ELAN CORP PLC
Form 6-K
September 26, 2005

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 September, 2005

Commission File Number 001-13896

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

Treasury Building, Lower Grand Canal Street, 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 333-121021).

EXHIBIT LIST

| Exhibit | Description |
|---|---|
| 99.1 | Press release dated September 26, 2005 titled: Biogen Idec and Elan submit supplemental Biologics License Application to the FDA for TYSABRI(R) in multiple sclerosis. |

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
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William F. Daniel
EVP, Company Secretary

Date: September 26, 2005

Exhibit 99.1

[Graphic Omitted]

For More Information Contact:
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## BIOGEN IDEC AND ELAN SUBMIT SUPPLEMENTAL BIOLOGICS LICENSE APPLICATION TO THE FDA FOR TYSABRI(R) IN MULTIPLE SCLEROSIS

Cambridge, MA and Dublin, Ireland - September 26, 2005 - Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc. (NYSE: ELN) announced today that they have submitted a supplemental Biologics License Application (sBLA) for TYSABRI(R) (natalizumab) to the U.S. Food and Drug Administration (FDA) for the treatment of multiple sclerosis (MS).

The sBLA includes:

- final two-year data from the Phase III AFFIRM monotherapy trial and SENTINEL add-on trial with AVONEX(R) (Interferon beta-1a) in MS;
- integrated safety assessment of patients treated with TYSABRI in clinical trials; and
- revised label and risk management plan.

The companies have requested Priority Review status for the sBLA which, if granted, would result in action by the FDA approximately six months from the submission date, rather than 10 months for a standard review.

Biogen Idec and Elan will submit a similar data package to the European Medicines Agency (EMEA). This information will be supplied as part of the ongoing review process, which was initiated in the summer 2004 with the filing for approval of TYSABRI as a treatment for MS.

"We are grateful to the MS community for their patience and support over the last several months while we've conducted an extensive safety evaluation of TYSABRI in collaboration with leading experts. We look forward to working with regulatory authorities during the review process, and ultimately, we hope to provide TYSABRI to people living with MS, a disease with significant unmet need," said Burt Adelman, MD, executive vice president, Development, Biogen Idec.

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"We are very encouraged by this filing. We strongly believe in the therapeutic benefit of TYSABRI and the difference it could make in the lives of patients with MS. We are committed to working closely with regulatory authorities to define a path forward for TYSABRI as a treatment choice for patients who struggle with the debilitating effects of the disease," said Lars Ekman, MD, executive vice president and president, Research and Development, Elan.

On February 28, 2005, Biogen Idec and Elan announced that they voluntarily suspended TYSABRI from the U.S. market and all ongoing clinical trials based on reports of progressive multifocal leukoencephalopathy (PML), a rare and potentially fatal, demyelinating disease of the central nervous system. Biogen Idec and Elan subsequently launched a comprehensive safety evaluation in collaboration with leading experts in PML and MS.

About Biogen Idec
Biogen Idec creates new standards of care in oncology, neurology 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 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 http://www.elan.com.

Safe Harbor/Forward Looking Statements
This press release contains forward-looking statements regarding the potential and regulatory path forward of TYSABRI. The commercial potential and regulatory path forward of TYSABRI are 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 concerns may arise from additional data or analysis, including the ongoing safety evaluation, or that the companies may encounter other unexpected delays or hurdles. There is also no assurance that the companies will be able to gain sufficient information to fully understand the risks associated with TYSABRI or that the companies will be able to resume marketing and sales of TYSABRI. 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 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.

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