SKYEPHARMA PLC
Form 6-K
July 08, 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 July, 2004

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 X 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 X

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
8 July, 2004

SKYEPHARMA AND ASTRAZENECA ANNOUNCE COMPLETION OF PHASE III TRIALS OF HFA-MDI VERSION OF PULMICORT®

LONDON, UK, 8 July 2004 -- SkyePharma PLC (LSE: SKP, Nasdaq: SKYE) and AstraZeneca (LSE:AZ) today announce the completion of Phase III trials of a new version of AstraZeneca's Pulmicort® (budesonide), an inhaled corticosteroid for the treatment of asthma. The Metered Dose aerosol Inhaler (MDI) uses a hydrofluoroalkane (HFA) propellant, replacing the chlorofluorocarbon (CFC) propellant used in the currently marketed MDI version of Pulmicort®. CFCs are being withdrawn on environmental grounds because of their potential to damage the ozone layer. However the replacement of CFC propellants with HFAs can lead to substantial differences in MDI performance. Pulmicort® HFA-MDI incorporates proprietary SkyePharma formulation technology to ensure accurate and consistent delivery that matches the release profile of the current version of Pulmicort® MDI.

Under the terms of agreements signed in December 2001, SkyePharma is responsible for all pre-clinical and clinical development of Pulmicort® HFA-MDI, as well as compiling regulatory filings for marketing approval in Europe. AstraZeneca will pursue filing of the marketing application and following approval will market Pulmicort® HFA-MDI in Europe and other non-US territories. AstraZeneca is responsible for the commercial supply of the product and has recently appointed Inyx, Inc. (OTC BB: IYXI) as contract manufacturer responsible for scale-up activities and commercial production, initially for a three year period.

A milestone will become payable to SkyePharma upon delivery of the final Phase III Clinical Trial Reports and Stability Reports to AstraZeneca, expected in the autumn. This is part of the total milestone payments of up to US$ 12 million due to SkyePharma under this agreement. In addition, SkyePharma will receive royalties on net sales of Pulmicort® HFA-MDI.

Michael Ashton, Chief Executive of SkyePharma, said: "SkyePharma already has an established presence in the important and fast-growing pulmonary delivery market, with both breath-actuated dry-powder inhalers and metered-dose aerosol inhalers that use non-CFC propellants. The completion of the Phase III trial of the HFA-MDI version of Pulmicort® that we have developed for AstraZeneca is an important milestone towards eventual commercialisation and also towards validation of our MDI formulation technology."

For further information please contact:

SkyePharma PLC	**+44 207 491 1777**
Michael Ashton, Chief Executive Officer	
Peter Laing, Director of Corporate Communications	**+44 207 491 5124**
Sandra Haughton, US Investor Relations	**+1 212 753 5780**
Buchanan Communications	**44 207 466 5000**
Tim Anderson / Mark Court	

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.

About AstraZeneca

AstraZeneca is a major international healthcare business engaged in the research, development, manufacture and marketing of prescription pharmaceuticals and the supply of healthcare services. It is one of the world's leading pharmaceutical companies with healthcare sales of over $18.8 billion and leading positions in sales of gastrointestinal, oncology, cardiovascular, neuroscience and respiratory products. AstraZeneca is listed in the Dow Jones Sustainability Index (Global and European) as well as the FTSE4Good Index. For more information, visit www.astrazeneca.com.

About Inyx
Inyx, Inc. is an emerging specialty pharmaceutical company with niche aerosol drug delivery technologies and products. Inyx focuses its expertise on contract manufacturing of prescription and over-the-counter pharmaceutical products, and provides specialty pharmaceutical development and production consulting services to the international healthcare market.

About Pulmicort®
Pulmicort® (budesonide) is an inhaled corticosteroid that is available in about 90 countries for the treatment of asthma. Pulmicort® is also approved in a number of countries for the treatment of chronic obstructive pulmonary disease. First launched in 1981, it is available in both dry-powder inhaler and metered-dose aerosol inhaler versions and also as Pulmicort Respules® for use in nebulizers. In 2003 world sales were US$968 million.

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 though 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 has also entered into 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 SkyeHalerdevice.

SkyePharma is developing various pulmonary drugs in HFA metered-dose aerosol inhalers. Apart from Pulmicort® HFA-MDI for AstraZeneca, 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.

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 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.

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: July 8, 2004