

SKYEPHARMA PLC  
Form 6-K  
April 13, 2007

**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 April, 2007

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-

---

**Press Announcement**

## Edgar Filing: SKYEPHARMA PLC - Form 6-K

### Once-Daily **REQUIP®** (ropinirole HCl) XL 24-Hour Extended-Release Tablets Accepted for

LONDON, UK, APRIL 13, 2007 - SkyePharma PLC (LSE:SKP; NASDAQ: SKYE) today announces Administration has accepted for filing the application by its partner, GlaxoSmithKline Extended-Release Tablets, the proposed brand name for a once-daily formulation of ropinirole fo been designed to provide a steady rate of absorption in the body to help reduce blood plasma fluct

Ropinirole is a non-ergot dopamine agonist currently marketed as **REQUIP®** (ropinirole HCl) Tablet. It has an indication in the U.S. for the treatment of the signs and symptoms of idiopathic Par three times a day. **REQUIP XL 24-Hour** uses SkyePharma's proprietary GeoMatrix technology and ha and to have a simpler and faster titration schedule.

On 3 April 2007, GlaxoSmithKline announced positive results of the Ropinirole 24-Hour Efficac (EASE-PD Adjunct) study, which were published in the 3 April issue of *Neurology*. In that study to Parkinson's patients' existing levodopa (L-dopa) therapy significantly reduced "off" time day when compared with baseline prior to treatment, thus allowing these patients to continue period of time.

**REQUIP** is indicated for Parkinson's disease and Restless Legs Syndrome in the U.S. Parkinson of current **REQUIP** sales in the U.S. If approved for Parkinson's disease, future sales of mid-single digit royalties for SkyePharma.

Parkinson's disease is a chronic, progressive and debilitating neurological condition that balance. Researchers have determined that Parkinson's disease involves pathways in the brain functioning improperly. Patients with Parkinson's disease experience a reduction in dopam communicates messages about movement, resulting in the symptoms of Parkinson's disease. The (slower-than-normal voluntary movements), rigidity (stiffness), tremor (involuntary shaking) balance).

More than one million people in the United States have Parkinson's disease, and it is estima diagnosed in the U.S. each year. Most people develop Parkinson's disease between the ages develop at an earlier age.

Commenting on today's announcement, Frank Condella, CEO of SkyePharma, said: "This is an important step towards gaining approval in the US for **REQUIP XL 24-Hour** which significant product for SkyePharma. Dopamine agonists are increasingly recommended by doctors suffering from Parkinson's disease and this new, once-daily version of **REQUIP** could deliver si and may improve compliance."

#### **For further information please contact:**

SkyePharma PLC	Frank Condella Ken Cunningham Peter Grant	+44 20 7491 1777
Financial Dynamics (UK Enquiries)	David Yates Deborah Scott	+44 20 7831 3113
Trout Group (US Enquiries)	Christine Labaree Seth Lewis	+1 617 583 1308
GSK European Analyst/Investor inquiries:	Anita Kidgell Sally Ferguson David Mawdsley	+44 20 8047 5542 +44 20 8047 5543 +44 20 8047 5564

#### **NOTES TO EDITORS**

## Edgar Filing: SKYEPHARMA PLC - Form 6-K

### About the EASE-PD Study

The EASE-PD Adjunct study was a multi-center, double-blind, placebo-controlled study, comparing treatment of Parkinson's disease not adequately controlled with L-dopa. Subjects were randomized (1:1) to *REQUIP XL 24-Hour* (n=202) or placebo (n=191) in addition to L-dopa for 24 weeks. The primary endpoint was mean time spent "off" (measured via patient diaries). "Off" time describes the return of Parkinson's symptoms. *REQUIP XL 24-Hour* decreased patients' awake time spent "off" by an average of 2.1 hours per day compared to baseline prior to treatment.

The study also included a wide variety of motor and non-motor secondary endpoints, including time spent "on" during which medication is working and providing benefit, and "on" time without troublesome dyskinesia (without involuntary movements interfering with function or causing discomfort, a common problem with L-dopa). *REQUIP XL 24-Hour* significantly increased both "on" time and "on" time without troublesome dyskinesia by 12 percent (12 percent increase) and reduced the percentage of "off" time by more than 12 percent compared to placebo. *REQUIP XL 24-Hour* also improved sleep problems associated with Parkinson's disease, as measured by the Parkinson's Disease Sleep Scale.

There were other motor and non-motor secondary endpoints in the study that were statistically significant. Significant differences between *REQUIP XL 24-Hour* and placebo in PDQ-39 subscales of social support and quality of life. Additionally, there was no significant difference between *REQUIP XL 24-Hour* and placebo on the Epworth Sleepiness Scale, signifying no increase in daytime sleepiness.

In the EASE-PD Adjunct study, once daily use of *REQUIP XL 24-Hour* was generally well tolerated. Adverse events was low and similar between the two groups (*REQUIP XL 24-Hour* 5 percent versus placebo 4 percent). Adverse events reported in patients taking *REQUIP XL 24-Hour* (n=202) versus placebo (n=191) were dyskinesia (11 percent versus 4 percent), dizziness (8 percent versus 3 percent), somnolence (7 percent versus 4 percent), nausea (11 percent versus 4 percent), dizziness (8 percent versus 3 percent), somnolence (7 percent versus 4 percent), and orthostatic hypotension (5 percent versus 2 percent).

### About SkyePharma PLC

Using its proprietary drug delivery technologies, SkyePharma develops new formulations of drugs to improve drug advantage and life-cycle extension. The Company has nine approved products in the areas of oral and injectable drugs are marketed throughout the world by leading pharmaceutical companies. For more information, visit [www.skyepharma.com](http://www.skyepharma.com).

### About GlaxoSmithKline

GlaxoSmithKline, with U.S. operations in Philadelphia and Research Triangle Park, N.C., is one of the world's leading pharmaceutical and health care companies.

### About REQUIP Tablets (Immediate-Release Formulation)

Prescription *REQUIP* is not for everyone. *REQUIP* Tablets may cause patients to fall asleep or feel drowsy during activities such as driving; or to faint or feel dizzy, nauseated, or sweaty when they stand up. Patients should tell their doctor if they or their family notices that they develop any unusual impulses or behaviors, such as hypersexuality. Hallucinations may occur at anytime during treatment. *REQUIP* may potentiate the effects of other drugs. Side effects include nausea, dizziness, drowsiness or sleepiness, headache, and dyskinesia (uncontrollable movements). Patients not bothered enough to stop taking *REQUIP*. This is not a complete list of side effects and should be discussed with patients' healthcare providers. Their doctor or pharmacist can give patients a more complete list of side effects. Patients should talk to their doctor about any side effects they may have.

### **Cautionary statement regarding forward-looking statements**

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, this report contains any forward-looking statements or projections made by the company, including those made in this report. Actual results and uncertainties that may cause actual results to differ materially from those projected.

## 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**

Edgar Filing: SKYEPHARMA PLC - Form 6-K

By: /s/ John Murphy

Name: John Murphy  
Title: Company Secretary

Date: April 13, 2007