

BIOGEN IDEC INC.
Form DEFA14A
April 15, 2008

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
SCHEDULE 14A**

Proxy Statement Pursuant to Section 14(a) of the Securities
Exchange Act of 1934 (Amendment No.)

Filed by the Registrant ☐

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

☐ Definitive Proxy Statement

☐ Definitive Additional Materials

☐ Soliciting Material Pursuant to §240.14a-11(c) or §240.14a-12

Biogen Idec Inc.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

☐ No fee required.

☐ Fee computed on table below per Exchange Act Rules 14a-6(i)(4) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

☐ Fee paid previously with preliminary materials.

☐ Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

MEDIA CONTACTS:

Biogen Idec
Shannon Altimari
Ph: 617 914 6524

Elan
Jonathan Birt
Ph: 212 850 5664

Elizabeth Headon
Ph: + 353 1 498 0300

INVESTOR CONTACTS:

Biogen Idec
Eric Hoffman
Ph: 617 679 2812

Elan
Chris Burns
Ph: + 353 1 709 4444
800 252 3526

BIOGEN IDEC AND ELAN PRESENT NEW TYSABRI[®] DATA AT THE 60th ANNUAL MEETING OF THE AMERICAN ACADEMY OF NEUROLOGY

*Approximately 26,000 Patients on Commercial and Clinical Therapy Worldwide
Additional Analyses Show TYSABRI Significantly Increased the Proportion of Multiple
Sclerosis (MS) Patients Who are Considered Disease Free for Over Two Years*

Chicago, IL April 15, 2008 Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced new data on the global utilization, safety and overall patient exposure of TYSABRI[®] (natalizumab). As of the end of March 2008, approximately 26,000 patients were on commercial and clinical therapy worldwide with no cases of progressive multifocal leukoencephalopathy (PML) reported since re-launch in the U.S. and launch internationally in July 2006. Growth in global utilization plus increasing confidence in the favorable benefit-risk profile of TYSABRI indicate the companies are making great progress toward the goal of 100,000 patients on therapy by year-end 2010. These data were presented today at the 60th Annual Meeting of the American Academy of Neurology (AAN).

These data suggest that neurologists and patients are increasingly choosing TYSABRI for the treatment of their disease. The significant clinical benefits are established and TYSABRI continues to offer the potential for compelling efficacy and hope for those patients living with MS, said Michael Panzara, MD, MPH, Vice President and Chief Medical Officer, Neurology Strategic Business Unit, Biogen Idec.

Positive outcomes for patients continue to support TYSABRI's strength as a valuable treatment for multiple sclerosis patients in more than 30 countries around the world. We are also excited that patients with Crohn's Disease are now enrolling in the TOUCH program and beginning to receive TYSABRI treatment in the U.S., said Gordon Francis, MD, Senior Vice President, Global Clinical Development, Elan.

According to data available as of the end of March 2008:

- In the U.S., approximately 15,300 patients were on TYSABRI therapy commercially and approximately 2,750 physicians have prescribed the therapy;

- Outside of the U.S., more than 10,200 patients were on TYSABRI therapy commercially;

- In global clinical trials, more than 600 patients were on TYSABRI therapy; and

- There have been no cases of PML since re-launch in the US and launch internationally in July 2006.

Cumulatively, in the combined clinical trial and post-marketing settings:

- More than 36,700 patients have been treated with TYSABRI; and

- Of those patients, over 9,900 have received at least one year of TYSABRI therapy and more than 3,600 patients have been on therapy for 18 months or longer.

TYSABRI is available in the U.S. through the TOUCH Prescribing Program. All U.S. prescribers, infusion sites, and patients receiving TYSABRI are required to enroll in TOUCH. Safety information is also collected through ongoing clinical trials and registries, including TYGRIS and the pregnancy registry, making this the largest long-term patient follow-up effort undertaken for any MS therapy.

The abstract for this study, Natalizumab Utilization and Safety in Patients with Relapsing Multiple Sclerosis: Updated Results from TOUCH and TYGRIS (Presentation #S02.002), is available online at the AAN's Web site.

TYSABRI Increases the Proportion of MS Patients Considered Disease Free

Biogen Idec and Elan also announced today at the meeting that TYSABRI treatment significantly increases the proportion of patients with MS considered to be disease free, according to post-hoc analyses of the AFFIRM and SENTINEL clinical trials. The proportion of patients considered disease free in the studies was determined based upon both clinical and MRI criteria. In the studies, the proportion of patients considered disease free over two years was significantly higher in the TYSABRI-treated group compared with the placebo group, regardless of how disease free was defined.

Clinically, disease free was defined as no relapses and no progression of disability (as defined by ≥ 1.0 -point increase in Expanded Disability Status Scale (EDSS) score from a baseline score of ≥ 1.0 , or a ≥ 1.5 -point increase from a baseline score of 0.0, sustained for 12 weeks) over two years. MRI disease free was defined as no gadolinium-enhancing lesions seen on annual MRI scans and no new or enlarging T2-hyperintense lesions over two years.

The ultimate goal of an MS treatment is to help patients remain symptom free for as long as possible. These data show natalizumab may do just that as about one-third of patients were

shown to have no relapses, no disability progression and no new MRI markers. This is further evidence that treatment with natalizumab can result in truly dramatic outcomes for a large group of patients, said the study's lead author, Steven Galetta, MD, Professor of Neurology, University of Pennsylvania School of Medicine.

In the AFFIRM trial, patients were randomized to receive TYSABRI or placebo, while in the SENTINEL trial, randomized patients received TYSABRI plus interferon beta-1a or placebo plus interferon beta-1a. Over a two-year period, patients were evaluated utilizing clinical criteria, MRI criteria and combined criteria with both trials demonstrating TYSABRI treatment significantly increased the proportions of patients considered disease free. Using clinical and MRI disease-free criteria combined, a stringent definition of disease free, 36.7% and 31.7% of patients in the TYSABRI groups were disease free compared with 7.2% and 10.9% given placebo in the AFFIRM and SENTINEL trials, respectively. By individual criteria, TYSABRI benefit was also demonstrated using clinical (AFFIRM: 64.3% vs. 38.9%; SENTINEL: 47.4% vs. 28.0%) and MRI definitions of disease free (AFFIRM: 57.7% vs. 14.2%; SENTINEL: 65.5% vs. 27.6%). In both studies, results were similar in patients with highly-active and non-highly active MS.

The abstract for this study, *Natalizumab Increases the Proportion of Patients Free of Clinical or MRI Disease Activity in Relapsing Multiple Sclerosis* (Poster #P02.156), is available online at the AAN's Web site.

About TOUCH and TYGRIS

Before initiating treatment, all U.S. patients, prescribers and infusion sites must be enrolled in the TOUCH Prescribing Program (TYSABRI Outreach: Unified Commitment to Health). TOUCH is designed to determine the incidence of and risk factors for serious opportunistic infections (OIs), including PML, and to monitor patients for signs and symptoms of PML while promoting informed benefit-risk discussions prior to initiating TYSABRI treatment. Physicians report on PML, other serious OIs, deaths and discontinuation of therapy on an ongoing basis. TYGRIS (TYSABRI Global Observation Program In Safety) is expected to enroll 5,000 patients worldwide, including approximately 2,000–2,500 patients from TOUCH. Patients in TYGRIS are evaluated at baseline and every six months thereafter for five years. Researchers will evaluate data including medical/MS history; prior TYSABRI use; prior use of immunomodulatory, antineoplastic, or immunosuppressive agents; and all serious adverse events, including PML and other serious OIs and malignancies.

Adverse event reporting in the post-marketing setting is voluntary. It is possible that not all reactions have been reported, or that some reactions are not reported to Biogen Idec or Elan in a timely manner.

About TYSABRI

TYSABRI is a treatment approved for relapsing forms of MS in the United States and relapsing-remitting MS in the European Union. According to data that have been published in the *New England Journal of Medicine*, after two years, TYSABRI treatment led to a 68% relative reduction ($p<0.001$) in the annualized relapse rate compared to placebo and reduced the relative risk of disability progression by 42-54% ($p<0.001$).

TYSABRI was recently approved to induce and maintain clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Other serious adverse events that have occurred in TYSABRI-treated patients included hypersensitivity reactions (e.g., anaphylaxis) and infections. Serious opportunistic and other atypical infections have been observed in TYSABRI-treated patients, some of whom were receiving concurrent immunosuppressants. Herpes infections were slightly more common in patients treated with TYSABRI. In MS and CD clinical trials, the incidence and rate of other serious adverse events, including serious infections, were similar in patients receiving TYSABRI and those receiving placebo. Common adverse events reported in TYSABRI-treated MS patients include headache, fatigue, infusion reactions, urinary tract infections, joint and limb pain and rash. Other common adverse events reported in TYSABRI-treated CD patients include respiratory tract infections and nausea. Clinically significant liver injury has been reported in patients treated with TYSABRI in the post-marketing setting.

TYSABRI is approved in more than 30 countries including the United States and many countries throughout the European Union, as well as Switzerland, Canada, Australia, New Zealand and Israel.

For more information about TYSABRI please visit www.tysabri.com, www.biogenidec.com or www.elan.com or call 1-800-456-2255.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Elan

Elan Corporation, plc is a neuroscience-based biotechnology company committed to making a difference in the lives of patients and their families by dedicating itself to bringing innovations in science to fill significant unmet medical needs that continue to exist around the world. Elan shares trade on the New York, London and Dublin Stock Exchanges. For additional information about the company, please visit www.elan.com.

Safe Harbor/Forward-Looking Statements

This press release contains forward-looking statements regarding TYSABRI. These statements are based on the companies' current beliefs and expectations. The commercial potential of TYSABRI is subject to a number of risks and uncertainties. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that we may be unable to adequately address concerns or questions raised by the FDA or other regulatory

authorities, that concerns may arise from additional data, that the incidence and/or risk of PML or other opportunistic infections in patients treated with TYSABRI may be higher than observed in clinical trials, that the companies may encounter other unexpected hurdles, or that new therapies for MS with better efficacy or safety profiles or more convenient methods of administration are introduced into the market. Drug development and commercialization involves a high degree of risk.

For more detailed information on the risks and uncertainties associated with the companies' drug development and other activities, see the periodic and current reports that Biogen Idec and Elan have filed with the Securities and Exchange Commission. The companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Biogen Idec Important Information

Biogen Idec and its directors, executive officers and other members of its management and employees may be deemed to be participants in the solicitation of proxies from the stockholders of Biogen Idec in connection with the Company's 2008 annual meeting of stockholders. Information concerning the interests of participants in the solicitation of proxies will be included in any proxy statement filed by Biogen Idec in connection with the Company's 2008 annual meeting of stockholders. In addition, Biogen Idec files annual, quarterly and special reports with the Securities and Exchange Commission (the "SEC"). The proxy statements and other reports, when available, can be obtained free of charge at the SEC's web site at www.sec.gov or from Biogen Idec at www.biogenidec.com. Biogen Idec stockholders are advised to read carefully any proxy statement filed in connection with the Company's 2008 annual meeting of stockholders when it becomes available before making any voting or investment decision. The Company's proxy statement will also be available for free by writing to Biogen Idec Inc., 14 Cambridge Center, Cambridge, MA 02142. In addition, copies of the proxy materials may be requested from our proxy solicitor, Innisfree M&A Incorporated, by toll-free telephone at (877) 750-5836 or by e-mail at info@innisfreema.com.