SKYEPHARMA PLC
Form 6-K
January 12, 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 January, 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 12 January, 2004

SkyePharma PLC
Press Announcement

SkyePharma Welcomes Canadian Approval of Paxil CR

LONDON, ENGLAND, January 12, 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes the recent announcement by GlaxoSmithKline (NYSE: GSK) that the Therapeutic Products Directorate of Health Canada has approved Paxil CR (paroxetine hydrochloride Controlled Release tablets) for the treatment of depression, panic disorder and social anxiety disorder. Paxil CR, a selective serotonin reuptake inhibitor (SSRI) antidepressant, is already approved and marketed in the US for the treatment of major depressive disorder, panic disorder, premenstrual dysphoric disorder (PMDD) and, most recently, social anxiety disorder and is currently under FDA review for the intermittent 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: "We are pleased by this additional market opportunity for Paxil CR. Clinical studies have demonstrated that Paxil CR significantly reduces the incidence of nausea, a common and troublesome side-effect in the first few weeks of treatment 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. Paxil CR currently accounts for about one in twelve new US prescriptions for SSRI antidepressants and we hope for a similar level of success in Canada."

To develop Paxil CR, GlaxoSmithKline's 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. GlaxoSmithKline launched Paxil CR in the US in April 2002. Paxil CR offers flexible dosing and in Canada will be available in two different dosing strengths: 12.5 mg and 25 mg.

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.

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.

For further information please contact:

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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: January 12, 2004