

SKYEPHARMA PLC
Form 6-K
July 18, 2005

**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 July, 2005

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-

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SkyePharma PLC

Triglide Launched on US Market

Addresses Major Market Opportunity in the Treatment of Lipid Disorders

LONDON, ENGLAND, 18 July, 2005 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces that its partner First Horizon Pharmaceutical Corporation ("First Horizon") has launched Triglide (fenofibrate) and the product is now available in pharmacies in the United States. Triglide is a once-daily oral treatment for lipid disorders such as elevated cholesterol and triglycerides. Fenofibrate not only lowers levels of total triglycerides and LDL cholesterol ("bad cholesterol") in the bloodstream but also has the valuable property of raising abnormally low levels of HDL cholesterol ("good cholesterol"), which is increasingly recognized as a major cardiovascular risk factor. SkyePharma received FDA approval for Triglide on 7 May 2005.

Michael Ashton, SkyePharma's Chief Executive Officer, said: "Elevated cholesterol already affects over half of the US population and treatment represents a major area of unmet medical need. Triglide, our new formulation of fenofibrate, overcomes a major drawback of an otherwise valuable medication and fenofibrate is more effective than statins in boosting HDL levels. We see a substantial opportunity for Triglide."

First Horizon's 400-strong representative force focuses on cardiovascular physicians and high-prescribing primary care practitioners and has a proven ability to capture market share in the cardiovascular therapeutic area."

Fenofibrate is highly insoluble in water, resulting in variable uptake from the stomach and requiring the patient to take the tablets with food. Triglide, the new formulation of fenofibrate developed by SkyePharma, has a comparable absorption under fed and fasting conditions and therefore allows patients to take the drug at any time, improving compliance and simplicity for both patients and prescribers. Triglide is the first approved product utilizing SkyePharma's proprietary IDD®-P solubilization technology.

In May 2004, SkyePharma announced that it had granted First Horizon exclusive U.S. marketing and distribution rights for Triglide. Under this agreement, SkyePharma will receive up to \$50 million in milestone payments, \$30 million of which are sales-based milestone payments. SkyePharma received a payment of \$5 million upon signature of the agreement and a further \$15 million on FDA approval in May 2005. In addition SkyePharma will receive a royalty of 25% of First Horizon's net sales of the product. SkyePharma will manufacture and supply the product from its Lyon manufacturing facility. SkyePharma will also make a contribution of up to \$5 million to First Horizon's initial marketing expenses to establish the product.

For further information please contact:

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Notes to Editors

About SkyePharma

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 eleven 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.

About lipid disorders

Lipid disorders are a group of conditions associated with excessive levels of lipids (fatty substances) in the bloodstream. Hyperlipidaemia (elevated blood lipids) is an important risk factor in the development of atherosclerosis and heart disease.

The major lipids in the blood are triglycerides and cholesterol, either free or in the form of lipoproteins, molecules of fat or cholesterol linked to protein. Types of lipoproteins include very low-density lipoproteins (VLDL), low-density lipoproteins (LDL), and intermediate-density lipoproteins (IDL). High-density lipoproteins (HDL), or "good cholesterol," actually reduce the risk of heart disease and are therefore protective factors.

The treatment guidelines for hyperlipidaemia of the US National Institutes of Health aim to reduce the incidence of heart disease. The current guidelines are that LDL levels should be below 100 mg/dl and total cholesterol below 200 mg/dl and HDL levels should be above 40 mg/dl. Although these guidelines are widely accepted, it is estimated that over half of the American population have total cholesterol above 200 mg/dl. Of these, less than half are currently treated and of the treated group less than one third achieve the target goals.

The principal drug treatments for hyperlipidaemia are "statins" (HMG-CoA reductase inhibitors that block endogenous synthesis of cholesterol in the liver) and fibrates (PPAR- α agonists that increase the metabolic elimination of lipoproteins).

References: Amer J Cardiol 2003;92:79- 81, 2001;88:265-269; Europ Heart J 2001: 22:554-772; Current-Medical-Research-and-Opinion 2004:20:1025-1033

About fenofibrate

Fenofibrate, an oral fibrate lipid lowering agent, was developed by Groupe Fournier and first introduced internationally in 1975. In the US it was licensed to Abbott Laboratories, which launched it in 1996 as Tricor®. Abbott's sales of Tricor® in 2004 were US\$ 778 million (a year-on-year increase of 38%). Fenofibrate markedly reduces elevated plasma concentrations of triglycerides. It also decreases elevated plasma concentrations of LDL and total cholesterol. At the same time, fenofibrate increases abnormally low levels of HDL cholesterol. The latter property is particularly important as there is growing recognition that abnormally low levels of HDL cholesterol may represent a more important risk factor for cardiovascular disease than elevated LDL levels. Although statins are the most potent agents for lowering LDL levels, statins are only modestly effective in raising HDL cholesterol levels. The mode of action of fenofibrate is different from that of the statins and the two act synergistically, with a significantly greater effect on lipid levels when used together than when each is used individually. Both the current American Diabetes Association and NICE guidelines recommend the appropriate use of fenofibrate in combination with statins.

Fenofibrate is a prodrug of the active agent, fibric acid, and is virtually

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insoluble in water. Uptake from the stomach under fasting conditions is highly variable but uptake is substantially enhanced by food, especially by dietary fat.

About SkyePharma's IDD®-P technology

SkyePharma has a family of proprietary technologies designed to overcome the insolubility of many drug substances in water, which adversely affects bioavailability. SkyePharma's Insoluble Drug Delivery-MicroParticle (IDD®-P) technology involves preparing microparticles of active drug and then stabilizing these with phospholipid surface modifying agents that prevent the microparticles from reaggregating. Triglide tablets incorporate a novel fenofibrate formulation developed to optimize bioavailability independent of food. In this formulation, fenofibrate crystals have been reduced to sub-micron to micron size particles, stabilized by phospholipid (lecithin) surface modifiers. The tablets are designed to protect and rapidly release the fenofibrate microparticles. This expands the surface area of drug exposed to the dissolution medium and thereby increases bioavailability.

Certain statements in this news release are forward-looking statements and are made in reliance on the safe harbour provisions of the U.S. Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that these expectations will materialize. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward-looking statements based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. Factors that could cause differences between actual results and those implied by the forward-looking statements contained in this news release include, without limitation, risks related to the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

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: July 18, 2005