# 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): March 30, 2005

# Biogen Idec Inc.

(Exact name of registrant as specified in its charter)

**Delaware**(State or other jurisdiction of incorporation)

**0-19311** (Commission File Number)

**33-0112644** (I.R.S. Employer Identification No.)

14 Cambridge Center, Cambridge, Massachusetts

(Address of principal executive offices)

**02142** (Zip Code)

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

#### Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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#### **Item 7.01 Regulation FD Disclosure**

As a result of the voluntary suspension of the marketing of TYSABRI® (natalizumab) by Biogen Idec Inc., or the Company, and Elan Corporation plc, or Elan, as announced in a press release issued on February 28, 2005 (included as Exhibit 99.1 of the Company's Current Report on Form 8-K filed on March 3, 2005), and the development announced in the press release referenced in Item 8.01 of this Current Report, investors should no longer rely upon the financial guidance that the Company announced in a press release issued on February 7, 2005 (included as Exhibit 99.1 of the Company's Current Report on Form 8-K furnished on February 7, 2005).

#### **Item 8.01 Other Events**

On March 30, 2005, the Company and Elan publicly disseminated a press release announcing that their ongoing safety evaluation of TYSABRI has led to the revision of a previously reported diagnosis of malignant astrocytoma to progressive multifocal leukoencephalopathy in a patient in an open-label clinical study of TYSABRI in Crohn's disease. The information contained in the press release is incorporated herein by reference and filed as Exhibit 99.1 hereto.

#### **Item 9.01 Financial Statements and Exhibits**

- (c) Exhibits.
  - 99.1 The Registrant's Press Release dated March 30, 2005.

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## **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.

By: /s/ Anne Marie Cook
Anne Marie Cook
Acting General Counsel

Date: March 31, 2005

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# EXHIBIT INDEX

Exhibit Number Description

99.1 The Company's Press Release dated March 30, 2005.





# For More Information Contact: MEDIA CONTACTS:

Biogen Idec: Jose Juves Ph: 617 914 6524

Elan: Anita Kawatra or Brian McGlynn Ph: 212 407 5740 or 800 252 3526

# INVESTOR CONTACTS:

Biogen Idec: Elizabeth Woo

Ph: 617 679 2812

Elan: Emer Reynolds

Ph: 353 1 709 4000800 252 3526

#### ELAN AND BIOGEN IDEC ANNOUNCE TYSABRI® UPDATE

**Dublin, Ireland and Cambridge, MA – March 30, 2005** – Elan Corporation, plc (NYSE: ELN) and Biogen Idec (NASDAQ: BIIB) announced today that their ongoing safety evaluation of TYSABRI® (natalizumab) has led to a previously diagnosed case of malignant astrocytoma being reassessed as progressive multifocal leukoencephalopathy (PML), in a patient in an open label Crohn's disease clinical trial.

In light of the two previously reported cases of PML in multiple sclerosis clinical trials, Elan and Biogen Idec initiated an additional comprehensive safety evaluation of TYSABRI clinical trial patients. In the course of this safety review, the companies identified a case warranting reassessment in an open label Crohn's disease clinical trial. In July 2003, the case was reported by a clinical trial investigator as malignant astrocytoma. This diagnosis was confirmed at the time by histopathology. The patient died in December 2003.

As part of this ongoing safety review, the companies, in agreement with the clinical trial investigator, reassessed the case. Following this additional evaluation, the diagnosis is being reassessed as PML. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents.

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#### Page 2 Elan and Biogen Idec Announce Tysabri® Update

Elan and Biogen Idec's comprehensive safety evaluation concerning TYSABRI and any possible link to PML is ongoing. The companies are reviewing clinical trial data, working with investigators to evaluate the approximately 3,000 patients in multiple sclerosis, Crohn's disease, and rheumatoid arthritis trials, and working with PML and neurology experts. The results of this safety evaluation will be discussed with regulatory agencies to determine possible reinitiation of dosing in clinical trials and future commercial availability.

On February 28, 2005, the companies announced that they had suspended marketing of TYSABRI in multiple sclerosis and dosing in all clinical trials based on two previously reported cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system.

#### About Elan

Elan Corporation, plc is a neuroscience-based biotechnology company. We are committed to making a difference in the lives of patients and their families by dedicating ourselves 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 <a href="http://www.elan.com">http://www.elan.com</a>.

#### **About Biogen Idec**

Biogen Idec 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 <a href="http://www.biogenidec.com">http://www.biogenidec.com</a>.

#### **Safe Harbor/Forward Looking Statements**

This press release contains forward-looking statements regarding the potential for TYSABRI. These statements are based on the companies' current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. There is no assurance, for example, that the serious adverse events discussed above were not caused by TYSABRI, that there are not or will not be more such serious adverse events or that we will be able to gain sufficient information to fully understand the risks associated with the product. There is also no assurance that the companies will be able to resume marketing and sales of TYSABRI. For more detailed information on the risks and uncertainties associated with TYSABRI and the companies' drug development and other activities, see the periodic and other reports of Biogen Idec 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.