SKYEPHARMA PLC
Form 6-K
March 02, 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 March, 2004

SkyePharma PLC

(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

For Immediate Release

2 March 2004

SkyePharma PLC

Sanofi-Synthelabo begins marketing Uroxatral®
to US primary care physicians

LONDON, UK, 2 March 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes yesterday's announcement by its partner Sanofi-Synthelabo that it is to begin marketing Uroxatral® (alfuzosin hydrochloride extended-release tablets), a treatment for benign prostatic hyperplasia ("BPH"), directly to primary care physicians ("PCPs") in the United States.

The 10 mg once-daily extended-release formulation was developed for Sanofi-Synthelabo by SkyePharma and involves SkyePharma's proprietary GeoMatrix oral controlled-release delivery technology. SkyePharma receives a royalty on Sanofi-Synthelabo's global sales of the once-daily formulation of alfuzosin (known as Xatral® OD outside the USA). Uroxatral® was approved by the US Food & Drug Administration ("FDA") in July 2003. Since its

November launch, Sanofi-Synthelabo has focused on specialist urologists. Marketing to PCPs will involve a considerable expansion in Sanofi-Synthelabo's detail force for the product.

Michael Ashton, SkyePharma's Chief Executive, said: "The US launch of Uroxatral® in November was an important milestone for our Geomatrix drug delivery technology. Initial progress with specialist urologists has been encouraging and we anticipate a substantial increase in sales now that the product is to be marketed to the wider general practitioner market. The ageing population is driving an increase in the incidence of BPH, already a common condition. Alfuzosin is an effective treatment with a low incidence of side-effects and the once-daily formulation we developed for Sanofi-Synthelabo has enabled a significant increase in the market share of Xatral® outside 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 (also known as benign prostatic hypertrophy) is a common chronic condition that typically first affects males in middle age. Thereafter the incidence rises steeply with age. The urinary symptoms of BPH affect 22% of men aged 50-59 but 45% of men aged 70-80. Currently 8 million men in the USA are affected. 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. Left untreated, the symptoms may progress, which can lead to serious health problems including urinary tract infections, bladder and kidney damage, bladder stones, incontinence and acute urinary retention.

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-Synthelabo 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 alpha blockers that are less selective. In addition alfuzosin has a low risk of sexual side-effects whereas erectile dysfunction and ejaculatory disorders are well-recognized side-effects of competing alpha-blockers (and also of alternative treatments for BPH). Alfuzosin has recently been approved in Europe for a second related indication, acute urinary retention, and is in late-stage clinical trials for a US filing for this indication. 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. The increase in the average age of the population as the post-war "Baby Boom" reaches middle age is expected to drive a significant increase in both the prevalence of the condition and the size of the market. A 2002 analysis by Theta Reports estimated that by 2006 approximately 115 million men in the 50+ age bracket worldwide 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-Synthelabo 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-Synthelabo, was launched in Europe in April 2000 and is now on the market throughout Europe and in certain territories in Africa, the Middle East, Asia, Latin America and Canada. In 2003, Sanofi-Synthelabo's global sales of Xatral® in all forms were EUR222 million including US sales of Uroxatral® of EUR9 million (US$11 million). No version of Xatral® had been marketed in the USA before the introduction of Uroxatral® in November 2003.

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 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 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-Synthelabo

Sanofi-Synthelabo is a major global research-based pharmaceutical group with 32,500 employees in more than 100 countries and consolidated sales of over EUR8 billion in 2003. With an R&D portfolio of 55 compounds in development, Sanofi-Synthelabo is focused on a core group of four therapeutic areas: cardiovascular disease and thrombosis; diseases of the central nervous system; internal medicine; and oncology. For more 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.

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-_____

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: March 2, 2004