CELLTECH GROUP PLC
Form 6-K
April 01, 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 of

the Securities Exchange Act of 1934

For the month of **April, 2004**

Commission File Number: **1-10817**

CELLTECH GROUP PLC

(Translation of registrant's name into English)

208 Bath Road, Slough, Berkshire SL1 3WE ENGLAND

(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 whether the registrant by furnishing the information contained in this Form 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): 82-_____).

Enclosure: Celltech Submits Xyrem

Embargoed for release at 07:00 **1 April 2004**

CELLTECH GROUP PLC

CELLTECH SUBMITS XYREM FOR APPROVAL IN EUROPE

Celltech Group plc (LSE: CCH; NYSE: CLL) today announces that the European Medicines Evaluation Agency (EMEA) has accepted for review its marketing authorisation application for Xyrem (sodium oxybate) oral solution, a treatment for symptoms of narcolepsy. Xyrem has been filed through the EU centralised procedure, and has been granted Orphan Drug designation status in Europe, which provides a 10-year period of marketing exclusivity upon approval. Celltech will use its specialist sales forces to market the product to neurologists and sleep specialists across Europe following approval, anticipated during 2005.

Celltech in-licensed the European rights to Xyrem from Orphan Medical in October 2003. Under the terms of the agreement, Celltech will be responsible for the registration, sales and marketing of Xyrem in Europe. Celltech made a milestone payment to Orphan Medical related to the European regulatory filing and will make further payments tied to future product development milestones and sales related milestones. Celltech will also pay Orphan a royalty on sales of the product. The licensing agreement also provides Celltech with rights to negotiate in regard to other potential future indications including fibromyalgia syndrome.

Ingelise Saunders, Celltech's Global Commercial Director, commented: "We are pleased at having rapidly submitted our marketing authorisation application for Xyrem in narcolepsy, in line with our expectations. Xyrem will be an important product within our European specialist-focused commercial organisation. We are looking forward to progressing our European submission and working with sleep centres and physicians in order help fulfil the unmet medical need in patients with this serious disorder."

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Celltech Group plc (LSE: CCH; NYSE: CLL) is one of Europe's largest biotechnology companies, with an innovative development pipeline funded by its profitable, cash-generative pharmaceutical business. Celltech also possesses drug discovery capabilities of exceptional strength, including a leading position in antibody engineering. More details can be found at www.celltechgroup.com

Notes for editors

Narcolepsy

Narcolepsy is characterised by excessive daytime sleepiness, which can be complicated by an irresistible tendency to fall asleep, even in unlikely circumstances such as the middle of a conversation or at a meal.

Celltech desires to take advantage of the 'Safe Harbor' provisions of the US Private Securities Litigation Reform Act of 1995, with respect to forward-looking statements contained within this document. In particular certain statements with regard to the expected dates for approval and launch of Xyrem are forward-looking in nature. By their nature forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. In addition to factors set forth elsewhere in this document, the following factors, although not exhaustive, could cause actual results to differ materially from those the Company expects: pricing and product initiatives of the Company's competitors, failure to obtain and maintain required approvals for products from governmental authorities, unavailability of raw materials or other interruptions in production or product distribution, fluctuations in currency exchange rates, inability of the Company to market new products effectively, the failure of the Company's development, manufacturing and marketing partners to perform their contractual obligations and the risk of substantial product liability claims. Other factors that could affect these forward-looking statements are described in the Company's reports filed with the US Securities and Exchange Commission. The forward-looking statements included in this document represent the Company's best judgment as of the date hereof based in part on preliminary information and certain assumptions which management believes to be reasonable. The Company disclaims any obligation to update these forward-looking statements.

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.

CELLTECH GROUP PLC

(Registrant)

By: /s/ PETER ALLEN

Peter Allen
Chief Financial Officer

Dated: 1 April, 2004