

SKYEPHARMA PLC  
Form 6-K  
June 02, 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 June, 2004

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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**For Immediate Release**

**02 June, 2004**

## **SKYEPHARMA AND VECTURA FORM STRATEGIC ALLIANCE FOR PULMONARY DELIVERY TECHNOLOGIES**

LONDON, UK, 02 June 2004 -- SkyePharma PLC (LSE: SKP, Nasdaq: SKYE) today announces that it has entered into a strategic alliance with Vectura Limited ("Vectura") in the area of pulmonary delivery technologies. Both companies are leaders in the field of drugs delivered to the lung and see mutual benefit from collaborating in this rapidly growing area. Through this alliance SkyePharma will acquire rights to use Vectura's Aspirair® dry powder inhaler device for certain macromolecules on a non-exclusive basis. Although detailed commercial terms were not released, SkyePharma has made a £2 million equity investment in Vectura (acquiring a stake of approximately 4% on a fully diluted basis) as part of the alliance.

Michael Ashton, Chief Executive of SkyePharma, said: "SkyePharma already has an established presence in the important and fast-growing pulmonary delivery market. Foradil® Certihaler®, which we co-developed with Novartis, has now received its first European approvals and an "approvable" letter for this product was issued by the US Food & Drug Administration in October last year. We have also recently signed a second agreement with Novartis to jointly develop a dry-powder inhaler version of QAB 149, Novartis' novel long-acting bronchodilator, and an agreement with GlaxoSmithKline to license our formulation technologies for application to the delivery of respiratory drugs, either by breath-actuated dry powder inhaler or by metered-dose aerosol inhaler. This new alliance with Vectura will reinforce our capabilities in this important area. In particular it gives SkyePharma the opportunity to enter the promising area of pulmonary delivery of protein and peptide drugs."

Dr Chris Blackwell, Chief Executive of Vectura, added: "Our primary focus is on the development of our own inhaled drugs for local and systemic use, the latter requiring the high lung penetration and low variability that our Aspirair® technology makes possible. Aspirair® has been developed because of the need for a device that delivers dry powders with high efficiency to the deep lung, and a device that is suitable for delivery of both small molecules and macromolecules, such as proteins and peptides. The Aspirair® device is therefore a key element of our own product developments and this agreement, with SkyePharma, is an additional validation of this technology."

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

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### **Notes for editors:**

#### **About SkyePharma**

SkyePharma develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now ten 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 Vectura**

Vectura ([www.vectura.com](http://www.vectura.com)) is an emerging pharmaceutical company that is developing a range of inhaled drugs for the treatment of lung diseases and conditions where delivery via the lungs can provide significant benefits, such as a rapid onset of action, improved efficacy or tolerability compared with current therapies. The Company's strategy is to combine its proprietary pulmonary delivery technologies with existing, off-patent drugs either for use in new indications or for a new route of administration. Vectura is targeting specific product development opportunities in the areas of chronic obstructive pulmonary disease (COPD), sexual dysfunction, cystic fibrosis, migraine and asthma. The Company has development collaborations with a number of companies, including GSK, Chiesi, Arakis, Zambon and Ranbaxy.

### **About SkyePharma's pulmonary delivery technologies**

SkyePharma is one of the leading independent providers of inhaled pharmaceutical delivery technology. We can deliver pulmonary drugs either through our own breath-actuated multi-dose dry powder inhaler or by metered dose aerosol inhalers powered by environmentally-friendly hydrofluoroalkane (HFA) propellants. These propellants replace the widely-used chlorofluorocarbons (CFCs), now being phased out because of their potential to damage the ozone layer. Our formulation capability ensures consistent and accurate dose delivery even for hard-to-formulate materials.

SkyePharma has developed for Novartis Foradil® Certihaler®, a multi-dose dry powder inhaler version of Novartis' long-acting bronchodilator Foradil (formoterol). SkyePharma developed not only the Skyehaler™ dry powder inhaler device (to be marketed by Novartis as the Certihaler® for this specific product) but also the formulation technology that ensures accurate and consistent dosing. Foradil® Certihaler® has now received its first European approvals and the US Food & Drug Administration issued an "approvable" letter in October last year. SkyePharma also recently signed a second agreement with Novartis to jointly develop a dry-powder inhaler version of QAB 149, Novartis' novel long-acting bronchodilator. GlaxoSmithKline has also licensed SkyePharma's formulation technologies for application to the delivery of respiratory drugs, either by breath-actuated dry powder inhaler or by metered-dose aerosol inhaler. SkyePharma has also demonstrated the successful delivery of macromolecules with the Skyehaler™ device.

SkyePharma is developing various pulmonary drugs in HFA metered-dose aerosol inhalers. These include the bronchodilator formoterol (which has now completed Phase II development) and the combination product Flutiform™, SkyePharma's proprietary fixed-dose combination of formoterol with the inhaled corticosteroid fluticasone.

### **About Aspirair® - 'Active' DPI device technology**

Aspirair® is Vectura's high performance patent-protected inhaler technology, designed to deliver single unit doses with high lung penetration and low variability, essential for drugs that are intended for systemic delivery. Experiments to date indicate that Aspirair® is capable of delivering DPI formulations of both large and small molecules, either in the form of a pure drug particle or in combination with another excipient. Aspirair® generates an aerosol plume, triggered by a patient's inhalation, which is significantly slower than most "puffers" currently available, thus reducing the amount of drug that is unintentionally deposited in the mouth and throat and subsequently swallowed rather than reaching the lungs.

*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*

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*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.*

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: June 02, 2004