

SKYEPHARMA PLC  
Form 6-K  
November 28, 2006

**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 November, 2006

SkyePharma PLC

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(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

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(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-  
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### SkyePharma PLC Solaraze(R) Receives Approval in Australia

LONDON, ENGLAND, 28 November, 2006 - SkyePharma PLC (LSE: SKP; NASDAQ: SKYE) today announces that Solaraze(R), its topical 3% gel (diclofenac sodium) treatment for actinic keratosis, has been approved for registration by the Australian Government Department of Health and Ageing Therapeutic Goods Administration (TGA).

Actinic keratosis is the most frequently occurring form of carcinoma 'in situ'(1) and has approximately a 10% risk of developing into invasive squamous cell carcinoma(2).

SkyePharma's marketing partner in Australia is Shire Pharmaceuticals plc, which hopes to launch Solaraze(R) in early 2007 subject to discussions with distributors and approval of product information by the TGA.

SkyePharma will receive double digit royalty payments on net sales once marketed.

#### **Frank Condella, CEO, SkyePharma said:**

"We are delighted to receive approval from the Australian Therapeutic Goods Administration and look forward to the launch of Solaraze(R) in Australia next year."

#### **For further information please contact:**

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#### **Notes for editors**

##### **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 eleven approved products incorporating SkyePharma's technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit [www.skyepharma.com](http://www.skyepharma.com).

##### **About actinic keratosis**

Actinic Keratoses (AKs) are an early stage skin cancer recently defined by the European Dermatology Forum as in-situ squamous cell carcinoma (SCC). Approximately 10% of AK lesions are thought to progress to invasive SCC(2) and 40% of immuno-compromised patients will develop pre-malignant or malignant skin tumours(3). Epidemiological data show high occurrence rate of AKs in the population with skin phototype I-III and an increase in the last decades worldwide(1). In Europe a prevalence of 15% in men and 6% in women has been documented in a UK study(4). In those over the age of 70 years, 34% of males and 18% of females were found to have AKs(3). More than 10 million people in the USA are affected and in Australia a very high prevalence has been reported, 52% of Australian men aged 30-70 years and 36% of women in the same age range have been found to have AK(5,6).

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### About Solaraze(TM) 3% gel (diclofenac sodium)

Solaraze(TM) is a topical gel consisting of 3% diclofenac in a 2.5% hyaluronic acid base and is indicated for the management/treatment of actinic keratosis. Diclofenac, a widely used non-steroidal anti-inflammatory drug (NSAID) has a high affinity for cyclooxygenase-2 (COX-2), an enzyme that appears to play an important role in the development of AK. The hyaluronic acid component is an inert delivery system that intensifies the therapeutic effect of diclofenac by minimizing its systemic absorption and ensuring it locates to the target site within the epidermis(7).

Outside North America, Solaraze(R) is marketed by Shire Pharmaceuticals in Europe, and it has rights in Australia, New Zealand, South Africa and certain Pacific Rim territories. Bradley Pharmaceuticals is the licensee in North America. North American sales in the first half of 2006 more than doubled to \$10.0 million, whilst those outside North America by Shire Pharmaceuticals were \$6.9 million, up by 28% on the prior year period. SkyePharma receives a double digit royalty on licensees' sales of Solaraze(R). References:

1. Guideline for the management of actinic keratoses. Developed by the Guidelines subcommittee of the European Dermatology Forum 2006.
2. Glogau R. The risk of progression to invasive disease. J Am Acad Dermatol 2000; 42:23-24
3. Stockfleth et al. Epithelial malignancies in organ transplant patients: Clinical presentations and new methods of treatment. Recent results in cancer research Vol 160. Springer Verlag Berlin Heidelberg 2002
4. Memon AA et al. Prevalence of solar damage and actinic keratosis in a Merseyside population. British Journal of dermatology 2000;142:1154-1159
5. Frost CA et al, The prevalence and determinants of Solar Keratoses at a sun-tropical latitude (Queensland, Australia). Br J Dermatol 1998; 139: 1033-1039
6. Fact sheet: Actinic Keratoses and Skin Cancer. American Academy of Dermatology November 2006 p251-258  
<http://www.aad.org/public/News/DermInfo/ActKerSkCancerFAQ.htm>
7. Brown MB and Jones SA . Hyaluronic acid: a unique topical vehicle for the localized delivery of drugs to the skin. J Eur Acad Dermatol Venereol 2005; 19: 308-311

*Certain statements in this news release are forward-looking statements and are made in reliance on the safe harbour provisions of the U.S. Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that these expectations will materialize. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward-looking statements based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. Factors that could cause differences between actual results and those implied by the forward-looking statements contained in this news release include, without limitation, risks related to the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma's ability to manage growth. 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: November 28, 2006