

SKYEPHARMA PLC
Form 6-K
June 23, 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 June, 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 ☒ 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

23 June, 2004

SkyePharma plc

ANNUAL GENERAL MEETING STATEMENT

LONDON, UK, 23 June 2004 - The Annual General Meeting of SkyePharma plc (LSE:SKP, NASDAQ:SKYE) was held in London today. All resolutions were passed.

Chairman Ian Gowrie-Smith made the following comments to shareholders: "As I explained in the Annual Report, 2003 was a frustrating year. We made encouraging progress in some areas. In particular we were gratified to report that the rapid growth of sales of marketed products such as Paxil CR and Xatral® OD / Uroxatral® resulted in a tripling of our royalty income after a four-fold increase in the previous year. As I have said before, royalty income is the key to our future growth. In 2001 just 3% of our revenues came from royalties but last year the contribution was 35%. However this success was offset by delays to the completion of certain new agreements that we had expected to conclude in 2003: I shall return to this topic later. I am delighted to report today that 2004 looks likely to be a much more positive year for SkyePharma and we have already made great strides.

The most important recent event was the US Food & Drug Administration's approval of DepoDur (the new name for DepoMorphine) on 18 May. This was the first possible date on which the product could be approved. It is becoming increasingly uncommon for drugs to be approved at the first opportunity so this achievement is a real tribute to both the quality of the product and the skill of our clinical and regulatory teams. DepoDur is the first product for which we have undertaken full development ourselves and we expect it to be a major contributor to the company's future. We now look forward to the US launch of DepoDur by our partner Endo later this year. We also expect approval by the UK regulatory authorities in the second half. This will be used as the basis for approval throughout European Union using the EU's "mutual recognition" procedure. Our new partner Medeus Pharma is eagerly awaiting approval of DepoDur to commence marketing in Europe.

At the end of 2003, we reported that three key new deals were still outstanding. We have now completed two of these - on excellent terms. The first was with Medeus Pharma for a European licence for DepoDur . The second was with the US specialty pharmaceutical company First Horizon for a cardiovascular product that I cannot yet disclose. This is a very near-term market opportunity - we expect FDA approval in the autumn - and will bring us substantial milestone payments and a very satisfactory royalty rate. Both of these agreements illustrate our determination to hold out for deal structures that optimise royalties and other sales-related payments. This will progressively reduce the importance of upfront payments in our revenues.

We have also out-licensed our topical products and delivery technologies. We made a strategic decision last year that we did not have the resources to exploit these fully and that it would therefore be better to let someone else take on this development. Our agreement with Trigenesis gives us a share of future revenues and leaves intact our existing topical agreements (such as those for Solaraze®). We also retain the right to use these technologies in certain circumstances. Trigenesis has since been acquired by the Indian company Dr Reddy's, a move we welcome since it will put greater development and marketing resources behind these assets.

Negotiations to out-licence our pulmonary package, while not progressing as fast as we had expected, continue to proceed with a number of parties, including our preferred partner. Our expertise in pulmonary delivery was recognised in 2003 by new agreements with Novartis, GlaxoSmithKline and another

pharmaceutical company we cannot yet identify. Foradil® Certihaler, a version of Novartis' bronchodilator using our multi-dose dry-powder inhaler, has now received its first approvals in Europe and the US FDA issued an "approvable" letter in late 2003. We look forward to the launch of this product later this year. Novartis has also decided to use the same device for a new product, code named QAB149, which is still in development.

I am resigning today as Executive Chairman and seeking reappointment as Non-executive Chairman. I founded SkyePharma in 1996. Since then, the company has grown substantially and developed a strong internal organisation. I am confident that I can leave day-to-day management in the capable hands of Michael Ashton and his team. My particular area of expertise is in establishing new companies and I have a number of other interests where I believe these skills can more appropriately be applied. I am more certain than ever of SkyePharma's potential and you can be assured that I shall continue to be closely involved with the company in my new role."

For further information please contact:

SkyePharma PLC

+44 207 491 1777

Michael Ashton, Chief Executive Officer

Peter Laing, Director of Corporate Communications

+44 207 491 5124

Sandra Haughton, US Investor Relations

+1 212 753 5780

Buchanan Communications

+44 207 466 5000

Tim Anderson / Mark Court

Notes for editors:

About SkyePharma

SkyePharma 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.

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

Edgar Filing: SKYEPHARMA PLC - Form 6-K

Name: Douglas Parkhill

Title: Company Secretary

Date: June 23, 2004