SKYEPHARMA PLC
Form 6-K
February 25, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a - 16 OR 15d - 16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of February, 2004

SkyePharma PLC

(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

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

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-
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For Immediate Release

25 February 2004

SkyePharma PLC

PAXIL CR RECEIVES FDA APPROVAL FOR ADDITIONAL INDICATION

LONDON, UK, 25 February 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes yesterday's announcement by its partner GlaxoSmithKline that the US Food & Drug Administration ('FDA') has approved an additional therapeutic application for Paxil CR (paroxetine hydrochloride Controlled Release) for the intermittent treatment of premenstrual dysphoric disorder ('PMDD'). Paxil® is a leading selective serotonin reuptake inhibitor ('SSRI') antidepressant and Paxil CR is already on the market in the US for the treatment of depression, panic disorder, social anxiety and for the continuous treatment of PMDD. SkyePharma developed the controlled release formulation used in Paxil CR and receives a royalty on GlaxoSmithKline's sales.

Michael Ashton, SkyePharma's chief executive officer, commented: "Paxil CR is currently our leading source of royalty income. According to IMS market data, Paxil CR today accounts for about one in twelve new US prescriptions for SSRI antidepressants. The intermittent PMDD indication for Paxil CR should expand the market opportunity for the product since the original version of Paxil® was never approved for the PMDD indication."

PMDD is a condition that affects about 5% of menstruating women and is characterised by severe and disabling mood swings and physical symptoms around the end of the menstrual cycle. With the new intermittent dosing option, women suffering from PMDD can take Paxil CR once a day during the two week period prior to the onset of their menstrual cycle rather than throughout the month.

In Paxil CR GlaxoSmithKline's SSRI antidepressant Paxil® was reformulated using SkyePharma's Geomatrix oral drug delivery technology in which a multi-layered tablet controls the rate of dissolution and site of absorption of the drug in the body. Clinical studies have demonstrated that Paxil CR significantly reduces the incidence of nausea, a common and troublesome early side-effect that results in poor compliance with many SSRI antidepressants. The low drop-out rate for patients on Paxil CR may increase the likelihood that patients will obtain the full therapeutic benefit. For example, a study published in the February 2004 issue of the Journal of Clinical Psychiatry on the use of Paxil CR in treating social anxiety disorder showed that about three times as many patients taking Paxil CR achieved remission compared with placebo. In addition, the drop-out rate due to adverse events such as sexual dysfunction was low and comparable to the placebo level.

GlaxoSmithKline launched Paxil CR in the USA in April 2002. The FDA has already approved Paxil CR for the treatment of major depressive disorder, panic disorder and social anxiety and for the continuous treatment of PMDD. Paxil CR offers flexible dosing and is available in three different dosing strengths: 12.5 mg, 25 mg and 37.5 mg. In 2003, US sales of Paxil® and Paxil CR were £1.2 billion (US$1.9 billion). SkyePharma receives ongoing royalty payments on GlaxoSmithKline's net sales of Paxil CR .

For further information please contact:

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Notes to Editors

About SkyePharma

SkyePharma PLC uses its world-leading drug delivery technology to develop easier-to-use and more effective formulations of drugs. The majority of challenges faced in the formulation and delivery of drugs can be addressed by one of the Company's proprietary technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit http://www.skyepharma.com.

About Geomatrix

Geomatrix controlled release systems control the amount, timing and location of drug release into the body. This is achieved by constructing a tablet with two basic components: a core containing the active drug or drugs, and one or two additional barrier layers that control the drug's diffusion out of the core. Tablets with a wide range of predictable and reproducible drug release profiles can be made by combining different chemical components in the core and barrier layers, each with a different rate of swelling, gelling and erosion.

About GlaxoSmithKline

GlaxoSmithKline, one of the world's leading research-based pharmaceutical and health care companies, is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information visit http://www.gsk.com.

Except for the historical information herein, the matters discussed in this news release include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. These include without limitation risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for its products, other regulatory risks, risks relating to SkyePharma's ability to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning SkyePharma's ability to manage growth, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization and maintain or expand sales and market share for its products, risks relating to the ability to ensure regulatory compliance, risks related to the research, development and regulatory approval of new pharmaceutical products, risks related to research and development costs and capabilities, market acceptance of and continuing demand for SkyePharma's products and the impact of increased competition, risks associated with anticipated top and bottom line growth and the possibility that upside potential will not be achieved, competitive products and pricing, and risks associated with the ownership and use of intellectual property rights. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

END

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.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: February 25, 2004