SKYEPHARMA PLC
Form 6-K
September 23, 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 September, 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 **23 September, 2003**

SkyePharma's New Drug Application for DepoMorphine Accepted for Filing by US Food & Drug Administration

LONDON, ENGLAND, September 23, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announced today that on 16 September the US Food & Drug Administration ("FDA") formally accepted for filing a New Drug Application ("NDA") for DepoMorphine , SkyePharma's novel sustained-release injectable formulation of morphine for control of moderate-to-severe post-operative pain. SkyePharma submitted the NDA on 18 July. DepoMorphine was licensed to Endo Pharmaceuticals Inc. ("Endo", Nasdaq: ENDP) for North America at the end of 2002. Under the terms of this licence agreement, the FDA's acceptance of the DepoMorphine submission triggers a US$5 million milestone payment from Endo to SkyePharma.

SkyePharma's Chief Executive Michael Ashton said, "DepoMorphine is currently our most important pipeline product. We now look forward to its commercialisation, which we anticipate in the second half of 2004. Our clinical trials show that DepoMorphine has the potential to improve the treatment of pain after surgery. There is widespread recognition that pain relief is an under-served market and current approaches to control of post-operative pain leave much to be desired."

DepoMorphine 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 48 hours following surgery. There is no need for an indwelling catheter for continuous infusion, which overcomes a major drawback to the epidural route of administration for opioids.

DepoMorphine is designed for the control of moderate-to-severe post-operative pain. SkyePharma expects that its main use will be in control of post-operative pain in hospitalised patients undergoing surgical procedures requiring general or local 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.

SkyePharma has completed seven clinical trials of DepoMorphine . The Phase IIb and Phase III clinical development programme for DepoMorphine involved four separate pain models and included nearly 1000 patients.

SkyePharma plans to file DepoMorphine with the European Agency for the Evaluation of Medicinal Products (EMEA) in the autumn. SkyePharma expects to announce the appointment of licensees for DepoMorphine in Europe and other non-US territories later this year.

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 http://www.skyepharma.com.

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 tiny 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 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 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 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, 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 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.

For further information please contact:

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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: September 23, 2003