

SKYEPHARMA PLC  
Form 6-K  
September 06, 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 September, 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

#### **SkyePharma and Mundipharma Announce Exclusive Licence Agreement for Marketing and Distribution of Flutiform in Europe**

#### **15 million upfront and 70 million in milestones Double Digit Royalties**

LONDON, ENGLAND, 6 September, 2006 -- SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces today that it has entered into an agreement with Mundipharma International Corporation Limited ("Mundipharma") for the development, marketing and distribution in Europe and certain other international markets of Flutiform, its novel combination product for asthma and chronic obstructive pulmonary disease ("COPD").

Mundipharma will have exclusive rights to market Flutiform in Europe and other territories outside North, Central and South America, with an option to negotiate for exclusive rights in Japan. Mundipharma is a privately-owned pharmaceutical company that is already SkyePharma's licensee for its oncology drug DepoCyte®, in Europe and certain other markets.

SkyePharma's Chief Executive, Frank Condella, said: "I am pleased to announce another significant step in the strategic plan that we announced to shareholders earlier this year. We expect to reach the market with Flutiform in 2009, by which time the European market for combination treatments for asthma and COPD is expected to exceed \$3 billion.

"We are delighted to build on our existing relationship with Mundipharma in Europe with a licence for Flutiform, our leading pipeline product. Mundipharma has demonstrated its ability to market products effectively in the complex European pharmaceutical market and they are well placed to introduce Flutiform, which will be a key product for them."

Ake Wikstrom, Regional Director, Europe, Mundipharma International Limited, said: "This agreement is important to us for two reasons. Firstly, Flutiform offers the potential of an excellent therapeutic option in the management of asthma and COPD and thus represents a major opportunity for our continued growth. Secondly, having previously partnered with SkyePharma, this clearly demonstrates Mundipharma's ability to commit to licensing opportunities and really deliver on those commitments."

SkyePharma has received an upfront payment of 15 million (\$19 million) on signature and will receive additional milestone payments of up to a further 70 million (\$90 million) on attainment of various development and revenue targets. SkyePharma will receive royalties on sales by Mundipharma, with the royalty rate in double digits and escalating on attainment of various sales targets. In addition SkyePharma and Mundipharma's associate company, Mundipharma Medical Company, will be entering into a manufacturing and supply agreement under which SkyePharma will supply commercial goods and samples to Mundipharma Medical Company at cost plus an applicable margin.

SkyePharma is currently conducting the clinical trials required for US approval of Flutiform in adult asthma. Mundipharma will have access to data from these trials, which will be used as the basis for obtaining European approval of Flutiform. Mundipharma will also conduct, at its own expense, an additional clinical study needed for regulatory approval in Europe and also the studies that will be needed to extend the indication to paediatric patients and to a higher dose strength. The costs of these studies will be recouped from future royalty and milestone payments to SkyePharma.

Flutiform consists of a unique fixed-dose combination of the long-acting

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bronchodilator formoterol with the inhaled steroid fluticasone in a proprietary metered-dose aerosol inhaler with a dose counter. The product is taken twice a day. SkyePharma's proprietary formulation technology, designed to stabilise the active components and thereby ensure a reproducible dose even after prolonged storage, provides patent protection for Flutiform to 2019. Flutiform is currently in Phase III development for the indication of asthma in adults and adolescents and is expected to be submitted for approval in the USA in the second half of 2007 and in Europe in 2008 and to reach these markets in 2009.

In May SkyePharma announced that it had licensed Flutiform to Kos Pharmaceuticals, Inc. (NASDAQ: KOSP) for the US market, with an option on the Canadian market. SkyePharma remains in negotiations with potential partners for the remaining markets around the world.

### **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 twelve 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 Mundipharma**

Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies - privately owned companies and joint ventures covering the world's pharmaceutical markets. The companies worldwide are dedicated to bringing to patients with severe and debilitating diseases the benefits of novel treatment options in fields such as severe pain, haemato-oncology and respiratory disease. For more information: [www.mundipharma.co.uk](http://www.mundipharma.co.uk)

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

Asthma is an inflammatory condition that makes the airways in the lung (bronchi) abnormally responsive to external stimuli such as dust, pollen or cold air, resulting in constriction of the bronchi and difficulty in breathing. Patients with asthma are normally treated with two types of therapy: an anti-inflammatory drug that addresses the underlying cause of the condition and a bronchodilator that opens the airways, relieving the symptoms and allowing patients to breathe normally. The older short-acting bronchodilators have now largely been displaced by long-acting bronchodilators that provide symptom relief for 12 hours (particularly valuable overnight). Asthma drugs can be taken orally but most are inhaled, with the active drug delivered to the inner surface of the lung by means of an inhaler device, either a metered-dose aerosol inhaler (MDI) or a breath-actuated dry powder inhaler (DPI). The world market for asthma drugs is expected to exceed \$20 billion by 2010, with use in COPD, another inflammatory lung condition, expected to add a further \$10 billion. The US market accounts for approximately half of the global total.

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The fastest-growing part of this market is combination treatments, which combine a long-acting bronchodilator with an inhaled steroid in a single delivery device. Combinations are not only more convenient for patients than carrying two separate inhalers but also optimise the efficacy of the individual agents. Sales of GlaxoSmithKline's combination Advair (Seretide in Europe) already exceed \$6 billion, of which half is in the US, and AstraZeneca's Symbicort (which has recently been approved by the FDA but which is not yet on the US market) add another \$1 billion. By 2010 the combination category is expected to account for over half of the asthma/COPD market by value.

### About Flutiform

SkyePharma's product Flutiform consists of a unique fixed-dose combination of the long-acting bronchodilator formoterol with the inhaled steroid fluticasone in a proprietary non-CFC metered-dose aerosol inhaler with a dose counter. Formoterol provides 12 hours of bronchodilation and has a rapid onset of action (1-3 minutes). By contrast salmeterol, the bronchodilator used in GlaxoSmithKline's Advair/Seretide, also provides 12 hours of bronchodilation but has the drawback of needing up to 30 minutes after inhalation to take effect. The inhaled steroid fluticasone (a component of Advair/Seretide) has low systemic absorption and is perceived to have a better safety and efficacy profile than budesonide, the steroid used in AstraZeneca's Symbicort, and is the physician-preferred inhaled steroid in the US. The proprietary SkyeDry(TM) formulation technology employed in Flutiform, designed to stabilise the active components and thereby ensure a reproducible dose even after prolonged storage, provides patent protection to 2019. The product will be available in two dose combinations with each dose delivering 10 micrograms of formoterol with either 100 or 250 micrograms of fluticasone. A version with a higher dose of fluticasone is also being developed for the European market.

Flutiform completed its Phase II trial in asthma in 2005. The results confirmed that Flutiform behaved exactly as if the two component drugs had been taken separately, with rapid onset of bronchodilation that was maintained for 12 hours, no evidence of drug-drug interactions and no safety concerns.

Following discussions with the FDA on the Phase II trial results, the Phase III trial of Flutiform started on schedule in February 2006. The trial programme is on track for SkyePharma's target of regulatory submission to the FDA in the second half of 2007. SkyePharma believes that Flutiform should reach the US market in 2009. Mundipharma expects to file in Europe by the end of 2008 and Flutiform to reach the market by the end of 2009.

*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*

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*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.*

### **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 6, 2006