SKYEPHARMA PLC
Form 6-K
April 05, 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 April, 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 5 April, 2004

Euros 100 mn Marketing Agreement for DepoMorphine ™ in Europe

Illustrates transition in quality of earnings

SkyePharma to receive 35-50% of net sales

LONDON, ENGLAND, 5 April, 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces that it has entered into a strategic marketing agreement with Medeus Pharma for the marketing and distribution of DepoMorphine™ in Europe. DepoMorphine™ is SkyePharma's novel sustained-release injectable formulation of morphine for relief of moderate-to-severe post-operative pain. DepoMorphine™ was filed in the US and Europe last year and approvals are anticipated to commence in the second half of 2004.

SkyePharma Chief Executive Michael Ashton said: "The structure of this agreement represents a strategic shift away from upfront milestone payments towards deriving a greater share of future revenues for our products, and demonstrates our commitment to improve the quality of our earnings by reducing our dependence on irregular milestone payments. The premium share of sales we will receive for DepoMorphine™ reflects the substantial advantages that we believe our product can deliver for patients, physicians, anaesthetists and hospitals. Our clinical trials have shown that DepoMorphine™ has the potential to significantly improve the treatment of pain after surgery, a well-recognized area of unmet medical need. We believe Medeus Pharma has the right therapeutic focus and targeted sales effort to maximise the potential of DepoMorphine™ in Europe and we look forward to working with them.".

Bryan Morton, Chief Executive of Medeus Pharma, said: "Adding this terrific product to our portfolio of critical care and oncology products reflects the interest in our "Window on Europe" business model. We look forward to a strong collaboration with SkyePharma to bring DepoMorphine™ to the market in Europe.".

SkyePharma will receive a share of sales of DepoMorphine™ that will increase from an initial 35% to a maximum of 50% of net sales as certain sales thresholds are reached. SkyePharma will also receive an upfront payment and will receive further future milestone payments on attainment of marketing approvals, commercial launches and sales targets; if all targets are met these payments will amount to over EUR100 million. SkyePharma will be responsible for the cost of manufacturing the product and clinical development required to gain and maintain approvals throughout the expanded European Union. Medeus Pharma will be responsible for the cost of all sales and marketing of the product, including pre-launch development and any further clinical studies (other than Phase IV studies for market development, for which the parties will collaborate).

Medeus Pharma is a UK-based pharmaceutical company focused on European markets and is backed by Apax Partners, a leading European venture capital organisation. Through the February 2004 acquisition of Elan's European sales organization for US$120 million, Medeus Pharma now has a pan-European sales, medical and marketing organization and a range of products in the oncology, critical care and niche hospital areas, with current revenues of approximately US$80 million. Medeus Pharma recently appointed as its Chairman Sir Richard Sykes, Rector of Imperial College, London and former Chairman and Chief Executive of Glaxo Wellcome.

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 http://www.skyepharma.com.

About DepoMorphine™
DepoMorphine™ is a sustained-release injectable formulation of morphine sulphate. 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 in-dwelling catheter for continuous infusion, thereby overcoming a major drawback to the otherwise theoretically desirable epidural route of administration for opioid analgesics.

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 major 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.

On 16 September 2003 the US Food & Drug Administration ("FDA") formally accepted for filing a New Drug Application ("NDA") for DepoMorphine™. The FDA is due to make its initial response in May. On 20 November 2003 SkyePharma submitted an application 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 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.

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 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, 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.

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 05, 2004