

SKYEPHARMA PLC  
Form 6-K  
May 08, 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 May, 2006

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-

---

**SkyePharma PLC**

**SkyePharma and Kos Announce Exclusive Licence Agreement for Marketing and Distribution of Flutiform**

LONDON, ENGLAND, 8 May, 2006 -- SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces today that Kos Pharmaceuticals, Inc. (Nasdaq: KOSP) ("Kos") to jointly develop Flutiform, SkyePharma's new chronic obstructive pulmonary disease ("COPD"). Kos will have exclusive rights to market Flutiform in the US and Canada. SkyePharma could receive up to \$165 million in milestone payments and revenue targets (of which \$25 million has been paid upfront) together with royalties starting in 2009. The US represents the largest market opportunity for Flutiform. SkyePharma remains in negotiation with other pharmaceutical companies in other markets around the world.

SkyePharma's Chief Executive, Frank Condella, said: "We are delighted to announce this partnership for the development of product Flutiform. Kos has a tremendous track record of successful marketing with its cholesterol-lowering drug, Niaspan. In the past five years, sales of Niaspan have increased at a compound annual growth rate of over 50%, helping Kos become the fastest growing pharmaceutical company in the United States in 2005 (and the sixth fastest growing of all US pharmaceutical companies). Kos is a leader in the respiratory market with its recently acquired inhaled steroid product, Azmacort®. Kos currently has a strong presence on the cardiovascular and respiratory markets which it plans to increase and we expect Kos to have a significant presence at the time that Flutiform is launched. We believe Kos brings a therapeutically focused marketing strategy and commercial potential of Flutiform in the key US market."

Adrian Adams, President and Chief Executive Officer of Kos, said: "We are very pleased with the partnership for the development of Flutiform for the asthma indication and are excited about this commercial opportunity in a very competitive market. This strategic partnership should broaden our presence in the respiratory area, and provides access to the US market for Azmacort®, our inhaled corticosteroid therapy. Our partnership with SkyePharma is another excellent example of a model that includes measured and therapeutically aligned investments to fortify our R&D pipeline and support our scientific in-licensing activities. In addition, it provides an opportunity to diversify our product portfolio and another potentially significant revenue generating opportunity anticipated in 2009, further strengthening our pipeline of at least two products a year through the end of the decade, beginning in 2007."

Flutiform consists of a unique fixed-dose combination of the long-acting bronchodilator salmeterol and the corticosteroid fluticasone in a proprietary metered-dose aerosol inhaler with a dose counter. The product uses a novel proprietary formulation technology, designed to stabilise the active components and thereby provide prolonged storage, provides patent protection for Flutiform to 2019. Flutiform is currently in Phase III clinical trial for the indication of asthma in adults and adolescents and is expected to be submitted for approval by the FDA in 2008 and to reach the market in 2009. By then the US market for combination treatments for asthma and COPD is expected to be significant.

**Conference call later today**

Senior management from Kos and SkyePharma will host a conference call at 1330 BST / 0830 EDT on Friday, May 12, 2006. The call will be available live via the Internet by accessing the website of either company at [www.kospharm.com](http://www.kospharm.com). Presentation slides will also be available. Please go to the respective website at least 30 minutes before the call to register, download and install any necessary audio software. Those who cannot access the web page can also access the call by calling +1-913-312-1295, confirmation code 6963745. A replay will also be available on both the US and UK by calling +1-913-312-1295 and entering confirmation code 6963745 from 1130 EDT today until 2359 EDT on Friday, May 12, 2006.

**For further information please contact:**

**SkyePharma PLC**

Frank Condella, Chief Executive Officer +1 201 843 9500 x 6000  
Peter Laing, Director of Corporate Communications +1 201 843 9500 x 6000  
Sandra Haughton, US Investor Relations +1 201 843 9500 x 6000

**Kos Pharmaceuticals, Inc.**

Adrian Adams, President and Chief Executive Officer +1 201 843 9500 x 6000  
John J. Howarth, VP, Investor Relations and Corporate Affairs +1 201 843 9500 x 6000  
Nichol Harber, Senior Manager, Investor Relations & Corporate Communications +1 201 843 9500 x 6000

## Edgar Filing: SKYEPHARMA PLC - Form 6-K

### **Buchanan Communications**

Tim Anderson / Mark Court / Rebecca Skye Dietrich

### **Notes for editors**

#### **About SkyePharma**

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies and more effective drug formulations. There are now twelve approved products incorporating SkyePharma's oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit [www.skyepharma.com](http://www.skyepharma.com).

#### **About Kos Pharmaceuticals**

Kos Pharmaceuticals, Inc. is a fully integrated specialty pharmaceutical company engaged in development, manufacturing and marketing proprietary prescription products for the treatment of chronic diseases. The Company's revenue in 2005 and currently has a market capitalisation in excess of \$2 billion. The Company's strategy is to reformulate existing pharmaceutical products with large market potential to improve compliance. The Company currently markets Niaspan® and Advicor® for the treatment of cholesterol, treatment of asthma, Cardizem® LA for the treatment of hypertension and angina, and Teveten® and Teveten® for the treatment of hypertension. Kos is developing additional products, has proprietary drug delivery technologies including metered-dose inhalation administration and is pursuing certain strategic business development and marketing opportunities. For more information, visit [www.kospharm.com](http://www.kospharm.com).

#### **About the treatment of asthma**

Asthma is an inflammatory condition that makes the airways in the lung (bronchi) abnormally narrow. Dust, pollen or cold air, resulting in constriction of the bronchi and difficulty in breathing. Asthma is treated with two types of therapy: an anti-inflammatory drug that addresses the underlying inflammation and a bronchodilator that opens the airways, relieving the symptoms and allowing patients to breathe more easily. While bronchodilators although useful for treating acute asthma attacks have now largely been replaced by long-acting bronchodilators that provide symptom relief for 12 hours (particularly inhaled corticosteroids). Inhaled corticosteroids can be taken orally but most are inhaled, with the active drug delivered to the inner surface of the airways through a delivery device, either a metered-dose aerosol inhaler (MDI) or a breath-actuated dry powder inhaler (DPI). The global market for asthma is expected to exceed \$20 billion by 2010, with use in COPD, another inflammatory lung condition, also expected to reach \$20 billion. The US market accounts for approximately half of the global total.

The fastest-growing part of this market is combination treatments, which combine a long-acting corticosteroid and a long-acting bronchodilator in a single delivery device. Combinations are not only more convenient for patients than carrying two inhalers but have also been shown to optimise the efficacy of the individual agents. Sales of GlaxoSmithKline's combination product, Advair, have already exceed \$6 billion, of which half is in the US, and AstraZeneca's Symbicort (which is not yet approved in the US) is also expected to exceed \$6 billion. By 2010 the combination category is expected to account for over half of the asthma/COPD market.

#### **About Flutiform**

SkyePharma's product Flutiform consists of a unique fixed-dose combination of the long-acting beta<sub>2</sub>-agonist formoterol and inhaled steroid fluticasone in a proprietary non-CFC metered-dose aerosol inhaler with a dose of 10 microgrammes of formoterol and 50 microgrammes of fluticasone per inhalation and has a rapid onset of action (1-3 minutes). By contrast salmeterol, the long-acting beta<sub>2</sub>-agonist in GlaxoSmithKline's Advair/Seretide, also provides 12 hours of bronchodilation but needs up to 30 minutes to take effect. The inhaled steroid fluticasone (a component of Advair/Seretide) has low systemic side effects and a better safety and efficacy profile than budesonide, the steroid used in AstraZeneca's Symbicort. The proprietary SkyeDry formulation technology employed in Flutiform ensures that the active ingredients are delivered in their original components and thereby ensure a reproducible dose even after prolonged storage, provides patent protection and can be available in two dose combinations with each dose delivering 10 microgrammes of formoterol and 50 microgrammes of fluticasone.

Flutiform completed its Phase II trial in asthma in 2005. The results confirmed that Flutiform is a safe and effective combination of component drugs had been taken separately, with rapid onset of bronchodilation that was maintained over 12 hours. There were no drug-drug interactions and no safety concerns.

Following discussions with the FDA on the Phase II trial results, the Phase III trial of Flutiform in asthma is expected to start in 2006. The trial programme is on track for SkyePharma's target of regulatory submission in 2007. SkyePharma believes that Flutiform should reach the US market in 2009.

## Edgar Filing: SKYEPHARMA PLC - Form 6-K

*Certain statements in this news release are forward-looking statements and are made in reliance on 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. Because of a number of risks and uncertainties, actual results may vary significantly from those expressed or implied. These risks are based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. 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 commercialize 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 and management of SkyePharma, 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.*

### **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: May 08, 2006