ELAN CORP PLC
Form 6-K
June 04, 2004

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of June, 2004

Commission File Number 001-13896

Elan Corporation, plc
(Translation of registrant's name into English)

Lincoln House, Lincoln Place, Dublin 2, Ireland
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F /X/ Form 40-F / /

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes / / No /X/

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes / / No /X/

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other

Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes / / No /X/

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):

This Report of Foreign Issuer on Form 6-K is incorporated by reference into the Post-Effective Amendments on Forms F-3 and S-8 to Form F-4 Registration Statement of Elan Corporation, plc (Registration No. 333-12756), the Registration Statement on Form F-3 of Elan Corporation, plc and Athena Neuroscience Finance, LLC (Registration No. 333-13130), and the Registration Statements on Form S-8 of Elan Corporation, plc (Registration Nos. 333-13996, 333-12344, 333-11940, 333-09644, 333-09284, 333-09048, 333-08384, 333-07361, 333-07136, 333-14240, 33-27506, 333-100252 and 333-100556).

EXHIBIT LIST

Exhibit	Description
99.1	Press release dated June 4, 2004 titled: Biogen Idec and Elan submit application to the European Medicines Agency for approval of Antegren(R) for multiple sclerosis based on one-year data.

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, thereunto duly authorized.

ELAN CORPORATION, plc

By: /s/ William F. Daniel

William F. Daniel
Company Secretary

Date: June 4, 2004

Exhibit 99.1

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BIOGEN IDEC AND ELAN SUBMIT APPLICATION TO THE EUROPEAN MEDICINES AGENCY FOR APPROVAL OF ANTEGREN(R)FOR MULTIPLE SCLEROSIS BASED ON ONE-YEAR DATA

Cambridge, MA, San Diego, CA and Dublin, Ireland - June 4, 2004 - Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced today that they have submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency for approval of ANTEGREN(R) (natalizumab) as a treatment for multiple sclerosis (MS).

The submission includes one-year data from two ongoing Phase III trials. The companies are committed to completing these two-year trials. In order to protect the integrity of the trials, the companies are not disclosing the one-year data at this time. Last month, Biogen Idec and Elan submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the approval of natalizumab for MS.

"Based on the promising results in previous clinical trials and the one-year analysis from our Phase III studies, we believe natalizumab has the potential to meet a significant unmet need for MS patients around the world," said Burt Adelman, MD, executive vice president, Development,

Biogen Idec. "Natalizumab's novel mechanism of action represents an innovative approach to treating MS."

"This submission represents a significant milestone for Elan and Biogen Idec and demonstrates our ongoing commitment to new therapies for MS patients," said Lars Ekman, MD, executive vice president and president Research & Development, Elan. "We will continue to work with European regulators during the review process to

bring natalizumab to patients as quickly as possible."

MS is a chronic disease of the central nervous system that affects approximately 400,000 people in Europe and approximately one million people worldwide. It is a disease that affects more women than men, with onset typically between 20 and 40 years of age. Symptoms of MS may include vision problems, loss of balance, numbness, difficulty walking and paralysis.

About the MS Clinical Trials for ANTEGREN

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(R) (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 study protocols provided for 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 rate. The pre-specified primary endpoint of the one-year analysis was relapse rate.

About ANTEGREN (natalizumab)

Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new selective adhesion molecule (SAM) inhibitor class. The drug is designed to inhibit the migration of immune cells into chronically inflamed tissue where they may cause or maintain

inflammation. To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

Biogen Idec and Elan are collaborating equally on the development of natalizumab in MS, CD, and rheumatoid arthritis (RA).

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 http://www.biogenidec.com.

About Elan

Elan Corporation, plc is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. 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 Harbour/Forward Looking Statements

This press release contains forward-looking statements regarding the approval of ANTEGREN (natalizumab) and the potential of natalizumab 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, that regulatory authorities may require additional information or further studies or may fail to approve the drug, 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 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.

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