excess cash balances are invested.

In accordance with the accounting standard for fair value measurements we have classified our financial assets as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset.

As noted in Note 8, Fair Value Measurements to our consolidated financial statements, a majority of our financial assets have been classified as Level 2. These assets have been initially valued at the transaction price and subsequently valued utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

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

Impairment

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected within earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not

expect to receive cash flows sufficient to recover the amortized cost basis of a security and are reflected within earnings as an impairment loss.

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Royalty Cost of Sales

We make royalty payments to a number of third parties under license or purchase agreements associated with our acquisition of intellectual property. These royalty payments are typically calculated as a percentage (royalty rate) of the sales of our products within a particular year. That royalty rate may remain constant, increase or decrease within each year based on the total amount of sales during the annual period. Each quarterly period we estimate our total royalty obligation for the full year and recognize the proportional amount as cost of sales based on actual quarterly sales as a percentage of full year estimated sales. For example, if the level of net sales in any calendar year increases the royalty rate within the year, we will record our cost of sales at an even rate over the year, based on the estimated blended royalty rate.

Share-Based Compensation

We make certain assumptions in order to value and record expense associated with awards made under our share-based compensation arrangements. Changes in these assumptions may lead to variability with respect to the amount of expense we recognize in connection with share-based payments.

Determining the appropriate valuation model and related assumptions requires judgment, and includes estimating the expected market price of our stock on vesting date and stock price volatility as well as the term of the expected awards. Determining the appropriate amount to expense based on the anticipated achievement of performance targets requires judgment, including forecasting the achievement of future financial targets. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made throughout the performance as appropriate. The cumulative impact of any revision is reflected in the period of change. We also estimate forfeitures over the requisite service period when recognizing share-based compensation expense based on historical rates and forward-looking factors; these estimates are adjusted to the extent that actual forfeitures differ, or are expected to materially differ, from our estimates.

Contingent Consideration

For acquisitions completed after January 1, 2009, we record contingent consideration resulting from a business combination at its fair value on the acquisition date. Each reporting period thereafter, we revalue these obligations and record increases or decreases in their fair value as an adjustment to contingent consideration expense within the consolidated statement of income. Changes in the fair value of the contingent consideration obligations can result from adjustments to the discount rates and achievement and timing of any cumulative sales-based and development milestones, or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above, could have a material impact on the amount of contingent consideration expense we record in any given period.

Income Taxes

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

All tax effects associated with intercompany transfers of assets within our consolidated group, both current and deferred, are recorded as a prepaid tax or deferred charge and recognized through the consolidated statement of income when the asset transferred is sold to a third party or otherwise recovered through amortization of the asset's remaining economic life. If the asset transferred becomes impaired, for example through the discontinuation of a research program, we will expense any remaining deferred charge or prepaid tax.

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We account for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors, that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the "more-likely-than-not" threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews; we have no plans to appeal or litigate any aspect of the tax position; and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

We earn a significant amount of our operating income outside the U.S. As a result, a portion of our cash, cash equivalents, and marketable securities are held by foreign subsidiaries. We currently do not intend or foresee a need to repatriate these funds. We expect existing domestic cash, cash equivalents, marketable securities and cash flows from operations to continue to be sufficient to fund our domestic operating activities and cash commitments for investing and financing activities for the foreseeable future.

As of December 31, 2013, our non-U.S. subsidiaries' undistributed foreign earnings included in consolidated retained earnings and other basis differences aggregated approximately $3.8 billion. All undistributed foreign earnings of non-U.S. subsidiaries, exclusive of earnings that would result in little or no net income tax expense or which were previously taxed under current U.S. tax law, are reinvested indefinitely in operations outside the U.S. This determination is made on a jurisdiction by jurisdiction basis and takes into the account the liquidity requirements in both the U.S. and within our foreign subsidiaries.

If we decide to repatriate funds in the future to execute our growth initiatives or to fund any other liquidity needs, the resulting tax consequences would negatively impact our results of operations through a higher effective tax rate and dilution of our earnings. The residual U.S. tax liability, if cumulative amounts were repatriated, would be between $900 million to $1 billion as of December 31, 2013.

Contingencies

We are currently involved in various claims and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation and may revise our estimates. These revisions in the estimates of the potential liabilities could have a material impact on our consolidated results of operations and financial position.

New Accounting Standards

For a discussion of new accounting standards please read Note 1, Summary of Significant Accounting Principles to our consolidated financial statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We have operations or maintain distribution relationships in the U.S., Europe, Middle East, Canada, Central and South America, Australia, New Zealand, Japan, China, India and elsewhere in Asia in connection with the sale of AVONEX and TYSABRI and in Germany in connection with the sale of FUMADERM. TECFIDERA is commercially available in the U.S., Canada and Australia. FAMPYRA is commercially available throughout the European Union and in Canada, Australia, New Zealand, Israel and South Korea. In addition, we receive royalty revenues based on worldwide product sales by our licensees and through Genentech on sales of RITUXAN in the rest of world. As a result, our financial position, results of operations and cash flows can be affected by market fluctuations in foreign

exchange rates, primarily with respect to the Euro, Canadian dollar, Swiss franc, Danish krone, Swedish krona, British pound, and Japanese yen.

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We use foreign currency forward contracts to manage foreign currency risk but do not engage in currency speculation. The majority of our forward contracts are used to hedge certain forecasted revenue transactions denominated in foreign currencies. We also use forward contracts to mitigate the foreign currency exposure related to certain balance sheet items. We have not elected hedge accounting for the balance sheet related items.

The following quantitative information includes the impact of currency movements on forward contracts used in both programs. As of December 31, 2013 and 2012, a hypothetical adverse 10% movement in foreign exchange rates compared to the U.S. dollar across all maturities (for example, a strengthening of the Euro) would result in a hypothetical decrease in the fair value of forward contracts of approximately $101.6 million and $76.7 million, respectively. Our use of this methodology to quantify the market risk of such instruments should not be construed as an endorsement of its accuracy or the accuracy of the related assumptions. The quantitative information about market risk is limited because it does not take into account all foreign currency operating transactions.

In addition, the fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2013 and 2012, we estimate that such hypothetical adverse 100 basis point movement would result in a hypothetical loss in fair value of approximately $5.7 million and $23.8 million, respectively, to our interest rate sensitive instruments.

The returns from cash, cash equivalents and marketable securities will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease interest income by approximately $10.3 million and $17.5 million as of December 31, 2013 and 2012, respectively.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-69 of this report and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of December 31, 2013. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Management's Annual Report on Internal Control over Financial Reporting

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 1992 Internal Control — Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2013, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information concerning our executive officers is set forth under the heading “Our Executive Officers” in Part I of this report. The text of our code of business conduct, which includes the code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.biogenidec.com, under the “Corporate Governance” subsection of the “About Us” section of the site. We intend to make all required disclosures regarding any amendments to, or waivers from, provisions of our code of business conduct at the same location of our website. 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 response to the remainder of this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Proposal 1 - Election of Directors,” “Corporate Governance,” “Stock Ownership - Section 16(a) Beneficial Ownership Reporting Compliance” and “Miscellaneous - Stockholder Proposals” contained in the proxy statement for our 2014 annual meeting of stockholders.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Executive Compensation and Related Information” and “Corporate Governance” contained in the proxy statement for our 2014 annual meeting of stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Stock Ownership” and “Equity Compensation Plan Information” contained in the proxy statement for our 2014 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Certain Relationships and Related Person Transactions” and “Corporate Governance” contained in the proxy statement for our 2014 annual meeting of stockholders.

Item 14. Principal Accountant Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto in the section entitled “Proposal 2 — Ratification of the Selection of our Independent Registered Public Accounting Firm” contained in the proxy statement for our 2014 annual meeting of stockholders.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

a. (1) Consolidated Financial Statements:

The following financial statements are filed as part of this report:

(2) Financial Statement Schedules

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

(3) Exhibits

The exhibits listed on the Exhibit Index beginning on page A-1, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

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SIGNATURES

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

BIOGEN IDEC INC.

By: /S/ GEORGE A. SCANGOS
George A. Scangos
Chief Executive Officer

Date: February 6, 2014

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

Name	Capacity	Date
/S/ GEORGE A. SCANGOS George A. Scangos	Director and Chief Executive Officer (principal executive officer)	February 6, 2014
/S/ PAUL J. CLANCY Paul J. Clancy	Executive Vice President, Finance and Chief Financial Officer (principal financial officer)	February 6, 2014
/S/ GREGORY F. COVINO Gregory F. Covino	Vice President, Finance, Chief Accounting Officer (principal accounting officer)	February 6, 2014
/S/ WILLIAM D. YOUNG William D. Young	Director and Chairman of the Board of Directors	February 6, 2014
/S/ ALEXANDER J. DENNER Alexander J. Denner	Director	February 6, 2014
/S/ CAROLINE D. DORSA Caroline D. Dorsa	Director	February 6, 2014
/S/ NANCY L. LEAMING Nancy L. Leaming	Director	February 6, 2014
/S/ RICHARD C. MULLIGAN Richard C. Mulligan	Director	February 6, 2014
/S/ ROBERT W. PANGIA Robert W. Pangia	Director	February 6, 2014
/S/ STELIOS PAPADOPOULOS Stelios Papadopoulos	Director	February 6, 2014
/S/ BRIAN S. POSNER Brian S. Posner	Director	February 6, 2014
/S/ ERIC K. ROWINSKY Eric K. Rowinsky	Director	February 6, 2014
/S/ LYNN SCHENK Lynn Schenk	Director	February 6, 2014
/S/ STEPHEN A. SHERWIN Stephen A. Sherwin	Director	February 6, 2014

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BIOGEN IDEC INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

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BIOGEN IDEC INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share amounts)

	For the Years Ended December 31,		
	2013	2012	2011
Revenues:			
Product, net	$5,542,331	$4,166,074	$3,836,117
Unconsolidated joint business	1,126,017	1,137,923	996,597
Other	263,851	212,464	215,920
Total revenues	6,932,199	5,516,461	5,048,634
Cost and expenses:			
Cost of sales, excluding amortization of acquired intangible assets	857,726	545,494	466,780
Research and development	1,444,053	1,334,919	1,219,602
Selling, general and administrative	1,712,051	1,277,465	1,056,133
Amortization of acquired intangible assets	342,948	202,204	208,566
Collaboration profit sharing	85,357	317,895	317,771
(Gain) loss on fair value remeasurement of contingent consideration	(547)	27,202	36,065
Restructuring charges	—	2,225	19,026
Total cost and expenses	4,441,588	3,707,404	3,323,943
Gain on sale of rights	24,898	46,792	—
Income from operations	2,515,509	1,855,849	1,724,691
Other income (expense), net	(34,930)	(744)	(13,477)
Income before income tax expense and equity in loss of investee, net of tax	2,480,579	1,855,105	1,711,214
Income tax expense	601,014	470,554	444,528
Equity in loss of investee, net of tax	17,224	4,518	—
Net income	1,862,341	1,380,033	1,266,686
Net income attributable to noncontrolling interests, net of tax	—	—	32,258
Net income at			