

BIOGEN IDEC INC.
Form 8-K
July 31, 2008

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**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): **July 31, 2008**

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

(IRS 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):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

On July 31, 2008, Biogen Idec Inc. and Elan Corporation, plc notified relevant regulatory agencies of two confirmed cases of progressive multifocal leukoencephalopathy (PML) in multiple sclerosis (MS) patients treated with TYSABRI in the commercial setting. Additional information about these cases is set forth below.

Case 1

On July 30, 2008, following a period of clinical evaluation, Biogen Idec received confirmation of a diagnosis of PML in a MS patient in the European Union (EU).

The diagnosis was made based upon the detection of JC Virus (JCV) DNA in the cerebrospinal fluid (CSF) in the setting of clinical signs, symptoms and magnetic resonance imaging (MRI) findings consistent with the diagnosis of PML.

As reported to the company on July 31, 2008, the patient remains clinically stable and ambulatory at home.

Background:

- Patient in EU with aggressive MS who was naïve to prior disease modifying therapy;
- TYSABRI monotherapy for approximately 17 months;
- Clinical vigilance led to early identification of signs and symptoms of possible PML and medical work-up which included MRI scanning and CSF testing, but PML was not confirmed at that time;
- However, given continued clinical suspicion by treating physician plasma exchange was initiated as outpatient;
- Subsequent testing of CSF detected JCV DNA which was reported to the company on July 30, 2008;
- It was then determined by PML experts that the latest CSF results together with the clinical history, physical findings, and MRI results are consistent with the diagnosis of PML.

Case 2

On July 31, 2008, Biogen Idec was notified of a diagnosis of PML in a second MS patient in the EU.

The diagnosis was made based upon the detection of JCV DNA in the CSF in the setting of clinical signs, symptoms, and MRI findings consistent with the diagnosis of PML.

As reported to the company on July 31, 2008 the patient is currently hospitalized.

Background:

- Patient in EU with MS with a history of prior disease modifying therapies including azathioprine and beta-interferons;
- TYSABRI monotherapy for approximately 14 months;
- Evaluation for possible PML included MRI scanning and CSF testing;
- CSF testing detected JCV DNA, which was reported to the company on July 31, 2008;
- The CSF results together with the clinical history, physical findings, and MRI results are consistent with the diagnosis of PML.

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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/ Robert A. Licht
Robert A. Licht
Vice President and Assistant Secretary

Date: July 31, 2008