SKYEPHARMA PLC
Form 6-K
November 20, 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 November, 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
20 November, 2003

SkyePharma Files DepoMorphine with European Regulatory Agency

LONDON, ENGLAND, November 20, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announced today that it has submitted an application to the UK Medicines and Healthcare products Regulatory Agency ("MHRA") for approval of DepoMorphine , SkyePharma's novel sustained-release injectable formulation of morphine for control of moderate-to-severe post-operative pain. After national approval in the UK, SkyePharma intends to seek approval in other European countries under the European Union's Mutual Recognition procedure.

SkyePharma submitted a new drug application ("NDA") for DepoMorphine to the US Food &Drug Administration ("FDA") on 18 July, 2003. Formal acceptance of this submission was announced on 22 September, 2003, and the NDA is currently under review by the FDA.

SkyePharma's Chief Executive, Michael Ashton, said: "DepoMorphine is currently our most important pipeline product. We are proud to have achieved our stated objective of filing the product in both the US and Europe in 2003. We now look forward to its commercialisation, which we anticipate could commence 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 current approaches to control of post-operative pain leave much to be desired, suggesting a significant market opportunity for a superior analgesic."

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 up to 48 hours following surgery, normally the period of peak post-operative pain. By contrast, conventional opioid analgesics are relatively short-acting and therefore require an in-dwelling catheter for repeat or continuous infusion. DepoMorphine avoids the need for an in-dwelling catheter, thereby overcoming a major drawback to the theoretically desirable 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 more than 1000 patients. In the two Phase III trials, in hip surgery and lower abdominal surgery, DepoMorphine demonstrated sustained dose-related analgesia and achieved its primary endpoint (superiority over study comparators in terms of total demand for opioid analgesics after surgery) with a high degree of statistical significance ($p<0.0001$ and $p=0.0003$, respectively). DepoMorphine also achieved statistical significance on several secondary endpoints. Importantly, statistical significance was achieved for the current pain intensity scores at rest and with activity over a 48 hour period and for the ratings of overall pain control.

In two related Phase IIb trials, DepoMorphine was significantly better than study comparators in the caesarean section study ($p=0.0209$) and approached statistical significance in the knee arthroplasty study ($p=0.0902$), which used a novel endpoint: time-weighted pain intensity recall score over 48 hours. DepoMorphine achieved a high degree of statistical significance in total demand for opioid analgesics after surgery ($p=0.001$), a secondary endpoint in this trial but the primary endpoint in the three other studies. In all four of these studies the safety profile of DepoMorphine was typical for an epidural opioid

agent.

In December 2002 SkyePharma licensed DepoMorphine to Endo Pharmaceuticals Inc. for North American markets. SkyePharma expects to announce the appointment of licensees for DepoMorphine in Europe and other non-US territories later this year.

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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 http://www.skyepharma.com.

About DepoFoam
DepoFoam is SkyePharm'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.

About the European licensing system for pharmaceuticals
The European system for the registration of medicinal products is based on three complementary procedures: National, Centralised and Mutual Recognition.

1. National procedure
Used to authorise medicinal products for local use in individual European Union ("EU") member states. National authorisation can form the basis for a subsequent application to other member states via the Mutual Recognition procedure.
2.Centralised procedure
Applications are submitted directly to the European Agency for the Evaluation of Medicinal Products ("EMEA"). Within the EMEA, the Committee for Proprietary Medicinal Products ("CPMP") appoints two member states to assess the documentation forwarded and prepare detailed evaluation reports to form the basis for evaluation by other members and consequent discussions in the CPMP. The time limit for the evaluation procedure is 210 days. The CPMP considers the completed assessment and delivers a favourable or unfavourable opinion as to whether to grant the authorisation. Marketing authorisation is valid throughout the EU and also in Norway, Iceland and Liechtenstein. The Centralised procedure is compulsory for medicinal products derived from biotechnology and optional for new active substances and other innovative medicinal products.
3. Mutual Recognition procedure
Allows a pharmaceutical company that has obtained a National marketing authorisation in one EU member state to apply to one or more other member states to recognise the product. If the original National marketing authorisation cannot be mutually recognised by another member state, the points in dispute are referred to the CPMP for arbitration. A CPMP decision is binding on all states.

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.

END

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 20, 2003