SKYEPHARMA PLC
Form 6-K
October 25, 2004

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 October, 2004

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 **25 October 2004**

SkyePharma Announces Receipt of

Milestone Payment for DepoDur

LONDON, UK, 25 October 2004 -- SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces today that it has received a US$5 million milestone payment from Endo Pharmaceuticals Inc. ("Endo", Nasdaq: ENDP) in respect of DepoDur . DepoDur , which was approved by the US Food & Drug Administration ("FDA") on 18 May, is SkyePharma's novel single dose sustained-release injectable formulation of morphine for the relief of pain after major surgery. Endo is SkyePharma's licensee for DepoDur in North America.

Under the terms of an agreement signed in December 2002, SkyePharma is entitled to certain milestone payments from Endo. These include a payment of US$5 million once DepoDur has received FDA approval and SkyePharma has supplied launch quantities of the product to Endo. These conditions have now been satisfied.

Michael Ashton, Chief Executive of SkyePharma, said: "We are pleased to report the receipt of this payment. Our partner Endo commenced US promotion of DepoDur TM in the third quarter, with an encouraging initial response, and we now look forward to the formal US launch of our most important product in the fourth quarter. We are confident that DepoDur has great potential to improve the treatment of pain following major surgery."

For further information please contact:

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Notes for editors:

About SkyePharma PLC

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

About DepoDur

DepoDur is a single dose extended-release injectable formulation of morphine sulphate. DepoDur employs SkyePharma's proprietary DepoFoam technology and is supplied as a ready-to-use suspension. It is given as a single epidural injection before or during surgery and provides pain relief for up to 48 hours following surgery. There is no need for an in-dwelling catheter for continuous infusion, thereby overcoming a major drawback to the otherwise theoretically desirable epidural route of administration for opioid analgesics.

DepoDur is designed for the control of pain after major surgery. SkyePharma and Endo expect that its main use will be in control of post-operative pain in hospitalised patients undergoing major surgical procedures requiring general or regional anaesthesia such as major abdominal surgery, orthopaedic surgery and caesarean section. Currently there are an estimated 6 million such procedures every year in the USA and 5 million in Europe.

DepoDur is supplied in a 2 ml vial containing a 10 mg/ml suspension in sterile saline and is administered as a single dose epidural injection at the lumbar level prior to surgery (or after clamping of the umbilical cord during caesarean section). The recommended dose is 10 mg for caesarean section, 10-15 mg for lower abdominal surgery and 15 mg for major orthopaedic surgery of the lower extremities. Some patients may benefit from a dose of 20 mg. It should be appreciated that as with all opioids the incidence of serious adverse respiratory events is dose-related. Respiratory

depression is the chief hazard of all opioid preparations and occurs more frequently in elderly or debilitated patients. For elderly patients (age >65 years), the low end of the dosing range for DepoDur is recommended together with vigilant peri-operative monitoring.

On 16 September 2003 the FDA formally accepted for filing a New Drug Application ("NDA") for DepoDur , which had been submitted on 18 July 2003. On 20 November 2003 SkyePharma submitted an application for DepoDur to the UK Medicines and Healthcare products Regulatory Agency ("MHRA"). After national approval in the UK, SkyePharma intends to seek approval in other European Union countries under the Mutual Recognition procedure. SkyePharma has licensed DepoDur to Endo for North America and to Zeneus Pharma for Europe.

About DepoFoam
DepoFoam is SkyePharma's proprietary extended-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.

About post-operative pain
After a major surgical operation, the level of pain is usually very high for the first one to two days but the intensity of pain gradually subsides and by the end of the second day pain can normally be satisfactorily controlled with oral analgesics. For the immediate post-operative period, opioid analgesics like morphine (used alone or in combination with other non-opioid analgesics) are likely to remain the "gold standard" for relief of severe acute pain. However the relatively short duration of pain relief with opioids means that they require either continuous infusion or patient-controlled analgesia ("PCA") in which a pump delivers a series of doses of a short-acting opioid analgesic in response to the patient pressing a button (under computer control to prevent over-dosing). Both of these approaches require the patient to have an in-dwelling epidural or intravenous catheter. Such catheters can fall out or interfere with patient mobility and are a potential source of infections. Epidural catheters are also contra-indicated with concomitant use of anticoagulants because of the risk of bleeding in the spinal column that can potentially result in paralysis. There is a growing trend toward routine use of anticoagulants in patients undergoing orthopaedic surgery in order to prevent the formation of blood clots.

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: October 25, 2004