SKYEPHARMA PLC
Form 6-K
April 19, 2005

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 April, 2005

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

19 April, 2005

SkyePharma PLC

$80 million European Development and Marketing Agreement for Novel Pain Control Agent DepoBupivacaine

LONDON, ENGLAND, 19 April, 2005 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces that it has entered into a strategic development and marketing arrangement with Mundipharma International Holdings Limited ("Mundipharma") for the marketing and distribution of DepoBupivacaine in Europe and other international markets excluding the USA, Canada and Japan. Mundipharma is already SkyePharma's European marketing partner for the cancer treatment DepoCyte®

Under the agreement with Mundipharma, SkyePharma will receive $10 million on signature, most of which will be deferred and recognised to income to cover the cost of the Phase II clinical trials. SkyePharma will also receive further contributions of up to US$20 million towards the cost of the Phase III clinical trials required to gain approvals, and additional milestone payments on attainment of development milestones, marketing approvals and sales targets. If all targets are met total payments will amount to over US$80 million. SkyePharma will be responsible for clinical development. SkyePharma will also receive a 35% share of Mundipharma's sales of DepoBupivacaine in Europe (30% in other territories), out of which SkyePharma will bear the cost of manufacture.

SkyePharma's Chief Executive Michael Ashton said: "DepoBupivacaine is one of the most important products in our pipeline. With the possibility of providing extended localised pain relief for up to 4 days, DepoBupivacaine should become the analgesic of choice for the increasing number of day surgeries. This type of surgery has already overtaken hospital inpatient operations to become the most common surgical procedure and is the fastest growing part of the market. We are delighted to extend our relationship with Mundipharma, which is currently successfully marketing another of our products, DepoCyte®, in Europe.

This deal structure not only continues our recent trend towards a larger royalty share but also relieves our income statement of the considerable cost of Research and Development."

DepoBupivacaine is SkyePharma's novel sustained-release injectable formulation of the local anaesthetic bupivacaine, currently widely used as a local or regional anaesthetic during surgery, either in a hospital in-patient setting or in ambulatory (or "day") surgery in which the patient is discharged from the hospital or clinic shortly after surgery and recovers at home. DepoBupivacaine employs SkyePharma's proprietary DepoFoam technology and has been shown in Phase 1 studies to provide local relief of pain for up to 96 hours after a single injection instead of 8-12 hours for conventional immediate-release bupivacaine. Superior control of pain after discharge is expected to reduce the need for other analgesics and to improve patient recovery and rehabilitation. DepoBupivacaine is currently in Phase II clinical development. Endo Pharmaceuticals Inc., SkyePharma's North American marketing partner for DepoDur , SkyePharma's other product for relief of post-operative pain, has the right of first negotiation for rights to DepoBupivacaine in North America, exercisable once SkyePharma has requested an end of Phase II trial meeting with the US Food & Drug Administration.

For further information please contact:

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Notes to Editors

About SkyePharma
SkyePharma PLC uses its world-leading drug delivery technology to develop easier-to-use and more effective formulations of drugs. The majority of challenges faced in the formulation and delivery of drugs can be addressed by one of the Company's proprietary technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit www.skyepharma.com.

About Mundipharma
Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies, privately owned companies and joint ventures that cover the world's pharmaceutical markets. The companies have particular expertise in bringing to patients the benefits of novel drug delivery systems such as those used to enhance medicines for the relief of severe pain. For further information, visit www.mundipharma.co.uk.

About DepoBupivacaine
DepoBupivacaine is an extended-release injectable formulation of the local anaesthetic bupivacaine. Local anaesthetics temporarily block the transmission of pain signals along nerve fibres. DepoBupivacaine employs SkyePharma's proprietary DepoFoam technology to release bupivacaine over a period of several days and is supplied as a ready-to-use injectable suspension. DepoBupivacaine is designed for administration by local infiltration at wound sites, as a peripheral nerve block or by the lumbar epidural route. It is not suitable for intrathecal or intravenous administration.

DepoBupivacaine is designed for the prolonged control of pain after surgery. SkyePharma expects that its main use will be in control of post-operative pain in patients who have undergone ambulatory surgical procedures under local or regional anaesthesia. However DepoBupivacaine will also be suitable for use in surgery on hospital in-patients.

About DepoFoam
DepoFoam is SkyePharma's proprietary sustained-release injectable delivery technology. This is fully commercialised and approved by regulatory agencies in both the USA and Europe. DepoFoam consists of lipid-based particles containing discrete water-filled chambers dispersed through the lipid matrix. The particles are 10-30 microns in diameter and are suspended in saline. The suspension resembles skimmed milk and can be injected through a fine needle. The water-filled chambers containing active drug account for most of the weight of the particles. The lipids are naturally occurring substances (or close analogues) such as phospholipids and triglycerides. The small amount of lipid is cleared rapidly in the body as the particles deliver their drug payload over a period that can be modified from 1 to 30 days. For example in DepoCyt®/ DepoCyte® the circulating half-life of the drug cytarabine is increased from 3.4 hours to 141 hours.

About post-operative pain after ambulatory surgery
Ambulatory surgery (also known as "day" surgery) is normally performed in hospital out-patient facilities, free-standing ambulatory surgery centres or in physicians' offices. In contrast with a major surgical operation on a hospital in-patient, which routinely involves general anaesthesia followed by several days of recovery in the hospital, ambulatory surgery is normally conducted under a local or regional anaesthetic, and a few hours after the procedure the patient is discharged to recover at home. The development of less invasive surgical procedures and the drive to reduce the high costs of hospitalisation has led to a rapid growth in ambulatory surgery, which now accounts for about 65% of elective surgical procedures in the USA (against 16% in 1980). Today more than 30 million patients undergo

surgical procedures on an ambulatory basis each year in the United States. Typical ambulatory procedures include tonsillectomies, hernia repairs, gall bladder removals, colonoscopies, some cosmetic surgeries, and cataract surgeries.

Currently oral analgesics are the principal approach to control of pain after the anaesthetic used in ambulatory surgery wears off. Patients discharged from hospital after ambulatory surgery to recover at home are not under full-time medical supervision, which restricts both the type and quantity of analgesics that can be used. For example, the highly effective opioid analgesics are largely precluded in the home setting because of the accompanying risks of nausea and vomiting and respiratory depression. Patients are therefore often subject to inadequate pain relief during the immediate post-surgical period, which not only is undesirable but also can delay recovery. Recent surveys indicate that after ambulatory surgery up to 40% of outpatients suffered from moderate to severe pain during the first 24-48 hours after discharge. More invasive, and therefore more painful, surgical procedures (such as knee reconstruction) are increasingly being performed on an ambulatory basis, reinforcing the need for more effective ways of controlling post-operative pain.

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, SkyePharma's marketing partners' ability to market a pharmaceutical product on a large scale and manage their sales and marketing organisation 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: April 19, 2005