BIOGEN IDEC INC.
Form 10-K
February 09, 2010

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

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 0-19311
Biogen Idec Inc.
(Exact name of registrant as specified in its charter)

Delaware	**33-0112644**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
14 Cambridge Center, Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	*(Zip code)*

(617) 679-2000
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.0005 par value	**The Nasdaq Global Select Market**

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

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

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

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 o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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 o	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o 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 $13,005,469,098.

As of February 5, 2010, the registrant had 269,601,262 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

BIOGEN IDEC INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2009

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this report contains forward-looking statements that are based on our current beliefs and expectations. These forward-looking statements do not relate strictly to historical or current facts and they may be accompanied by such words as anticipate, believe, estimate, expect, forecast, intend, may, plan, will and other words and terms of similar meaning. Reference is made in particular to forward-looking statements regarding:

- the anticipated level, mix and timing of future product sales, royalty revenues, milestone payments, expenses, liabilities, contractual obligations and amortization of intangible assets;
- the growth trends for TYSABRI and our ability to improve the benefit-risk profile of TYSABRI;
- the assumed remaining life of the core technology relating to AVONEX;
- the markets for our products;
- competitive conditions and the development, timing and impact of competitive products;
- the incidence, timing, outcome and impact of litigation, proceedings related to patents and other intellectual property rights, tax assessments and other legal proceedings;
- our effective tax rate for future periods, our ability to realize the benefits of our deferred tax assets and the treatment of our undistributed foreign earnings of our non-U.S. subsidiaries;
- the timing and impact of accounting standards;
- the design, costs, development and timing of therapeutic areas and indications targeted by programs in our clinical pipeline;
- the outcome and impact of healthcare reform efforts;
- the timing and outcome of regulatory filings and meetings with regulatory authorities;
- our ability to finance our operations, meet our manufacturing needs and source funding for such activities;
- the impact that our Weston facility will have on our operating expenses and the timing of occupancy;
- the status, intended use and financial impact of our manufacturing facilities;
- our share repurchase programs;
- the drivers for growing our business; and
- our plans to expend additional funds and resources on external business development and research opportunities.

These forward-looking statements are based on our current beliefs and expectations and involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking

statements. Important factors that could cause actual results to differ from our expectations and could negatively impact our financial position and results of operations are discussed in the Risk Factors section of this report and elsewhere in this report.

Forward-looking statements, like all statements in this report, speak only as of the date of this report, unless another date is indicated. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Throughout this report, Biogen Idec, we, us and our refer to Biogen Idec Inc. and its consolidated subsidiaries, RITUXAN refers 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).

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NOTE REGARDING TRADEMARKS

AVONEX®, RITUXAN® and ADENTRI® are registered trademarks, and FUMADERM™ is a trademark of Biogen Idec Inc. or its subsidiaries. TYSABRI® and TOUCH® are registered trademarks of Elan Pharmaceuticals, Inc.;. The following are trademarks of the respective companies listed:
ACTEMRA® Chugai Seiyaku Kabushiki Kaisha; AMPYRA™ Acorda Therapeutics, Inc.; ANGIOMAX® and ANGIOX® The Medicines Company; ARZERRA™ Glaxo Group Limited; BETASERON® and BETAFERON® Bayer Schering Pharma AG; CAMPATH® Genzyme Corporation; CIMZIA® UCB Pharma, S.A.; COPAXONE® Teva Pharmaceutical Industries Limited; ENBREL® Immunex Corporation; EXTAVIA® Novartis AG; HUMIRA® Abbott Biotechnology Ltd.; ONCOVIN™ Eli Lilly and Company; ORENCIA® Bristol-Myers Squibb Company; REBIF® Ares Trading S.A.; REMICADE® Centocor Ortho Biotech Inc.; SIMPONI™ Johnson & Johnson; and TREANDA® Cephalon, Inc.

NOTE REGARDING REFERENCES TO THE CODIFICATION

In June 2009, the Financial Accounting Standards Board (FASB), issued the FASB Accounting Standards Codification (Codification). Effective July 1, 2009, the Codification became the single source for all authoritative generally accepted accounting principles (GAAP), recognized by the FASB and is required to be applied to financial statements issued for interim and annual periods ending after September 15, 2009. The Codification does not change GAAP and did not impact our financial position or results of operations; however the Codification does change the way we refer to GAAP within our financial statements.

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PART I

Item 1. *Business*

Overview

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

Marketed Products

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

Product	Summary of Approved Indications	Revenues to Biogen Idec (in millions) 2009	2008	2007
AVONEX (interferon beta-1a)	Multiple sclerosis	$ 2,322.9	$ 2,202.6	$ 1,867.8
RITUXAN (rituximab)	Non-Hodgkin s lymphoma Rheumatoid arthritis	$ 1,094.9	$ 1,128.2	$ 926.1
TYSABRI (natalizumab)	Multiple sclerosis Crohn s disease	$ 776.0	$ 588.6	$ 229.9
FUMADERM (dimethylfumarate and monoethylfumarate salts)	Psoriasis	$ 49.6	$ 43.4	$ 21.5

Additional financial information about our product revenues, other revenues and geographic areas in which we operate is set forth in our Consolidated Financial Statements and in Note 20, *Segment Information* to our Consolidated Financial Statements.

Research and Development

We devote significant resources to research and development programs and external business development opportunities. We intend to focus our research and development efforts on finding novel therapeutics in areas of high unmet medical need within our core and emergent focus areas of neurology, oncology, immunology, cardiopulmonary and hemophilia.

In 2009, 2008 and 2007, our research and development costs totaled $1,283.1 million, $1,072.1 million and $925.2 million, respectively. We incurred charges associated with acquired in-process research and development of $25.0 million and $84.2 million in 2008 and 2007 respectively. No acquired in-process research and development charges were incurred in 2009.

CEO Retirement

On January 4, 2010, we announced that James C. Mullen will retire as our President and Chief Executive Officer on June 8, 2010, and will retire from our Board of Directors upon the completion of his current term as a director at our 2010 Annual Meeting of Stockholders. We entered into a transition agreement with Mr. Mullen on January 4, 2010, which is filed as an exhibit to this report. Under the transition agreement, we agreed with Mr. Mullen (1) to continue to pay Mr. Mullen s current base salary of $1.2 million through June 8, 2010, (2) to pay Mr. Mullen a bonus for 2009 calculated as 125% of his 2009 base salary of $1.2 million multiplied by our corporate multiplier for 2009 determined based on our achievement of goals established at the beginning of 2009, (3) to pay Mr. Mullen a bonus for 2010 calculated as 125% of his prorated base salary, (4) to vest all of Mr. Mullen s unvested equity awards on the date of his retirement, (5) to allow Mr. Mullen to exercise his vested stock options until June 8, 2013 or their expiration, whichever is earlier, and (6) that if we make a public announcement of a transaction that constitutes a change in control prior to June 8, 2010, Mr. Mullen will be entitled to a severance payment in the

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amount of three times the sum of his annual base salary and target bonus and a related tax payment provided under his employment agreement upon consummation of the transaction. We have initiated a search for Mr. Mullen s successor.

Available Information

We were formed as a California corporation in 1985 and became a Delaware corporation in 1997. Our principal executive offices are located at 14 Cambridge Center, Cambridge, Massachusetts 02142 and our telephone number is (617) 679-2000. Our website address is www.biogenidec.com. We make available free of charge through the Investor Relations section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (SEC). We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this filing.

Marketed Products

Our marketed products address the following diseases: multiple sclerosis (MS); non-Hodgkin s lymphoma (NHL); rheumatoid arthritis (RA); Crohn s disease (CD); and psoriasis. As part of our ongoing development efforts, we are also seeking to expand our marketed products into other diseases, such as Antineutrophil cytoplasmic antibodies (ANCA) associated vasculitis, chronic lymphocytic leukemia (CLL), and ulcerative colitis. The approved indications for, and ongoing development of, our marketed products are summarized in the table below. Drug development involves a high degree of risk, and the status, timing and scope of our clinical trials, drug approvals and applications for approval are subject to change. Important factors that could adversely affect our drug development efforts are discussed in the Risk Factors section of this report.

Product	Approved or Targeted Indications	Status	Development or Marketing Collaborators
AVONEX	Relapsing MS	Approved in U.S. and numerous other countries worldwide	None
	Ulcerative colitis	Phase 2	None
RITUXAN(1)	NHL	Approved in U.S. and numerous other countries worldwide	Roche Group and its sublicensees
	RA	Approved in U.S. and numerous other countries worldwide	Roche Group and its sublicensees
	CLL	In U.S. registration	Roche Group and its sublicensees
	ANCA-associated vasculitis	Phase 2/3	Roche Group (Our rights are limited to U.S.)
TYSABRI(2)	Relapsing MS		Elan Pharmaceuticals

		Approved in U.S. and numerous other countries worldwide	
	CD	Approved in U.S.	Elan Pharmaceuticals
FUMADERM	Severe psoriasis	Approved in Germany	None

(1) RITUXAN is indicated for the treatment of (1)(a) relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent, (b) previously untreated follicular, CD20-positive, B-cell NHL in combination with cyclophosphamide, vincristine and prednisone (CVP) chemotherapy, (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 cyclophosphamide, doxorubicin, Oncovin and prednisone or other anthracycline-based chemotherapy regimens and (2) moderately- to severely-active RA, in combination with methotrexate, in adult patients who have inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

(2) TYSABRI is indicated for the treatment of (1) relapsing MS as a monotherapy and (2) moderately to severely active CD with evidence of inflammation with an inadequate response to or inability to tolerate conventional CD therapies and TNF inhibitors.

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AVONEX

AVONEX is one of the leading therapeutic products for relapsing forms of MS with over 135,000 patients currently using AVONEX. MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis and, in some cases, death. Patients with active relapsing MS experience an uneven pattern of disease progression characterized by periods of stability that are interrupted by flare-ups of the disease after which the patient returns to a new baseline of functioning. AVONEX is a recombinant form of the interferon beta protein produced in the body in response to viral infection. AVONEX has been shown in clinical trials in relapsing MS both to slow the accumulation of disability and to reduce the frequency of flare-ups.

2009 Developments

In September 2009, we were issued a U.S. patent for the use of 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 multiple sclerosis with AVONEX.

In April 2009, we announced data results from an open label, ten-year extension study of MS patients, known as CHAMPIONS, indicating that early treatment with AVONEX reduces relapse rates and may reduce disease progression for up to ten years.

RITUXAN

RITUXAN is one of the most prescribed oncology therapeutics in the world with over 2.1 million patient exposures across all indications. RITUXAN is a monoclonal antibody that is used worldwide to treat NHL and RA. NHL is a cancer that affects lymphocytes, which are a type of white blood cell that help to fight infection. RA is a chronic disease that occurs when the immune system mistakenly attacks the body s joints, resulting in inflammation, pain and joint damage.

We collaborate with the Roche Group, through its wholly-owned member Genentech, Inc., on the development and commercialization of RITUXAN. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

2009 Developments

In November 2009, the U.S. Food and Drug Administration (FDA) issued a complete response on applications for RITUXAN plus fludarabine and cyclophosphamide for the treatment of people with CLL, a cancer that affects white blood cells. The FDA has not requested any new data to complete its review of these applications. We and Genentech have engaged in final label discussions with the FDA and expect to finalize these discussions during the first quarter of 2010.

In October 2009, we announced that the FDA issued a complete response indicating that they did not believe that approval could be supported for RITUXAN in RA patients with an inadequate response to non-biological disease modifying agents.

In October 2009, data from a Phase 2/3 clinical trial of RITUXAN in ANCA-associated vasculitis, known as RAVE, was presented at the American College of Rheumatology. The trial met its primary endpoint of noninferiority, showing that RITUXAN is as effective as cyclophosphamide in treating ANCA-associated

vasculitis, a type of inflammation of the blood vessels.

In September 2009, we announced that a Phase 3 study showed that RITUXAN provided significant clinical benefit to patients with low-grade follicular lymphoma who were treated with RITUXAN as maintenance therapy after primary treatment with RITUXAN and chemotherapy.

In March 2009, we announced that a Phase 3 study of RITUXAN in lupus nephritis did not meet its primary endpoint.

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TYSABRI

We believe that TYSABRI is one of the most efficacious treatments for MS. TYSABRI is a monoclonal antibody (natalizumab) that was initially approved by the FDA in November 2004 to treat relapsing MS. In February 2005, in consultation with the FDA, we and our collaborator Elan Corporation plc (Elan) voluntarily suspended the marketing and commercial distribution of TYSABRI based on reports of cases of progressive multifocal leukoencephalopathy (PML) in patients treated with TYSABRI in clinical studies. PML is an opportunistic viral infection of the brain that often leads to death or severe disability. In July 2006, TYSABRI was reintroduced in the U.S., and introduced in the European Union, as a monotherapy treatment for relapsing MS. TYSABRI is also approved in the U.S. to treat CD, which is an inflammatory disease of the intestines.

TYSABRI is marketed under risk management or minimization plans as agreed to with local regulatory authorities. In the U.S., TYSABRI was reintroduced with a risk minimization action plan known as the TOUCH Prescribing Program, a rigorous system intended to educate physicians and patients about the risks involved and to assure appropriate use of the product.

We collaborate with Elan on the development and commercialization of TYSABRI. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

2009 Developments

In November 2009, we revised the U.S. prescribing information for TYSABRI to reflect that the risk of developing PML increases with longer treatment duration, and for patients treated for 24 to 36 months is generally similar to the rates seen in clinical trials. The revised label also reflects that there is limited experience beyond three years of treatment.

In the fourth quarter 2009, the European Medicines Agency (EMA) began a review of TYSABRI to determine whether any additional measures were necessary to ensure the safe use of TYSABRI. In January 2010, the EMA recommended updating the TYSABRI label in the E.U. to reflect that the risk of PML increases after two years of therapy. The EMA also recommended that patients have regular MRI scans and be re-informed of the risk of PML after two years on therapy.

FUMADERM

FUMADERM is the most prescribed oral systemic treatment for severe psoriasis in Germany. Psoriasis is a skin disease in which cells build up on the skin surface and form scales and red patches.

Other Sources of Revenue

We receive royalty revenues on sales by our licensees of other products covered under patents that we own. We have also sold or exclusively licensed to third parties rights to certain products previously included within our product line. Royalty or supply agreement revenues received based upon those products are recorded as corporate partner revenue.

Our royalty revenues are dependent upon our licensees sales of licensed products which could vary significantly due to competition, manufacturing difficulties and other factors that are outside our control. In addition, the expiration or invalidation of any underlying patents could reduce or eliminate the royalty revenues derived from such patents. Royalties on sales of ANGIOMAX (bivalirudin) by The Medicines Company (TMC) represent our most significant source of other revenue. TMC markets ANGIOMAX primarily in the U.S. and the European Union for use as an anticoagulant in patients undergoing percutaneous coronary intervention. Please read the subsection entitled Other

Revenue Royalty Revenues in the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this report for a description of this royalty arrangement and factors that could adversely effect this portion of our revenues.

In 2009, 2008 and 2007, our royalty revenues totaled $124.4 million, $116.2 million and $102.1 million, respectively, and our corporate partner revenues totaled $5.1 million, $13.4 million and $6.6 million, respectively. Additional financial information about our product revenues, other revenues and geographic areas in which we operate is set forth in our Consolidated Financial Statements and in Note 20, *Segment Information* to our Consolidated Financial Statements.

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Registrational Product Candidates

In addition to the ongoing development of our marketed products, we currently have a number of product candidates in or near registrational stage development. Drug development involves a high degree of risk, and the status, timing and scope of our clinical trials, drug approvals and applications for approval are subject to change. Important factors that could adversely affect our drug development efforts are discussed in the Risk Factors section of this report.

BG-12

BG-12 is an oral compound that is being tested in relapsing MS. During 2009, we completed patient enrollment in two Phase 3 trials of BG-12 in relapsing MS, known as DEFINE and CONFIRM, with the CONFIRM trial including a glatiramer acetate (COPAXONE) reference comparator arm. Both studies have a two year treatment period with each study involving approximately 1,200 to 1,500 patients worldwide. The FDA has granted BG-12 fast track status, which may result in an expedited review.

Daclizumab

Daclizumab is a monoclonal antibody that is being tested in relapsing MS. A Phase 2b trial of daclizumab in MS, known as SELECT, is currently underway. The SELECT trial has a one year treatment period and is expected to involve approximately 600 patients worldwide. The SELECT trial is the first of two registrational trials required by regulatory authorities. We expect to begin patient enrollment in a Phase 3 trial of daclizumab in relapsing MS, known as DECIDE, during the first half of 2010. The DECIDE trial has a two year treatment period and is expected to involve approximately 1,400 patients worldwide. The DECIDE trial is the second registrational trial required by regulatory authorities.

We collaborate with Facet Biotech Corporation (Facet) on the development and commercialization of daclizumab. In January 2010, we agreed with our collaborator, Facet, to assume the manufacture of daclizumab and began the process of transferring from Facet the manufacturing technology necessary for us to manufacture daclizumab. Any delay in completing or implementing such transfer could adversely affect the timing of our daclizumab trials. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

Fampridine

Fampridine is an oral compound that is being developed as a treatment to improve walking ability in people with MS. In December 2009, we filed for approval of fampridine in the European Union and Canada for this indication. Fampridine was approved in the U.S. on January 22, 2010 under the trade name AMPYRA (dalfampridine). AMPYRA is indicated to improve walking in patients with MS. This was demonstrated by an increase in walking speed. Acorda is developing and marketing AMPYRA in the U.S. We collaborate with Acorda on the development and commercialization of fampridine in markets outside the U.S. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

GA101

GA101 is a monoclonal antibody that is being tested in CLL. During the second half of 2009, we began patient enrollment in a Phase 3 trial of GA101 in combination with chlorambucil as compared to rituximab plus chlorambucil or chlorambucil alone in patients with previously untreated CLL. The study is designed to have a treatment period of approximately 6 months, with a minimum five year follow-up period, and involve approximately 800 patients

worldwide.

We collaborate with the Roche Group, through its wholly-owned member Genentech, on the development and commercialization of GA101. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

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Humanized Anti-CD20 MAb (ocrelizumab)

Ocrelizumab is a monoclonal antibody that is being tested in RA. We and Genentech initiated four Phase 3 trials evaluating ocrelizumab in RA, known as SCRIPT, FEATURE, STAGE and FILM, and a Phase 2 trial known as CINEMA.

The SCRIPT study will evaluate the efficacy and safety of ocrelizumab, compared with placebo, in patients with active RA who have an inadequate response to at least one anti-TNF-alpha therapy. This study has a one year treatment period and involves approximately 800 patients worldwide.

In January 2010, we and Genentech determined that the FEATURE study, which evaluated a single infusion of ocrelizumab versus placebo (with dual infusions as an active control) in seropositive RA patients with an inadequate response to prior therapies, did not meet its primary efficacy endpoint as a single infusion.

In December 2009, we and Genentech announced that STAGE, which evaluated ocrelizumab in combination with methotrexate, met its primary endpoint of improving signs and symptoms (as measured by criteria, known as the ACR 20 response, established by the American College of Rheumatology) in RA patients who had an inadequate response to methotrexate at both 24 and 48 weeks.

In October 2009, a safety review of ocrelizumab data in RA and lupus nephritis (LN) clinical trials was performed revealing an apparent imbalance in opportunistic infections among ocrelizumab-treated RA and LN patients in these clinical trials. Based upon this review, redosing was stopped in FILM, which evaluated ocrelizumab given in combination with methotrexate to methotrexate naïve RA patients. Redosing was also stopped in the Asia Pacific region for the SCRIPT, FEATURE and STAGE studies.

The CINEMA study will evaluate the efficacy and safety of ocrelizumab in combination with methotrexate compared with infliximab plus methotrexate in patients with active RA who have an inadequate response to certain anti-TNF-alpha therapies. This study has a treatment period of approximately 6 months and involves approximately 300 patients.

We collaborate with the Roche Group, through its wholly-owned member Genentech, on the development and commercialization of ocrelizumab. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

Lixivaptan

Lixivaptan is an oral compound that is being tested in hyponatremia, an electrolyte disorder that contributes to negative patient outcomes in congestive heart failure and many other chronic diseases. Three Phase 3 trials of lixivaptan in hyponatremia are currently underway. These studies have a 60 day or six month treatment period and involve approximately 100 to 650 patients worldwide.

We collaborate with Cardiokine Biopharma LLC on the development and commercialization of lixivaptan. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

Long-Acting rFactor IX

Long-acting recombinant Factor IX (Factor IX) is a proprietary long-acting Factor IX product that is being tested in hemophilia B, a disorder in which blood clotting is impaired. In January 2010, we began patient enrollment in a Phase 2b/3 trial of Factor IX in hemophilia B, known as B-LONG. This study has a 14 month treatment period and will

involve approximately 75 patients. Factor IX has received orphan drug designation for the treatment of hemophilia B from both the FDA and EMA.

We collaborate with Swedish Orphan Biovitrum AB (Biovitrum) on the development and commercialization of Factor IX. Please read Note 17, *Collaborations* to our Consolidated Financial Statements for a description of this collaboration.

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PEGylated interferon beta-1a

PEGylated interferon beta-1a is designed to prolong the effects and reduce the dosing frequency of interferon beta-1a. During the first half of 2009, we began patient enrollment in a Phase 3 trial of PEGylated interferon beta-1a in relapsing MS, known as ADVANCE. The study is designed to have a two year treatment period and involve approximately 1,200 patients worldwide. The FDA has granted PEGylated interferon beta-1a fast track status, which may result in an expedited review.

Former Registrational Programs

Based upon the October 2009 safety review of ocrelizumab data in RA and LN clinical trials described above, we decided to close the ocrelizumab BELONG study in LN. The SCRIPT study of ocrelizumab in RA described above remains ongoing. We plan to work with regulators to determine the next step for this program.

In October 2009, after a strategic review of our Anti-CD80 MAb (galiximab) and Anti-CD23 MAb (lumiliximab) programs, we decided to stop recruitment in the lumiliximab LUCID trial in CLL and end the galiximab TARGET trial in NHL. Neither decision was a consequence of any safety concerns. We are evaluating our options for these programs.

In December 2009, we determined to close our ADENTRI clinical trial for the treatment of acute decompensated heart failure with renal insufficiency after reviewing preliminary results from the trial.

Other Research and Development Programs

We intend to continue to commit significant resources to research and development opportunities, focusing on novel therapeutics in areas of high unmet medical need. Highlighted below are several of our development programs that currently are not in registrational trials. Drug development involves a high degree of risk, 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	Status	Development or Marketing Collaborators
Neurology	BIIB014	Parkinson s disease early and late stage	Phase 2	
	Ocrelizumab	MS	Phase 2	Roche Group
	Neublastin	Neuropathic pain	Phase 1	
	LINGO	MS	Phase 1	
	BART	Alzheimer s Disease	Preclinical	Neurimmune SubOne AG
Oncology	Hsp90 Inhibitor (CNF2024)	Solid tumors gastrointestinal stromal tumors	Phase 2	
	GA101	NHL	Phase 2	

			Roche Group (Our rights are limited to U.S.)
Anti-CD80 MAb (galiximab)	NHL	Phase 2	
Anti-CD23 MAb (lumiliximab)	CLL	Phase 2	
Anti-IGF-1R (BIIB022)	Solid tumors liver cancer	Phase 2	
Volociximab (M200)	Non-small cell lung cancer	Phase 1	Facet Biotech Corporation
Anti-CRIPTO	Solid tumors	Phase 1	
RAF Inhibitor (BIIB024)	Solid tumors	Preclinical	
Anti-Fn14	Solid tumors	Preclinical	