

Edgar Filing: ELAN CORP PLC - Form 6-K

ELAN CORP PLC
Form 6-K
March 30, 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 March, 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/

-2-

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

Edgar Filing: ELAN CORP PLC - Form 6-K

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 March 30, 2004 titled: Elan announces agreement with Vernalis regarding North American rights for Frova(TM).
99.2	Press release dated March 30, 2004 titled: Elan announces strategic transaction - Eisai to purchase Elan's interests in Zonegran(TM) in North America and Europe.

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

Edgar Filing: ELAN CORP PLC - Form 6-K

undersigned, thereunto duly authorized.

ELAN CORPORATION, plc

By: /s/ William F. Daniel

William F. Daniel
Company Secretary

Date: March 30, 2004

Exhibit 99.1

FOR IMMEDIATE RELEASE

Investors:

Emer Reynolds

Ph: 353-1-709-4000
800-252-3526

Media:

Anita Kawatra

Ph: 212-407-5755
800-252-3526

Elan ANNOUNCES AGREEMENT WITH VERNALIS REGARDING
NORTH AMERICAN RIGHTS FOR FROVA(TM)

Dublin, Ireland, March 30, 2004--Elan Corporation, plc today announced an agreement with Vernalis plc for the termination of the development and license agreements between Elan and Vernalis regarding Frova (frovatriptan). Vernalis agreed to purchase Elan's commercialisation rights in North America for Frova.

Kelly Martin, Elan's president and chief executive officer, said, "This transaction allows Elan to further align against our strategic architecture in research, development and marketing. We will focus our resources on preparing for the expected launch of our late-stage pipeline candidates, Antegren for multiple sclerosis and Crohn's disease, and Prialt for pain."

Under the terms of the agreement, Vernalis will pay Elan a total of approximately \$55 million for rights to frovatriptan in North America, comprising the following payments. Upon closing, Elan will receive \$5 million; on December 31, 2004 and December 31, 2005, Elan will receive payments of \$20 million and \$25 million respectively; and no later than December 31, 2004, Elan will receive a payment for its Frova inventory, estimated at approximately \$5 million. Additionally, Elan's co-promotion agreement with UCB Pharma, Inc. will be terminated at closing, and Elan will pay UCB about \$10 million as a result of the termination.

For the full-year 2003, Elan recorded net revenue and gross profit for Frova of \$37.5 million and \$8.1 million, respectively. The carrying value of the Frova intangible asset is approximately \$23 million.

Edgar Filing: ELAN CORP PLC - Form 6-K

The sale proceeds will be used for development and launch of late-stage pipeline candidates. The completion of the transaction is subject to the approval of Vernalis' shareholders, U.S. anti-trust clearance if required, third party consents and other customary conditions. The transaction is expected to close before the end of the second quarter of 2004.

About Frova

Frova is a prescription medicine used for acute treatment of migraine attacks in adults. It is in the class of drugs called selective serotonin receptor agonists.

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 (NYSE: ELN) shares trade on the New York, London and Dublin Stock Exchanges.

Safe Harbor/Forward Looking Statements

This news release contains forward-looking statements that involve risks and uncertainties and reflects Elan's judgment as of the date of this release. Actual events or results may differ from Elan's expectations. For example, the proposed transaction may not close. In addition, the late stage pipeline candidates mentioned in this news release may never be launched. A further list of risks, uncertainties and other matters can be found in Elan's Annual Report on Form 20-F for the fiscal year ended December 31, 2002, and in its Reports of Foreign Issuer on Form 6-K. Elan assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Exhibit 99.2

FOR IMMEDIATE RELEASE

Investors:

Emer Reynolds

Ph: 353-1-709-4000
800-252-3526

Media:

Anita Kawatra

Ph: 212-407-5755
800-252-3526

ELAN ANNOUNCES STRATEGIC TRANSACTION

Eisai to Purchase Elan's Interests in Zonegran(TM) in North America and Europe

Dublin, Ireland, March 30, 2004--Elan Corporation, plc today announced an agreement with Eisai Co., Ltd. for the purchase of Elan's interests in Zonegran (zonisamide) in North America and Europe.

Elan President and CEO Kelly Martin said, "This transaction further aligns Elan's strategy in research, development, sales and marketing with our therapeutic areas. In research, it sharpens our focus in neurology, in which we continue research and advances in neurodegenerative diseases, including multiple sclerosis, Alzheimer's disease, and Parkinson's disease. In development, sales, and marketing, it enables us to focus our resources on the expected launch of our late-stage pipeline candidates, Antegren for multiple sclerosis and Crohn's disease, and Prialt for severe pain. In addition, the agreement creates an opportunity for Eisai to leverage the potential for Zonegran."

Terms of Transaction

Under the terms of the agreement, if the transaction closes by April 30, 2004, Eisai will pay Elan total consideration of approximately \$130 million for Elan's

Edgar Filing: ELAN CORP PLC - Form 6-K

interests in Zonegran in North America and Europe. Elan's interests comprise U.S., Canadian, Mexican, and European rights to Zonegran, along with related assets and liabilities, Zonegran inventory with an estimated value of \$26 million, and the associated sales team of approximately 115 employees.

If the transaction closes after April 30, 2004, the amount paid to Elan will be adjusted downward. In addition, Elan may earn future deferred purchase payments of up to \$110 million,

primarily contingent on when generic zonisamide is introduced in the U.S., and including up to \$25 million contingent on receiving marketing approval for Zonegran in Europe. Elan will also receive additional deferred purchase payments on net sales of Zonegran in North America and Europe if certain additional conditions are met.

Elan will continue to manufacture Zonegran in all three dosage strengths of 25 mg, 50 mg, and 100 mg capsules in Athlone, Ireland.

Based on a closing by April 30, Elan expects to record a pre-tax gain of approximately \$25 million from this transaction, after writing off the intangible assets related to Zonegran, a payment of \$17 million to Dainippon Pharmaceutical Co., Ltd. for the assignment of the Zonegran North American and European license agreements to Eisai and other transaction costs. Additionally, Elan expects to record further pre-tax gains of up to \$110 million on receipt of future milestone payments. For the full-year 2003, Elan recorded net revenue and gross profit for Zonegran of \$80.7 million and \$59.4 million, respectively.

The transaction is subject to regulatory approvals, third party consents and other customary conditions, and is expected to close before the end of second quarter 2004. The proceeds of this transaction will be used for development and potential launch of late-stage pipeline candidates.

EBITDA Guidance

As a result of this transaction and the Vernalis transaction announced earlier today, negative EBITDA guidance for 2004 will change from the range of negative \$150-170 million to negative \$180-200 million, and product revenue guidance for 2004 will decrease from \$575-625 million to \$475-525 million. This guidance does not include any additional costs, which may be substantial, that may be incurred from anticipated early filings and potential launch preparation for Antegren for multiple sclerosis in the U.S. and Europe.

About Zonegran

Zonegran is an anti-epileptic drug approved by the U.S. Food and Drug Administration in March 2000 as adjunctive therapy for the treatment of partial seizures in adults with epilepsy. Zonegran

2

is commercially available in 25 mg, 50 mg, and 100 mg capsules. Zonegran was developed in Japan and in the United States by Dainippon Pharmaceutical Co., Ltd. of Osaka, Japan. Elan licensed the sales and marketing rights for Zonegran from Dainippon for North America and Europe, and these rights will be transferred to Eisai.

About Elan

Elan Corporation, plc is a neuroscience-based biotechnology company that is

Edgar Filing: ELAN CORP PLC - Form 6-K

focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. Elan (NYSE: ELN) shares trade on the New York, London and Dublin Stock Exchanges.

Safe Harbor/Forward Looking Statements

This news release contains forward-looking statements that involve risks and uncertainties and reflects Elan's judgment as of the date of this release. Actual events or results may differ from Elan's expectations. For example, the proposed transaction may not close. Even if the proposed transaction is consummated, it may not close by April 30, 2004. If the transaction closes after April 30, 2004, the consideration to be received by Elan will be diminished. The agreements governing the transaction contain additional provisions that could cause the payments to Elan to be reduced. In addition, Elan may not receive any of the milestone payments or deferred compensation discussed in this news release. Further, the early regulatory filings for the late stage pipeline candidates mentioned in this news release may not be made, and such product candidates may never be launched. Elan may not achieve the results forecast in the EBITDA or product revenue guidance for 2004. A further list of risks, uncertainties and other matters can be found in Elan's Annual Report on Form 20-F for the fiscal year ended December 31, 2002, and in its Reports of Foreign Issuer on Form 6-K. Elan assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.