

SKYEPHARMA PLC
Form 6-K
January 02, 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, 2002

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 ☒ 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-

For Immediate Release
2 January, 2003

ENZON AND SKYEPHARMA FORM STRATEGIC ALLIANCE

Enzon Licenses North American rights to SkyePharma's DepoCyt

Bridgewater, NJ and London, UK - January 2, 2003 - Enzon Pharmaceuticals, Inc. (NASDAQ: ENZN) and SkyePharma PLC (NASDAQ: SKYE; LSE:SKP) announced today a strategic alliance based on a broad technology access agreement. The two companies will draw on their combined drug delivery technology and expertise to jointly develop up to three products for future commercialisation. These products will be based on SkyePharma's proprietary platforms in the areas of oral, injectable and topical drug delivery, supported by technology to enhance drug solubility and Enzon's proprietary PEG modification technology, for which Enzon will receive a US\$3.5 million technology access fee. SkyePharma will receive a milestone payment for each product based on its own proprietary technology that enters Phase II clinical development. Research and development costs related to the technology alliance will be shared equally, as will future revenues generated from the commercialisation of any jointly-developed products.

Effective December 31, 2002, Enzon has also licensed the North American rights to SkyePharma's DEPOCYT®, an injectable chemotherapeutic approved for the treatment of patients with lymphomatous meningitis. SkyePharma has re-acquired DEPOCYT marketing, distribution and sales rights for the U.S. from Chiron Corporation (NASDAQ:CHIR) in return for an undisclosed cash payment, and for Canada from Paladin Labs Inc. (TSX:PLB) for a nominal sum.

"This alliance will allow both companies to further capitalize on the valuable product development opportunities that exist in the drug delivery arena," said Arthur Higgins, chairman and chief executive officer of Enzon. "Not only does this deal broaden Enzon's development capabilities by complementing our powerful PEG platform with SkyePharma's impressive array of drug delivery technologies, it also brings DEPOCYT, a profitable oncology product with significant upside potential to Enzon."

Michael Ashton, SkyePharma's chief executive officer agreed on the prospects for value creation by the alliance. On DEPOCYT, he added, "Enzon shares our view that the market for DEPOCYT, the only FDA-approved chemotherapeutic agent for the treatment of lymphomatous meningitis, is largely under-developed. We believe that Enzon's focused oncology marketing effort is well placed to promote DEPOCYT to physicians treating this life-threatening illness, and to achieve the product's full potential."

Enzon will pay a license fee of US\$12 million for the North American rights to DEPOCYT. SkyePharma will manufacture DEPOCYT and Enzon will purchase finished product at 35% of net sales, which can reduce should a defined sales target be exceeded. SkyePharma is also entitled to milestone payments based on the achievement of certain sales levels and the approval of additional indications.

Approximately 25,000 cases of neoplastic meningitis occur annually, of which approximately 40 percent are lymphomatous meningitis and 60 percent are neoplastic meningitis in patients with solid tumors. SkyePharma is currently conducting Phase IV clinical studies that seek to expand the DEPOCYT label to include the latter, neoplastic meningitis, indication. SkyePharma understands that 2002 North American sales of DEPOCYT may approximate US\$5 million. The companies believe that the product has annual sales potential in North America of at least US\$25 million.

Enzon plans to market DEPOCYT through its focused, specialty oncology sales representatives currently responsible for marketing ONCASPAR®. The marketing strategy will aim to increase awareness of the benefits of DEPOCYT in treating lymphomatous meningitis, a serious, disabling and potentially fatal complication of cancer.

DEPOCYT is an injectable, sustained-release formulation of the chemotherapeutic agent, cytarabine or Ara-C. Using SkyePharma's proprietary lipid-based drug delivery technology, DEPOFOAM, DEPOCYT gradually releases cytarabine into the cerebral spinal fluid and extends the dosing interval to once every two weeks, as compared to the standard twice-weekly intrathecal chemotherapy dosing of cytarabine.

Enzon is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases. The company has developed three marketed products, including PEG-INTRON®, marketed by Schering-Plough. Enzon's product-focused strategy includes an extensive drug development program that leverages the Company's PEG modification and single-chain antibody (SCA®) technologies. Internal research and development efforts are complemented by strategic transactions that provide access to additional products, projects, and technologies. Enzon has several drug candidates in various stages of development, independently and with partners.

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. Currently, there are nine approved products that incorporate three of SkyePharma's five technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilization capabilities. For more information, visit www.skyepharma.com.

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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 Enzon's Form 10-K, Form 10-Q's, Form 8-K's and other documents on file with the SEC, including without limitation, risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for DEPOCYT and other regulatory risks, risks relating to both companies' abilities to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning both companies' abilities 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 DEPOCYT, risks relating to the achievement of actual 2002 North American sales of DEPOCYTE, 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 both companies' 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.

This release is also available at <http://www.enzon.com> and <http://www.skyepharma.com>

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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: January 2, 2003