SKYEPHARMA PLC Form 6-K May 17, 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 May, 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-

For Immediate Release

17 May 2004

SkyePharma PLC

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# "Undisclosed Pipeline Product" SkyePharma and First Horizon Enter into Exclusive Licence and Supply Agreement for Cardiovascular Product

LONDON, UK, 17 May 2004--SkyePharma PLC (LSE: SKP, Nasdaq: SKYE) today announces an exclusive agreement with First Horizon Pharmaceutical Corporation ("First Horizon", Nasdaq: FHRX) through which SkyePharma grants First Horizon the exclusive U.S. marketing and distribution rights for a cardiovascular product. This product is currently under review by the U.S. Food & Drug Administration ("FDA") for approval, which is expected by the end of this year. First Horizon intends to commence marketing and distribution shortly after FDA approval. First Horizon has also obtained the right of first refusal to negotiate a licence to develop and commercialize a future cardiovascular product utilising the SkyePharma delivery technology.

SkyePharma will receive a total of up to \$50 million in milestone payments and 25% of First Horizon's net sales of the product. \$5 million will be paid to SkyePharma upon signing the Agreement and up to an additional \$15 million is payable thereafter, all of which are contingent upon milestones related to FDA approval. In addition to the \$20 million in payments, SkyePharma will receive up to \$30 million in sales-based milestone payments. SkyePharma will manufacture and supply the product from its Lyon manufacturing facility. SkyePharma will also make a contribution of up to \$5 million to First Horizon's initial marketing expenses to establish the product.

Michael Ashton, SkyePharma's Chief Executive Officer, said: "First Horizon is a perfect partner to promote this product to cardiovascular physicians as well as general and family practitioners. They have a significant sales force which is expanding to 400 representatives, a proven ability to move market share in this therapeutic area and a commitment to evaluate future product opportunities utilising our drug delivery technologies. This product also moves the company closer to our objective of fully commercialising our investment in the Lyon, France manufacturing operation."

"Consistent with our strategy to develop a strong cardiology franchise, we are pleased to have entered into this agreement with SkyePharma and to have secured a new product which is well suited to our existing portfolio," said Patrick Fourteau, Chief Executive Officer and President of First Horizon. "This partnership also initiates our objective of establishing strategic relationships with development-based companies such as SkyePharma, which is integral to the future growth of our company. We expect this deal to be accretive upon sale of the product."

#### For further information please contact:

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Tim Anderson / Mark Court

#### **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 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 First Horizon**

First Horizon Pharmaceutical Corporation is a specialty pharmaceutical company that markets and sells prescription products with a primary focus on cardiology and women's health/pediatrics. The Company has a portfolio that includes 14 branded prescription products of which 6 are actively promoted to high-prescribing physicians through its

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nationwide marketing and sales force of approximately 360 representatives. The Company's website address is: http://www.firsthorizonpharm.com. Please visit the Company's website for full prescribing information on the Company's products.

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. Specifically SkyePharma is unable to provide assurance that the product specified in this announcement will receive FDA approval or that it will be possible to successfully market the product. If the anticipated FDA approval is not received or the product is not successfully marketed SkyePharma will have expended substantial resources on the product with less than expected returns. 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: May 17, 2004