

SKYEPHARMA PLC
Form 6-K
June 11, 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 June, 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 ☒ 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 ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

For Immediate Release:

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BSKYEPHARMA RESEARCH & DEVELOPMENT DAY

New Data on DepoMorphine and Propofol IDD-D to be Presented

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LONDON, ENGLAND, June 11, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) is today presenting an update on its Research and Development programmes. The presentation provides institutional shareholders and analysts with an update on the Group's extensive product pipeline and features clinical development of its lead pipeline products, DepoMorphine and Propofol IDD-D, as well as details of the product portfolio including both internally developed products and those developed for SkyePharma's clients.

The presentation begins with a brief introduction by Michael Ashton, SkyePharma's Chief Executive who provides an overview on the Group's major marketed products: Paxil CR, a controlled-release version of GlaxoSmithKline's antidepressant Paxil; Solaraze for actinic keratosis (marketed by Quintiles Transnational in North America and by Shire Pharmaceuticals in Europe); Xatral OD, a once-daily version of Sandoz Xatral for urinary difficulties associated with benign prostatic hypertrophy; and Depocyt, a controlled-release injectable formulation of cytarabine for lymphomatous meningitis, marketed in North America by Endo Pharmaceuticals.

This is followed by a series of presentations from SkyePharma's senior management.

- **New Phase III trial data on DepoMorphine to be presented.**

SkyePharma's novel controlled-release injectable formulation of morphine for control of post-operative pain, DepoMorphine, is given as a single epidural injection before surgery and provides highly effective pain relief for up to 48 hours, the period of peak pain after an operation. By contrast conventional morphine only provides pain relief for up to 12 hours and repeat administration normally requires catheters and infusion pumps that are a source of problems. Dr Gordon Schooley, head of clinical development for SkyePharma, reviews the results of the programme for DepoMorphine which involved four separate pain models involving nearly 1000 patients. In hip surgery and lower abdominal surgery, DepoMorphine demonstrated sustained dose-related pain relief 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. DepoMorphine also achieved statistical significance at several secondary endpoints such as patient perception of pain intensity and adequacy of pain relief. In the Phase IIb trials, DepoMorphine was significantly better than study comparators in the caesarean section study and approached statistical significance in the knee arthroplasty study. In the latter study, the primary endpoint was not met as recalled pain intensity. DepoMorphine did achieve a high degree of statistical significance in terms of patient satisfaction with opioid analgesics after surgery, a secondary endpoint in this trial but the primary endpoint in the Phase III trial. SkyePharma expects to file DepoMorphine with the FDA around the middle of this year and with the EMA in late September. DepoMorphine was licensed to Endo Pharmaceuticals for North America at the end of 2002 and to appoint licensees in other territories this year.

- **New Phase II clinical data Propofol IDD-D 2%, a new proprietary formulation of the injectable anaesthetic and sedative propofol.**

The global market for AstraZeneca's Diprivan and some generic versions was \$650 mn in 2002. The market is constrained by the fact that Diprivan cannot support microbial growth, a recognized problem with current versions that requires opening the vial and allowing the tubing to be disposed of after 8-12 hours. Propofol IDD-D 2% should provide uninterrupted sedation and analgesia, reduce the need for preservatives and reduces the risks of hyperlipidemia and fluid overload associated with Diprivan. In the recently completed Phase II trial, the SkyePharma version was shown to be similar to Diprivan in terms of pharmacokinetics, anaesthetic efficacy and safety. Propofol IDD-D 2% will commence Phase III trials over 700 patients, by the end of 2003. Propofol IDD-D 2% was licensed to Endo Pharmaceuticals for North America at the end of 2002. SkyePharma expects to appoint licensees in other territories later this year.

This is followed by an overview of SkyePharma's pulmonary product pipeline. This includes a dry-powder inhaler of Novartis' bronchodilator Foradil which was filed with the FDA and European authorities in December 2002. Dr Niederlander, head of SkyePharma's pulmonary unit in Basel, Switzerland, also reviews an HFA formulation of formoterol (due to enter Phase III trials later this year); an HFA aerosol inhaler version of formoterol (AstraZeneca's Pulmicort) which will also enter Phase III trials later this year; and an HFA aerosol inhaler of a fixed dose combination of formoterol and fluticasone (to move into Phase II development in the near future).

Dr Richard Jones, head of R&D, will then present SkyePharma's controlled-release injectable delivery systems, DepoFoam and Biosphere and their application to the delivery of biologics. Protein drugs do not have a simple oral system and so cannot be taken orally but injections are unpopular with patients. SkyePharma's two delivery technologies reduce injection frequency and provide scope for improved products that overcome the limitations of current protein drugs. Proof of principle has recently been published and SkyePharma is in negotiations with various potential partners.

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Dr Paul Wotton, SKP's head of Business Development, presents an outline of the company's Business and CEO Michael Ashton concludes with a summing up.

The presentation will commence at 09.45 a.m. BST at Salters Hall, Fore Street, London, EC2Y 5DE. This meeting will be webcast live on www.skyepharma.com.

On Thursday, June 12th, SkyePharma will also host a lunch presentation in New York for its U.S. audience at the St. Regis Hotel, 2 East 55th Street at 5th Avenue, commencing at 11.45 a.m EDT.

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technology, easier-to-use and more effective drug formulations. There are now nine approved products incorporating SkyePharma's five delivery technologies in the areas of oral, injectable, inhaled and topical delivery, and advanced solubilisation capabilities. SkyePharma has two FDA- and EMA-approved manufacturing plants in the USA, and Lyon, France. For more information, visit www.skyepharma.com

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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: June 11, 2003