SKYEPHARMA PLC
Form 6-K
January 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 January, 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 January, 2004

SKYEPHARMA PROVIDES END-2003 TRADING UPDATE

LONDON, UK, 5 January 2004-- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces a Trading Update for the year ending 31 December 2003.

As a result of delays in concluding a number of key deals in 2003, revenues for the year will be substantially below the GBP85-100 million range indicated at the time of the Interim Results in September and below the GBP70 million achieved in 2002. Milestone payments remain a major source of our revenues, and this shortfall primarily arises because several key deals that we had expected to conclude in 2003 are still in negotiation, with finalisation now expected in early 2004. With revenues below our budgeted revenue target, coupled with greater than expected research and development costs (arising from delays to completion of agreements involving the transfer of costs to the partner), the Company now expects to report a loss for the second half of 2003 albeit less than the loss we reported for the first half. A number of key deals, potentially involving total milestone payments of up to $200 million and double digit royalty income, remain in advanced stage negotiation with multiple potential partners. We remain confident that these agreements can be concluded on satisfactory or better terms in the current year. This would have a correspondingly positive impact on the profit already budgeted for 2004 (which assumed these agreements were signed in 2003).

The company expects to have cash balances of approximately GBP20 million at 31 December 2003, marginally lower than as at 30 June 2003, with debt levels marginally higher than as at 30 June 2003. However cash should increase substantially in 2004 as the above deals are concluded.

During the second half of 2003, the company signed several new product collaboration deals. Announced today is a further technology licence deal in the pulmonary area that was signed with GlaxoSmithKline at the end of 2003. However, discussions to finalise the major deals that we had expected to be concluded by 31 December remain ongoing. A signed term sheet is in place for one transaction, which we would anticipate closing within the next few weeks. In addition one of our pipeline products, due to be filed for approval with the FDA in March, is currently under advanced review by several potential licensees. Our largest licensing opportunity is a package of products in the pulmonary field, for which we are also in advanced discussions with a number of parties. A major clinical study published in November suggests a substantial increase in the potential commercial value of the bronchodilator formoterol, both alone and in combination with an inhaled steroid. Our own combination with the steroid fluticasone is making very satisfactory progress in clinical development, with a Phase I trial now completed. We believe that these factors have significantly raised the value of our inhaled product range and support our stance that the Company should refrain from entering any collaboration that undervalues this part of our product pipeline. The Company is so convinced of the potential value of this particular product opportunity that we have already rejected terms including milestones of up to $90 million and double digit royalty returns. We remain confident that we will be able to finalise a deal with an appropriate partner in the first quarter of 2004.

While every effort was made to bring these deals to completion on appropriate terms by the 2003 year-end, the Company strongly believes that it is in shareholders' best interests to conclude the best deal possible for these critical products. Unfortunately the time required for due diligence and the final stages of negotiations does not always accommodate the constraints imposed by a year-end date. Indeed, this restriction has proved a significant impediment to obtaining the deal terms we feel that our products warrant. We remain confident that this is only a delay and expect to conclude these agreements in early 2004.

OUTLOOK FOR 2004

Turning to the current year, we see the outlook as very positive for the Company. Revenues and cash will be improved by the finalisation of the deals referred to above that are currently under discussion, augmented by anticipated milestone payments from deals agreed in prior years. As important, we expect a further significant increase in our royalty income, which is becoming an increasingly dominant factor in our revenues and, importantly, also in our

profits. We had already budgeted a profit for 2004 (assuming the agreements still in negotiation were signed in 2003) and deferral of those agreements to the current year would therefore have a correspondingly positive impact.

With the completion of the development phase of our growth, we are further reorganising our R&D operations and some other business functions in order to align the development base with our projected future R&D activities. Regrettably this will mean some redundancies but we expect to emerge from this reorganisation in a leaner and fitter form. This will involve a one-off cash cost of approximately GBP3.5 million and some associated non-cash asset write-offs. These will be taken as exceptional charges in both 2003 and 2004 as appropriate. Thereafter shareholders should expect to see growth in operating profits more closely aligned with the future growth in royalty income that we expect, generated by products such as DepoMorphineTM.

Commenting on the Trading Update, Chief Executive Michael Ashton said: "We are disappointed that we have not been able to meet the ambitious target we set ourselves in April of revenue growth in excess of 40%. On the positive side, royalty income should more than triple for the full year after increasing fourfold in 2002, fulfilling our expectations. With our main royalty-earning products Paxil(R) CR and Xatral(R) OD/UroXatral(R) likely to be joined in 2004 by Foradil(R) CertiHaler and DepoMorphineTM, we expect this gratifying trend to continue in the current year. We cannot stress sufficiently that rising income from royalties is the key to future sustainable profit growth for SkyePharma. At our present stage of development, revenues and profitability are still largely dependent on the level and timing of milestone payments, which by their nature are very difficult to predict. While we are striving to become consistently profitable, it would clearly not be in shareholders' best interests to enter into new agreements with milestone payments that would produce current profitability if those upfront payments did not reflect the value of our investment or came at the expense of future royalty streams.

"With our increasing royalty share, the deals currently under negotiation and an improved cost base, I am excited by the prospects for 2004.

"I can also report that the Company has been in discussion with our partner GlaxoSmithKline over the royalty rate we receive on sales of Paxil(R)? CR. Legal advice received by SkyePharma leads us to believe that we are entitled to a substantial increase in the royalty rate from the date of entry of generic paroxetine in the US market. If we are unable to reach agreement on this issue, there is an arbitration procedure in place."

ends

A conference call on this Trading Update will be held today. Michael Ashton, SkyePharma's Chief Executive Officer, will host the conference call. Investors and other interested parties may access the conference call at 4:00 p.m. (GMT) / 11:00 a.m. (EST) by dialling +1 (612) 288 0337 for International callers and (800) 230 1085 for US callers.

A replay will be available shortly after the conclusion of the conference call by dialling +1 (320) 365 3844 for International callers and (800) 475 6701 in the US and entering Access Code 716063.

The Company intends to publish its full-year results for 2003 at the end of March.

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now nine approved products incorporating three of SkyePharma's five 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. There can be no certainty that agreement in respect of the additional royalty for Paxil(R)? CR claimed by the company will be reached with GlaxoSmithKline, or that SkyePharma will succeed in the arbitration process or that an increased royalty will be paid. 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: January 05, 2004