SKYEPHARMA PLC
Form 6-K
May 19, 2003

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, 2003

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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Immediate Release **19**
May 2003

KING PHARMACEUTICALS AND SKYEPHARMA ANNOUNCE

LICENSING AGREEMENT TO DEVELOP

MODIFIED-RELEASE FORMULATION OF ALTACE

BRISTOL, TENNESSEE & LONDON, UK, May 19, 2003 - King Pharmaceuticals, Inc. (NYSE:KG) and SkyePharma PLC (NASDAQ: SKYE; LSE:SKP) announced today that they have entered into a licensing agreement for the purpose of developing and commercializing a modified-release formulation of King's product Altace (ramipril) utilizing SkyePharma's patented oral drug delivery technology Geomatrix. Altace is a patented angiotensin converting enzyme ("ACE") inhibitor with net sales in the United States and Puerto Rico totalling $534.7 million for the last twelve months ending March 31, 2003.

SkyePharma's Geomatrix range of technologies involves a fully-developed, multi-layered tablet technology that controls the release of a product's active ingredient for the purpose of optimizing a drug's pharmacokinetic behavior. The specific Geomatrix technology planned for use in the development of a modified-release formulation of Altace should provide the product with extended duration of action and improved bioavailability. SkyePharma has various issued patents covering the Geomatrix drug delivery technologies, with patent protection in the U.S. extending to 2017. Also, SkyePharma has patent applications for additional patents under review covering its Geomatrix drug delivery technologies.

Jefferson J. Gregory, Chairman and Chief Executive Officer of King, stated, "We are very pleased to collaborate with SkyePharma in the development and potential commercialization of a modified-release formulation of our leading product Altace. SkyePharma's patented Geomatrix delivery platform and proven formulation expertise should result in the improved bioavailability of Altace." Mr. Gregory added, "We continue to work diligently on additional product life-cycle strategies intended to enhance the value of our Altace franchise."

Michael R. D. Ashton, SkyePharma's Chief Executive Officer, said, "We are delighted that King has chosen SkyePharma to help develop an improved formulation of their lead product, Altace. This development project, involving a unique delivery formulation within our Geomatrix range of technologies, highlights the importance to SkyePharma of our oral delivery franchise, which can improve both new and currently marketed products. Strategically this deal is another example of our growing number of relationships with pharmaceutical companies where our delivery technologies help to expand the commercial potential of their product portfolios. Additionally it may potentially provide another manufacturing opportunity for our Lyon plant."

Altace was first approved by the U.S. Food and Drug Administration ("FDA") in 1991 for use in the treatment of hypertension and subsequently approved by the FDA for the treatment of congestive heart failure after a patient suffers a heart attack. Additionally, based on evidence from the landmark HOPE trial, Altace remains the only differentiated ACE inhibitor because it has received FDA approval to reduce the risk of stroke, myocardial infarction and death from cardiovascular causes in patients 55 and older either with a history of coronary artery disease, stroke, or peripheral vascular disease or with diabetes and one other cardiovascular risk factor (e.g., elevated cholesterol levels, cigarette smoking, etc.)."

Under the Development, Commercialization and Licensing Agreement, King has agreed to pay SkyePharma $1 million on signing and will pay potential additional future payments of up to $6.5 million for certain milestones that may occur up to and including FDA approval of an Altace product utilizing SkyePharma's drug delivery technologies. King has also agreed to reimburse SkyePharma for direct expenses associated with SkyePharma's development of a modified-release formulation of Altace. Furthermore, King will have sole responsibility for all clinical studies and costs associated with any such modified-release formulation of Altace and all the necessary regulatory submissions leading to potential approval of such a product. King will pay SkyePharma a royalty on net sales of any FDA-approved formulation of Altace utilizing SkyePharma's patented drug delivery technology during the term of King's license."

About Altace

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, use of Altace should be immediately discontinued. Common adverse events associated with Altace include persistent dry cough, dizziness, and symptomatic hypotension. Hypoglycemia has been reported rarely in concomitant therapy with oral hypoglycemics or insulin, and therefore patients should be closely monitored for symptoms of hypoglycemic reactions. Rare cases of angioedema, including intestinal angioedema, have been reported. Altace is contraindicated in patients who are hypersensitive to the product or have a history of angioedema related to previous treatment with an ACE inhibitor."

King Pharmaceuticals, Inc., headquartered in Bristol, Tennessee, is a vertically integrated pharmaceutical company that develops, manufactures, markets, and sells branded prescription pharmaceutical products. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry created by cost containment initiatives and consolidation among large global pharmaceutical companies. King's strategy is to acquire branded pharmaceutical products and to increase their sales by focused promotion and marketing and through product life cycle management."

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 nine approved products incorporating three of SkyePharma's five delivery technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. SkyePharma has two FDA- and EMEA-approved manufacturing plants in San Diego, USA, and Lyon, France. For more information, visit www.skyepharma.com.

This release contains forward-looking statements which reflect management's current views of future events and operations, including, but not limited to, statements pertaining to the development and potential commercialization of a modified-release formulation of Altace by SkyePharma and King, statements pertaining to existing U.S. patent protection through 2017 covering the specific Geomatrix technology planned for use in the development of a modified-release formulation of Altace, and a potential manufacturing opportunity for SkyePharma's Lyon plant. These forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from the forward-looking statements. Some important factors which may cause results to differ include: dependence on King's and Wyeth Pharmaceuticals' ability to successfully market Altace under the co-promotion agreement between King and Wyeth, dependence on the development and implementation of successful marketing strategies for Altace by King and Wyeth, dependence on King's ability to maintain effective patent protection for Altace through October 2008, and successfully defend against any attempt to challenge the enforceability of patents relating to the product, dependence on SkyePharma's and King's ability to successfully develop a modified release formulation of Altace with extended duration of action and improved bioavailability, dependence on SkyePharma's and King's ability to maintain effective patent protection for a modified release formulation for Altace through 2017, dependence on SkyePharma's and King's ability to obtain the issuance of additional U.S. patents covering the specific Geomatrix technology used in the development of a modified-release formulation of Altace, dependence on the development and implementation of successful launch and marketing strategies for a modified-release formulation of Altace, once approved, dependence on sales of King's currently marketed products, including, in particular, but not limited to, Altace, Levoxyl (levothyroxine sodium tablets, USP), and Thrombin-JMI (thrombin, topical, bovine, USP), dependence on whether King chooses to utilize SkyePharma's manufacturing facilities in Lyon, France for the purpose of manufacturing any modified-release formulation of Altace that may be successfully developed by King and SkyePharma, dependence on King's ability to continue to successfully execute the Company's proven growth strategies, management of King's growth and integration of its acquisitions, and the high cost and uncertainty of research, clinical trials, and other development activities involving pharmaceutical products, including, but not limited to, a modified release formulation of Altace. Other important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the "Risk Factors" section and other sections of King's Form 8-K dated April 15, 2003, previously submitted to the Securities and Exchange Commission (SEC), and of SkyePharma's SEC filings. Both King & SkyePharma do not undertake to publicly update or revise any of their forward-looking

statements even if experience or future changes show that the indicated results or events will not be realized.

For further information please contact:

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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 19, 2003