Table of Contents

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): February 18, 2004

# Biogen Idec Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **0-19311** | **33-0112644** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**14 Cambridge Center, Cambridge, Massachusetts 02142**
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code: **(617) 679-2000**

**Not Applicable**
(Former name or former address, if changed since last report)

**TABLE OF CONTENTS**

**ITEM 5. OTHER EVENTS AND REGULATION FD DISCLOSURE.**

On February 18, 2004, the Registrant and Elan Corporation, plc publicly disseminated a joint press release announcing that they intend to submit to the U.S. Food and Drug Administration an application for approval of ANTEGREN® (natalizumab) as a treatment for multiple sclerosis in mid-year 2004. The information contained in the press release is incorporated herein by reference and filed as Exhibit 99.1 hereto.

**ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.**

(c) Exhibits.

99.1 The Registrant's Press Release dated February 18, 2004.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Biogen Idec Inc.
(Registrant)

Date: February 19, 2004

/s/ Anne Marie Cook

Anne Marie Cook
Vice President, Chief Corporate Counsel

EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 99.1 | The Registrant's Press Release dated February 18, 2004. |

**Exhibit 99.1**

**For More Information Contact:**


**MEDIA CONTACTS:**

| | |
|---|---|
| Biogen Idec | Elan |
| Amy Brockelman Ph: 617 914 6524 | Anita Kawatra Ph: 212 407 5755 |

**INVESTOR CONTACTS:**

| | |
|---|---|
| Biogen Idec | Elan |
| Elizabeth Woo Ph: 617 679 2812 | Emer Reynolds Ph: 353 1 709 4000 |


**BIOGEN IDEC AND ELAN ANNOUNCE INTENTION TO SUBMIT ANTEGREN® FOR APPROVAL FOR MULTIPLE SCLEROSIS BASED ON ONE-YEAR DATA**

**Cambridge, MA, San Diego, CA and Dublin, Ireland (February 18, 2004) –** Biogen Idec and Elan Corporation, plc today announced that they expect to submit to the U.S. Food and Drug Administration (FDA) an application for approval of ANTEGREN® (natalizumab) as a treatment for multiple sclerosis (MS). The companies expect to submit the filing mid-year 2004.

The decision to file a Biologics License Application (BLA) was made after discussions with the FDA of one-year data from the two ongoing two-year Phase III trials in MS. The companies are committed to completing the two-year trials. To protect the integrity of the trials, the companies are not disclosing the one-year data at this time.

Biogen Idec and Elan are collaborating equally on the development of natalizumab for MS, Crohn's disease, and rheumatoid arthritis.

**About the ANTEGREN MS Clinical Trials**

The AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 900 patients, evaluating the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses. The SENTINEL (safety and efficacy of natalizumab in combination with AVONEX® (Interferon beta-1a)) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing the progression of disability and reducing the rate of clinical

relapses. Both studies have protocols that included a one-year analysis of the data. The primary endpoints for both Phase III two-year trials in MS are based on the Expanded Disability Status Scale (EDSS) and relapse rates. The pre-specified primary endpoint of the one-year analysis was relapse rates.

**About ANTEGREN (natalizumab)**

Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new SAM (selective adhesion molecule) inhibitor class. The drug was designed to selectively inhibit immune cells from leaving the bloodstream and to prevent these cells from migrating into chronically inflamed tissue as occurs in a variety of inflammatory diseases. To date, approximately 2,800 patients have received natalizumab in clinical studies. In previous clinical trials, the following adverse events occurred more commonly with natalizumab when compared to placebo: headache, nausea, abdominal pain, infection, urinary tract infection, pharyngitis and rash. Serious adverse events have included infrequent hypersensitivity-like reactions.

**About Biogen Idec**

Biogen Idec (NASDAQ: BIIB) creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labeling, press releases and additional information about the company, please visit http://www.biogenidec.com.

**About Elan**

Elan Corporation, plc (NYSE: ELN) is focused on the discovery, development, manufacturing, selling and marketing of novel therapeutic products in neurology, severe pain and autoimmune diseases. Elan shares trade on the New York, London and Dublin Stock Exchanges. For additional information about the company, please visit http://www.elan.com.

**Safe Harbor/Forward Looking Statements**

*This press release contains forward-looking statements regarding the companies' intent to file with the FDA for approval of ANTEGREN (natalizumab) and the potential of ANTEGREN as a treatment for MS. These statements are based on the companies' current beliefs and expectations. Drug development involves a high degree of risk. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that unexpected concerns may arise from additional data or analysis or that regulatory authorities may require additional information or further studies or that the companies may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with the companies' drug development and other activities, see the periodic reports of IDEC Pharmaceuticals Company, Biogen, Inc. and Elan Corporation, plc 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.*