SKYEPHARMA PLC
Form 6-K
January 13, 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: 13 January, 2004
SkyePharma and Critical Therapeutics to develop controlled release formulation for treatment of asthma and COPD

LONDON, UK, 13 January 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces an agreement with Critical Therapeutics Inc ("CTI"), a privately-held US company, to develop a controlled-release formulation of the oral asthma drug zileuton for asthma and chronic obstructive pulmonary disease ("COPD"). A four times a day immediate-release version of zileuton was marketed by Abbott Laboratories as Zyflo® Filmtab® (zileuton tablets). SkyePharma developed a controlled-release formulation of zileuton, using its Geomatrix technology. Abbott has completed Phase III development in asthma with this product.

SkyePharma will collaborate with CTI on the further development of this formulation for the indications of moderate to severe asthma and chronic obstructive pulmonary disease (COPD). Once approved by the FDA, CTI will market this product in the US through its own specialist salesforce. CTI will reimburse SkyePharma for its development costs and SkyePharma will receive a royalty on CTI's sales of zileuton and will also manufacture the product for CTI at its plant in Lyon, France. Skyepharma received an unspecified milestone payment on signature and will receive additional milestone payments on achievement of various technical and commercial targets.

Michael Ashton, Chief Executive of SkyePharma, said: "We are delighted that CTI has decided to take this project forward. CTI shares our view that there is considerable untapped potential in this controlled release formulation of zileuton, particularly for asthma and COPD, currently areas of significant unmet medical need. We look forward to working with CTI on this additional application of our Geomatrix technology. For the avoidance of doubt, this is a new agreement and is not one of the three major deals mentioned in our recent trading update as being still under negotiation."

Paul Rubin MD, CTI's Chief Executive, said: "This agreement provides us with the potential of near-term revenue from a product that has already completed a Phase III program. We see an opportunity to broaden the use of zileuton through new indications and new formulations."

Zileuton is an oral inhibitor of the enzyme 5-lipoxygenase, thereby blocking formation of leukotrienes and so controlling a key part of the inflammatory cascade that follows allergic challenge and leads to bronchoconstriction and mucus secretion. Chronic use of zileuton may allow reduction of other therapies, such as the use of ß-agonists and oral or inhaled steroids, which have undesirable side-effects.

The labelling approved by the US Food and Drug Administration ("FDA") for Zyflo® Filmtab® (zileuton tablets) indicated that it is not for use in the reversal of acute asthma attacks. Patients with active liver disease should not take Zyflo. Liver function tests are recommended prior to and during treatment with Zyflo. When taking Zyflo, theophylline dose should be reduced by 50% and appropriately monitored; patients taking propranolol or warfarin should be monitored and doses adjusted if necessary. The only adverse event reported significantly more often by Zyflo patients than placebo-treated patients was upset stomach (8.2% vs. 2.9%, respectively).

About SkyePharma
SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now nine approved products incorporating three of SkyePharma's five technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit www.skyepharma.com.

About Critical Therapeutics
Critical Therapeutics, Inc. is a privately held biopharmaceutical company focused on critical care medicine. CTI's mission is the discovery, development and commercialization of novel therapies for the treatment of acute trauma, cardiopulmonary disease and infectious and inflammatory illness. The Company is headquartered in Cambridge, Massachusetts. More information about CTI is available at www.criticaltherapeutics.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.

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 13, 2004