SKYEPHARMA PLC
Form 6-K
November 03, 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

3 November, 2003

SkyePharma PLC

Sanofi-Synthélabo launches Uroxatral® in USA

LONDON, ENGLAND, November 3, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces that Sanofi-Synthélabo (Euronext: SASY; NYSE: SNY) has launched Uroxatral® (alfuzosin hydrochloride) in the US market for the relief of urinary symptoms associated with benign prostatic hypertrophy ('BPH'), a common condition affecting middle-aged males. Uroxatral® was approved by the US Food & Drug Administration ('FDA') on 16 June. The 10 mg once-daily extended-release formulation was developed for Sanofi-Synthélabo by SkyePharma and involves SkyePharma's proprietary GeoMatrix oral controlled-release delivery technology. SkyePharma receives a royalty on Sanofi-Synthélabo's global sales of the once-daily formulation of alfuzosin (known as Xatral® OD outside the USA).

Michael R.D. Ashton, SkyePharma's chief executive officer, commented 'We are excited by the launch of Uroxatral® representing another product being introduced into the US market utilising SkyePharma's Geomatrix drug delivery technology. The market for products for the effective relief of the signs and symptoms of BPH, already a common condition, is increasing due to an ageing population. Alfuzosin is an effective treatment with a low incidence of side-effects and the once-daily formulation we developed for Sanofi-Synthélabo has enabled a significant increase in Xatral®'s share of market outside the US, we therefore see a great opportunity for this important new product in the US. Rising royalty income from Xatral® OD and Uroxatral® will be a key part of moving SkyePharma closer to its goal of having the greater proportion of our earnings derived from product-related revenues.'

BPH is a common chronic condition that typically first affects males in middle age. Thereafter the incidence rises steeply with age. Gradual enlargement of the prostate gland causes progressive obstruction of the urethra. Patients feel the need for frequent micturition but this results in incomplete emptying of the bladder. The urinary symptoms of BPH affect 22% of men aged 50-59 but 45% of men aged 70-80. Alfuzosin is not a primary treatment for enlarged prostate but addresses the urinary symptoms by selectively blocking alpha-1 adrenergic receptors in smooth muscle of the urinary tract, causing smooth muscle in the bladder neck and prostate to relax and thereby improving urine flow. Extensive clinical studies conducted by Sanofi-Synthélabo have demonstrated that alfuzosin has a high degree of selectivity for urinary tract smooth muscle, resulting in a low incidence of vasodilatory side-effects such as postural hypotension and syncope (fainting) that can affect patients treated with competing less selective alpha blockers. In addition alfuzosin has a low risk of sexual side-effects whereas impotence and ejaculatory disorders are well-recognized side-effects of some other alpha-blockers (and also of alternative treatments for BPH). Alfuzosin is also in late-stage clinical trials for a second related indication, acute urinary retention. Alfuzosin is the only alpha-1 blocker that has been shown in clinical trials to result in a significant decrease in post-void residual urine volume, a known risk factor for acute urinary retention.

IMS estimates that the US market for treatments for BPH is currently in excess of US$1.0 billion, two-thirds of which comes from sales of alpha-blockers. A 2002 analysis by Theta Reports estimated that by 2006 approximately 115 million men in the 50+ age bracket will suffer from BPH and that even though BPH is not life-threatening, the rising incidence will drive the value of the global market to nearly $10 billion. Sanofi-Synthélabo has marketed alfuzosin as Xatral® outside the USA since 1988. Xatral® was initially introduced as a three times a day formulation and subsequently a twice-daily formulation was marketed. Xatral® OD, the once a day formulation developed by SkyePharma for Sanofi-Synthélabo, was launched in Europe in April 2000 and is now on the market in Europe and certain territories in Africa, the Middle East, Asia, Latin America and Canada. For the first nine months of 2003, Sanofi-Synthélabo's sales of Xatral® in all forms outside the USA were EURO156 mn. No version of Xatral® has previously been marketed in the USA.

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 Geomatrix

Geomatrix controlled release systems control the amount, timing and location of drug release into the body. This is achieved by constructing a tablet with two basic components: a core containing the active drug or drugs, and one or two additional barrier layers that control the drug's diffusion out of the core. Tablets with a wide range of predictable and reproducible drug release profiles can be made by combining different chemical components in the core and barrier layers, each with a different rate of swelling, gelling and erosion.

About Sanofi-Synthélabo

With 2002 annual sales in excess of $8.4 billion and 33,000 employees in more than 100 countries, Sanofi-Synthélabo ranks among the world's top 20 pharmaceutical companies and the top seven pharmaceutical companies in Europe. World headquarters are in Paris, France. The Sanofi-Synthélabo group is a major player on the world's pharmaceutical market, especially in four fields of expertise: cardiovascular/thrombosis, central nervous system, internal medicine and oncology. For further information, visit http://www.sanofi-synthelabo.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.

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: November 3, 2003