SKYEPHARMA PLC
Form 6-K
January 03, 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 January, 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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For Immediate Release 3 January, 2003

SkyePharma PLC

Endo Pharmaceuticals Licenses Rights from SkyePharma For Two Critical Care Products

CHADDS FORD, Pa., and London, 3 January 2003 - Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP;ENDPW) and SkyePharma PLC (Nasdaq:SKYE; LSE:SKP) today announced that they reached a development and commercialization agreement on 31 December 2002 under which Endo's wholly owned subsidiary, Endo Pharmaceuticals Inc., received an exclusive license to the U.S. and Canadian marketing and distribution rights for two of SkyePharma's patented development products, DEPOMORPHINE and Propofol IDD-DTM, with options for other development products.

In return, SkyePharma will receive a US$25 million upfront payment. In addition, SkyePharma may receive further milestone payments totaling US$95 million which includes total milestones of US$10 million for DEPOMORPHINE through FDA approval. The milestone payments also include US$50 million for Propofol IDD-D, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further comprises a US$15 million milestone payment receivable when net sales of DEPOMORPHINE reach US$125 million in a calendar year, and a US$20 million milestone payment when net sales of DEPOMORPHINE reach US$175 million in a calendar year. SkyePharma will also receive a share of each product's sales revenue that will increase from 20% initially, to a maximum of 60% net sales as the products' combined sales achieve certain thresholds.

"We are delighted that SkyePharma recognizes Endo as its partner of choice in bringing these products to market," said Carol A. Ammon, chairman and chief executive officer of Endo. She noted that DEPOMORPHINE, a sustained-release injectable formulation, and Propofol IDD-D, administered intravenously, are Endo's first post-surgical, critical-care drugs. "Once approved, these medications would expand our presence in the hospital-based setting, consistent with our strategy of growing our franchise in pain management and complementary therapies."

"DEPOMORPHINE and Propofol IDD-D are lead candidates in SkyePharma's development portfolio of pain management products," said Michael Ashton, chief executive officer of SkyePharma. "We wanted a strategic partner with a focused specialty sales force who would be able to maximize the sales potential for these exciting, value-added products. This deal recognizes SkyePharma's creative focus on developing new innovative products utilizing our wide range of drug delivery technologies and importantly brings substantial value into the Company."

The agreement provides for the parties to work together and complete the necessary clinical, regulatory and manufacturing work for regulatory approval of DEPOMORPHINE and Propofol IDD-D in the U.S. and Canada. SkyePharma will be primarily responsible for clinical development up to final U.S. Food and Drug Administration (FDA) approval, and for product manufacture, including all associated costs. Upon approval, Endo will market each product in the U.S. and Canada, with SkyePharma as the supplier. Endo will be responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses.

Currently in Phase III clinical trial development, DEPOMORPHINE is a sustained-release injectable formulation of morphine sulfate, the sole active ingredient, encapsulated with SkyePharma's patented DEPOFOAM controlled-release delivery technology. DEPOMORPHINE, administered epidurally, is intended for the management of post-operative pain. The first pivotal Phase III clinical study has shown that DEPOMORPHINE administered in patients undergoing hip surgery has a safety profile typical for an epidural opioid agent and that patients experienced dose-related post-operative pain relief for 48 hours. The results were statistically significant. If the additional clinical trial results are positive, SkyePharma expects to submit a New Drug Application (NDA) to the FDA in mid-2003.

Propofol IDD-D is an IV formulation of propofol as the sole active ingredient using SkyePharma's patented Insoluble Drug Delivery (IDD-D) technology to improve solubility. Intended for the maintenance of anesthesia in adults during surgery and for sedation of adults hospitalized in an intensive-care setting, Propofol IDD-D is currently being studied in a Phase II clinical trial.

Under the agreement, Endo obtained options on other SkyePharma development products, including DEPOBUPIVACAINE , a long-acting, sustained release formulation of the local anesthetic bupivacaine. Endo has the option to obtain commercialization rights for this product, when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the DEPOFOAM technology successfully developed for the prophylaxis or treatment of pain.

The agreement contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. For a full description of the arrangement, please see the companies' public filings with the Securities and Exchange Commission.

About Endo

Endo Pharmaceuticals Holdings Inc. is a fully integrated specialty pharmaceutical company with market leadership in pain management products. Through its Endo Pharmaceuticals Inc. subsidiary, the company researches, develops, produces and markets a broad product offering of branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at www.endo.com.

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 nine approved products incorporating three from SkyePharma's five technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit www.skyepharma.com.

Forward Looking Statement

This press release contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on both companies' managements' beliefs and assumptions, current expectations, estimates and projections. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are not historical facts and include information regarding both companies' possible or assumed results of operations. Also, statements or expressions that are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects," "intends," "estimates" or similar expressions are forward-looking statements. Estimated or anticipated future results, product performance or other non- historical facts are forward-looking and reflect either company's current perspective on existing trends and information. Many of the factors that will determine either company's future results are beyond the ability of each company to control or predict. The reader should not rely on any forward-looking statement. The companies undertake no obligations to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect future results of either company and could cause those results to differ materially from those expressed in the forward-looking statements contained herein. Important factors that may affect future results include, but are not limited to: market acceptance of the named products and the impact of competitive products and pricing; dependence on sole source suppliers; the success of the named product development activities and the timeliness with which regulatory authorizations and product launches may be achieved; successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions; the availability on commercially reasonable terms of raw materials and other third party manufactured products; exposure to product liability and other lawsuits and contingencies; dependence on third party suppliers, distributors and collaboration partners; uncertainty associated with pre-clinical studies and clinical trials and regulatory approval; uncertainty of market acceptance of new products; the difficulty of predicting FDA approvals; risks with respect to technology and product development; uncertainties regarding intellectual property protection; uncertainties as to the outcome of litigation; changes in operating results; changes in laws and regulations; customer demand; possible future litigation; availability of future financing and reimbursement policies of government and private health insurers and others; and other risks and uncertainties detailed in Endo's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended; also in Endo's Registration Statement on Form S-3 dated October 17, 2001: also SkyePharma's Form 20-F dated June 24, 2002. Readers should evaluate any statement in light of these important factors.

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For further information please contact:

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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: January 3, 2003