

SKYEPHARMA PLC
Form 6-K
September 07, 2005

**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 September, 2005

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 ☒ 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 ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

Edgar Filing: SKYEPHARMA PLC - Form 6-K

For Immediate Release

SkyePharma PLC

FORADIL® CERTIHALER LAUNCHED IN GERMANY

LONDON, UK, 7 September 2005 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces today (Novartis) has launched FORADIL® CERTIHALER (formoterol fumarate inhalation powder) on the German and chronic obstructive pulmonary disease (COPD). The German pharmaceutical regulatory authority has approved FORADIL® CERTIHALER on 6 June. FORADIL® CERTIHALER is a trademark of Novartis. FORADIL® CERTIHALER, co-developed by SkyePharma and Novartis, was submitted for regulatory review in Europe on a country-by-country basis beginning in December 2004 in Switzerland, Austria, Finland, Portugal and the Netherlands as well as in Germany. It has also been approved in Latin America and in South Africa. FORADIL® CERTIHALER was also submitted for regulatory review in the US. The Food and Drug Administration (FDA) has assessed the product as "approvable" and Novartis has provided the data that were requested. The US FORADIL® franchise has been licensed by Novartis to Schering-Plough Company.

Michael Ashton, SkyePharma's Chief Executive Officer, commented: "We are delighted that FORADIL® CERTIHALER is now available in the German market in Germany, and we expect patients to appreciate the design features in this sophisticated device."

FORADIL® CERTIHALER embodies two proprietary SkyePharma technologies, the SKYEHALER, a novel breath-actuated inhaler ("MDDPI") device, and SKYEPROTECT, a powder formulation that protects the drug from moisture, ensuring stability and dose-to-dose reproducibility.

Formoterol, the active ingredient in FORADIL® CERTIHALER, is a long-acting beta2-agonist bronchodilator of action (within 5 minutes) with a long-lasting bronchodilation effect for 12 hours. This feature provides patients who suffer from asthma and COPD. The breath-actuated FORADIL® CERTIHALER dry-powder inhaler provides patients the convenience of 30 days of therapy in a single inhaler. This evolution of the FORADIL® is a valuable and convenient option for asthma and COPD patients who require maintenance therapy with a long-acting beta2-agonist.

SkyePharma will earn a royalty on future sales of FORADIL® CERTIHALER in all markets. SkyePharma is a subsidiary of Novartis. FORADIL® CERTIHALER.

For further information please contact:

SkyePharma PLC

Michael Ashton, Chief Executive Officer

Peter Laing, Director of Corporate Communications

Sandra Haughton, US Investor Relations

+44 207 491 1777

+44 205 491 5124

+1 212 753 5780

Buchanan Communications

Tim Anderson / Mark Court / Rebecca Skye Dietrich

+44 207 466 5000

Notes to Editors

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies and more effective drug formulations. There are now eleven approved and marketed products incorporating the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation technologies. For more information, visit www.skyepharma.com.

Certain statements in this news release are forward-looking statements and are made in reliance upon the U.S. Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations expressed in these statements are reasonable, it can give no assurance that these expectations will materialize. There are many risks and uncertainties, actual results may vary significantly from those expressed or implied. These forward-looking statements are based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. These factors may cause differences between actual results and those implied by the forward-looking statements. Without limitation, risks related to the development of new products, risks related to obtaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to maintain or expand market share on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to maintain or expand market share in the face of changes in customer requirements, competition and regulatory compliance, the risk of product liability claims, risks related to the ownership of intellectual property, risks related to SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to update or revise any 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: September 7, 2005