SKYEPHARMA PLC
Form 6-K
November 01, 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 November, 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 **1 November, 2005**

Maruho and SkyePharma Sign Development and Marketing Agreement for Novel Pain Control Agent DepoBupivacaine in Japan

LONDON, ENGLAND, 1 November, 2005 -- Maruho Company Limited ("Maruho") and SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announce that they have entered into a strategic agreement for the development, marketing and distribution of DepoBupivacaine in Japan. DepoBupivacaine is SkyePharma's novel sustained-release injectable formulation of the local anaesthetic bupivacaine and is designed to provide localised pain relief for more than 48 hours after a surgical operation.

Maruho shall pay to SkyePharma up to 18 million dollars including up-front and milestone payments in consideration of this agreement. Maruho will conduct at its own cost the clinical development of DepoBupivacaine required for regulatory approval in Japan. Additionally, SkyePharma will receive a share of Maruho's sales of this product in Japan, out of which SkyePharma will bear the cost of manufacture.

Maruho's president Koichi Takagi said: "Pain is one of Maruho's target strategic care domains. We believe that DepoBupivacaine addresses the disadvantage of short-time efficacy of conventional anaesthetics. By using DepoFoam technology, a single injection at operation sites or affected sites provides long-term efficacy without the need for continuous epidural injection, which is complicated and also whose technique is more difficult, and improves the quality of life of patients who suffer pain."

SkyePharma's Chief Executive Michael Ashton said: "DepoBupivacaine is a key pipeline product for SkyePharma. We are delighted to have found in Maruho an excellent development partner for the important Japanese market. There are approximately 5 million surgical procedures each year in Japan and the number is growing fast because of the ageing population. We and Maruho believe that DepoBupivacaine will bring important advantages to patients undergoing surgery."

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 to recover at home. DepoBupivacaine employs SkyePharma's proprietary DepoFoam technology and has been shown in Phase 1 studies to provide local relief of pain for more than 48 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 outside Japan, the results of which are expected to be available by the end of 2005.

In April 2005, SkyePharma announced that it had entered into a development and marketing agreement with Mundipharma Inc. for all territories outside North America and Japan. Endo Pharmaceuticals Inc., SkyePharma's North American marketing partner for DepoDur , SkyePharma's first 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:

SkyePharma PLC **+44 207 491 1777**
Michael Ashton, Chief Executive Officer
Peter Laing, Director of Corporate Communications **+44 207 491 5124**
Sandra Haughton, US Investor Relations **+1 212 753 5780**

Maruho **+81-6-6371-8438**
Strategy & Licensing Department

Buchanan Communications **+44 207 466 5000**
Tim Anderson / Mark Court / Rebecca Skye Dietrich

Notes to Editors

About Maruho

Maruho, established in Osaka in 1915, is a research-based pharmaceutical company with a focus on dermatological and orthopaedic products. In 2004 it employed over 800 staff and had revenues of Y37 billion (US$345 million). For further information, visit www.maruho.co.jp.

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 DepoBupivacaine

DepoBupivacaine is an extended-release injectable formulation of the widely-used 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, subarachnoid 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 during 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.

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: November 01, 2005