

SKYEPHARMA PLC  
Form 6-K  
April 19, 2006

---

# 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, 2006

---

## 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  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: 19 April, 2006

FOR IMMEDIATE RELEASE

19 APRIL 2006

SkyePharma PLC

Preliminary Results Announcement

for the year ended 31 December 2005

**LONDON, UK, April 19, 2006** SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces the Company's preliminary results for the year ended December 31, 2005.

**Operating highlights**

Paxil CR™ back on US market

Triglide™ launched in USA

Pulmicort® HFA-MDI filed

Foradil® Certihaler now approved in more than 20 markets

Flutiform™ starts Phase III clinical trials

DepoBupivacaine™ completes Phase II clinical trials

Flutiform™ licence negotiations ongoing with several parties

DepoBupivacaine™ licensed to Mundipharma and Maruho

Rights issue raised £35 million (net of expenses)

Strategic decision to divest injectables business unit

**Financial highlights (under IFRS)**

Turnover down by 18% to £61.3 m (2004: £75.2 m)

Absence of Flutiform™ licensing revenues

Strategic shift from up fronts to royalties

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

Royalty income decreased by 16% to £21.7 m (2004: £25.9 m)

Paxil CR™ supply problems

Royalties excluding Paxil CR™ up 38%

Gross profit down 32% to £32.1 m (2004: £47.0 m)

Exceptional items of £21.4 m (2004: £8.9 m)

Non cash investment impairments £19.4m

Abortive transaction costs £2.0m

Operating loss before exceptionals £16.1 m (2004: £0.4 m)

Operating loss after exceptionals £37.5 m (2004: £3.1 m)

Net loss £50.9 m (2004: £18.6 m)

Loss per share 8.1p (2004: 3.0p)

End 2005 net cash £34.3 m (2004: £15.3 m)

Dr Jerry Karabelas, Non-executive Chairman, said: 2005 was a difficult year for SkyePharma but the Company now has a new management team and has adopted a new strategy. We are focused in the short term on the licensing of Flutiform and the divestment of our injectables business. While there is obviously uncertainty as to the timing of these two transactions, they will not only greatly reduce the Company's current and future cash requirements but also provide us with the funds to consider new opportunities related to oral and inhalation products. We remain convinced that Flutiform will become a major product. We believe that the strategic initiatives we have adopted will enable the Company to maximise the potential of Flutiform and other pipeline products, to become profitable in the near term and to deliver long-term value for shareholders.

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

#### **SkyePharma PLC**

Jerry Karabelas, Non-executive Chairman

Frank Condella, Chief Executive Officer

Peter Laing, Director of Corporate Communications

Today

Thereafter

Sandra Haughton, US Investor Relations

+44 207 466 5000

+44 207 491 1777

+1 212 753 5780

**Buchanan Communications**

Tim Anderson / Mark Court / Rebecca Skye Dietrich

+44 207 466 5000

## CHAIRMAN'S STATEMENT

There is no disguising that 2005 was a difficult year for SkyePharma. Despite a number of significant achievements, outlined in the Review of Operations below, we did not complete a development agreement for Flutiform, our major pipeline product. We believe that Flutiform has substantial commercial value. Faced with the prospect of a delay to the development of this important product, which might have impaired its commercial potential, we took the decision in September to raise £35 million (net of expenses) by means of a rights issue to keep Flutiform on its planned development timeline through Phase III. As such, our target launch date in the USA remains 2009. We are convinced that the decisions to proceed with the clinical development of Flutiform ourselves and to fund this development through a rights issue were in shareholders' best interests.

We continue to have negotiations with potential strategic marketing partners for Flutiform who could also fund development of additional indications following initial approval for asthma. We hope to finalise an agreement with one or more marketing partners for Flutiform™ as soon as reasonably possible. The Board remains confident that an agreement will be reached in 2006.

Prior to reaching the decision to ask shareholders for funding, we explored a number of financing alternatives to fund the development of Flutiform and also a variety of strategic options for the Company. These included discussions concerning a transaction that, had it been successful, would have created a combined company that could have marketed Flutiform itself in some markets. The discussions were called off by SkyePharma due to uncertainties over the other party's prospects. SkyePharma was unable to disclose this at the time due to reasons of confidentiality and the possibility that these discussions could resume at some time in the future.

In November, we also received an opportunistic takeover approach from Innovata PLC. As a result, the Board felt that it was in shareholders' interests to explore all options and consequently appointed Lehman Brothers to conduct a full strategic review of all the options open to the Company.

The conclusion of this review in early 2006 did not lead to an offer for the entire Company on terms that the Board felt able to recommend to shareholders. However, there were expressions of interest in individual parts of the business. The Board then took a strategic decision to divest the US-based injectables business in order to reduce the Company's projected cash outflow over the next few years and to raise funds to concentrate on the oral and inhalation businesses. The investment bank UBS has been retained recently to manage this sale and the process is ongoing. The injectables business includes DepoCyt and DepoDur, both marketed products, and the lead injectable pipeline product DepoBupivacaine.

In January 2006 certain shareholders requisitioned an Extraordinary General Meeting ( EGM ) seeking to remove the Company's then Chairman and to appoint a nominated director to SkyePharma's Board with the ultimate aim of having him appointed as Executive Chairman. Although this motion was defeated at the EGM in early March, the Board has since made a number of changes and introduced a process whereby major investors are now involved in the selection of new Non-Executive Directors.

### Board Changes

In January 2006, Ian Gowrie-Smith stepped down from his role as Non-Executive Chairman when I was appointed in his place. Ian subsequently resigned as a Director in February. As shareholders will be aware, Ian founded SkyePharma in 1996 and has seen it grow to become a substantial business. He remains a shareholder but will now be focusing his energies on a number of early-stage non-pharmaceutical companies. I have been a Non-Executive Director of SkyePharma since 2000 and I have also had extensive experience at senior management levels of the international pharmaceutical industry.

Michael Ashton, who has now reached the age of 60, indicated to the Board last year that it was his intention to retire as Chief Executive in 2006. Michael will continue to serve as a Director until the 2006 Annual General Meeting in June but will not be seeking re-election.

I am sure that shareholders will join me in thanking both Ian and Michael for their contribution to the development of SkyePharma since its formation.

The Board has appointed Frank Condella as Chief Executive, who joined the Company on 1 March 2006, having previously run the European operations of the leading generic company IVAX. Before joining IVAX, Frank was Chief Executive of Faulding Pharmaceuticals and before that built up the speciality pharmaceuticals business of Roche. Frank joined the Board on 4 April 2006.

The Board has also appointed Dr Ken Cunningham in the new role of Chief Operating Officer. Ken was formerly Chief Executive of the private UK company Arakis and has a wealth of experience in pharmaceutical development, especially in the areas of oral and inhalation products.

Two other Non-Executive Directors, Sir Michael Beavis and Dr Keith Mansford, will not be standing for re-election at the Annual General meeting. The Board will miss their wise counsel and wishes them well in retirement. In their place, we will be appointing two new Non-Executive Directors.

### **The Future**

The EGM process was costly and also diverted significant management time away from running the business. However, now that this is behind us we can focus on execution of the new strategy referred to above and outlined in more detail in the following pages. We are focused in the short term on the licensing of Flutiform and the divestment of our injectables business. While there is obviously uncertainty as to the timing of these transactions, they will not only greatly reduce the Company's current and future cash requirements but also provide us with the funds to consider new opportunities related to oral and inhalation products. We are also devoting a significant amount of resource to ensure that Flutiform continues on its planned development timeline. We remain convinced that Flutiform will become a major product, as is evident from the number of companies that have expressed an interest in obtaining licensing rights. We believe that the strategic initiatives we have adopted will enable the Company to maximise the potential of Flutiform and other pipeline products, to become profitable in the near term and to deliver long-term value for shareholders.

### **Dr Jerry Karabelas**

#### **Non-Executive Chairman**

### **STRATEGY**

SkyePharma's mission is to become one of the world's leading speciality pharmaceutical companies, powered through excellence in drug delivery.

On 2 February 2006, the Company announced the outcome of its Strategic Review. The Board concluded that in the interests of achieving sustainable profitability in the shortest reasonable time, SkyePharma should concentrate on oral and inhalation products and divest its injectable business interests. The proposed divestment, which the Board expects to be subject to approval by shareholders, would not only release cash but also relieve the Company of a significant cash burn and future capital expenditure. The Board believes that the residual core business would be able to achieve profitability in the near term. Furthermore, with greater focused resources the Company would be in a better position to further develop its pipeline of oral and inhalation products. Ultimately, it is the Company's strategy to add a niche sales and marketing capability in one or more markets that would improve profit growth and give it greater control over revenue generation.

The injectables business, located in San Diego, consists of two marketed products: DepoCyt® for a complication of cancer and Depodur® for the treatment of post-surgical pain. This business also has a pipeline of projects in various stages of development. These include controlled-release injectable formulations of a number of biological products and DepoBupivacaine, a long-acting injectable formulation of the local anaesthetic bupivacaine for the control of post-operative pain. The Company remains convinced that DepoBupivacaine addresses an important area of unmet medical need and has major commercial potential. However, further development of this business would require significant cash resources and would also impact the Company's ability to become profitable in the near term.

The Company has retained UBS to act as its investment bank to manage the divestment process. This process is ongoing and several third parties, both trade and financial, have already shown significant interest in the injectables business.

Funds raised by the divestment of the injectables business will be available to enhance the core oral and inhalation business. We expect to be able to accelerate the development of certain pipeline products whose development has had to be delayed in recent years. Several of these products are at an early stage of development but would address important therapeutic areas such as gastrointestinal, diabetes and hypertension. Development activities will continue to be based in Muttenz, Switzerland and manufacturing in Muttenz and Lyon, France.

Our oral and inhalation pipeline includes SkyePharma's most important project Flutiform<sup>™</sup>, a combination asthma product. The Company is convinced that Flutiform has substantial value as it is poised to enter a large and rapidly growing market with currently limited competition. We are currently negotiating with several companies for the rights to market Flutiform in the US, Canada, Japan and the countries of the European Union.

The core oral and inhalation business has seven products marketed by licensees, including Paxil CR, Xatral<sup>®</sup> OD and Triglide. These products will continue to generate revenues and cash for the Company. There are also a number of late-stage products that are close to the market.

The Company will focus its efforts on working with partners to maximise revenues from existing and future marketed products. We will also be able to devote more resources in this area to the development of additional products and to increase the size of our pipeline.

## OPERATIONAL REVIEW

### INHALATION PRODUCTS

#### Flutiform<sup>™</sup> HFA-MDI

Flutiform<sup>™</sup> HFA-MDI is a fixed-dose combination of the long-acting bronchodilator formoterol and the inhaled steroid fluticasone in a metered-dose aerosol inhaler (MDI) using a hydrofluoroalkane (HFA) propellant.

The world market for asthma drugs is expected to exceed \$20 billion by 2010, with use in chronic obstructive pulmonary disease (COPD) expected to add a further \$10 billion. The fastest-growing part of this market is combination treatments, which combine a long-acting bronchodilator with an inhaled steroid in a single delivery device. Combinations are not only convenient for patients but also optimise the efficacy of the individual agents. Sales of GlaxoSmithKline's combination *Advair* (*Seretide* in Europe) already exceed \$6 billion and AstraZeneca's *Symbicort* (which is not yet on the US market) add another \$1 billion. By 2010 the combination category is expected to account for over half of the asthma/COPD market by value.

Formoterol provides 12 hours of bronchodilation and has a rapid onset of action (1-3 minutes). By contrast salmeterol, the bronchodilator used in GlaxoSmithKline's *Advair/Seretide*, is also a twice-daily product but has the drawback of needing 30-45 minutes after inhalation to take effect. The inhaled steroid fluticasone (a component of *Advair/Seretide*) is perceived to have a better safety and efficacy profile than budesonide, the steroid used in AstraZeneca's *Symbicort*, and is the physician-preferred inhaled steroid in the US. The SkyePharma formulation technology employed in Flutiform provides patent protection to 2019.

In 2005 the Company completed phase II trials and a review of development activities with the FDA and European regulatory agencies. Subsequent to these meetings, the Company initiated Phase III trials for Flutiform in February 2006. The product is on track for its target filing date with the US Food and Drug Administration (FDA) in the second half of 2007, with US market entry expected in early 2009. SkyePharma expects Flutiform to be the third combination product to enter the US market, following GlaxoSmithKline's *Advair* and AstraZeneca's *Symbicort*. Despite the eventual likelihood of additional entrants, the Company believes that no competing product is likely to enter the US market before 2012. We believe that Flutiform will be at worst the third combination on the US market and differentiated from both *Advair* and *Symbicort*. There is potential to position Flutiform as Best in Class. Furthermore there is limited risk of generic competition in the combination asthma market because there is no recognised test for bioequivalence after inhalation dosing and therefore no basis for approval of an AB rated generic inhaled drug in the US market.



A generic company would therefore have to conduct clinical trials, which is much more expensive and risky than development of a conventional oral generic drug so typical generic deep-discount pricing would not be possible. We therefore anticipate a peak sales potential for Flutiform well in excess of \$1 billion with an appropriate marketing partner.

SkyePharma had previously sought a partner to pay for the clinical development of Flutiform but negotiations have taken longer than expected. In September 2005 we therefore decided to raise funds to proceed with Phase III development at our own expense. The Phase III trials will cost in excess of \$50 million. This decision kept development under our control and reduced the risk of delays to market entry that could jeopardise the sales potential of Flutiform. It is still our intention to appoint a licensee or licensees as soon as possible. However, SkyePharma's flexibility on the terms and structure of any licensing deal has been significantly increased by removal of the partner funding obligation, elimination of the majority of the development risk and proximity to launch. SkyePharma remains in discussions with various potential marketing partners.

#### **Foradil® Certihaler**

Foradil® Certihaler is our version of Novartis' long-acting bronchodilator Foradil® (formoterol). Global sales of Foradil® were \$332 million in 2005, of which the Certihaler version made up a very small proportion, the product having only been on the market for a short time. We developed not only the multi-dose dry-powder inhaler device but also the formulation technology that had been shown to ensure dose consistency. Foradil® Certihaler has now been approved in 22 countries in Europe, the Middle East and Latin America. The product was launched in Germany and Switzerland in September 2005 but a recall from these markets was initiated in January 2006 because of concerns that accidental mishandling of the device had resulted in inaccurate dosing in a small number of cases. SkyePharma is collaborating with Novartis and the relevant health authorities to investigate the reasons and the actions necessary before the product can be returned to the market. These are likely to include modification of the patient use instructions and the device. In the US, the FDA issued an approvable letter for Foradil® Certihaler in April 2006. However, the FDA is requiring device modification as a prerequisite for approval. Novartis is currently working with the FDA on the most effective way to address its concerns.

The Certihaler and related formulation technology are also involved in a second collaboration with Novartis to jointly develop QAB149 (indacaterol), a novel inhaled long-acting beta-2-agonist that provides sustained 24-hour bronchodilation with rapid onset of action, which has completed Phase II development in both asthma and COPD. Novartis is currently revising the indacaterol development plan in Certihaler to accommodate the device modifications mentioned above.

#### **Formoterol HFA-MDI**

This is a formulation of the long-acting bronchodilator formoterol in an HFA-powered MDI. Because of the growing use of combination products for asthma and COPD, there is now a correspondingly diminishing market opportunity for single agent bronchodilators. While this product has completed Phase II development, pending the divestment of the injectables business, the Company will conclude its strategic review of this product.

#### **Pulmicort® HFA-MDI**

This new HFA-powered MDI containing AstraZeneca's inhaled corticosteroid Pulmicort® (budesonide) was filed for marketing authorization in June 2005 on a country-by-country basis in Europe for the treatment of asthma in adults and children. In February 2006, the product received approval in Finland, its first European market. Other European approvals are expected this year. The currently available MDI formulation of Pulmicort® has been on the market since 1981 and uses chlorofluorocarbons (CFCs) as the propellant. In accordance with the Montreal Protocol, this version will now be replaced by the non-ozone depleting device using HFAs as propellant. SkyePharma developed this new HFA-MDI formulation, which employs its proprietary formulation technology, and also conducted the clinical development programme for AstraZeneca. SkyePharma will earn a double digit royalty on AstraZeneca's sales of this formulation of Pulmicort®.

---

## ORAL PRODUCTS

### Paxil CR™

Our improved formulation of GlaxoSmithKline's antidepressant Paxil® (paroxetine) remains a major source of royalty income. In March 2005 GlaxoSmithKline temporarily suspended production of Paxil CR™ and certain other products made at its Cidra plant in Puerto Rico. GlaxoSmithKline announced in April 2005 that it had entered into a consent decree with the FDA regarding manufacturing processes at the plant and recommenced supply of product to the market shortly thereafter. As previously reported, we concluded a new agreement with GlaxoSmithKline last year that not only provided us with a \$10 million lump-sum payment and increased the royalty rate on this product from 3% to 4% but also maintained our royalty income even while the product was temporarily off the market.

Despite the product's return to the market, new documentary procedures introduced as part of the consent decree have hindered the Cidra plant's ability to meet demand and GlaxoSmithKline alerted customers to supply constraints in January 2006. Paxil CR™ currently holds about 3% of new prescriptions in this market, well below the 7% share held before the March 2005 withdrawal. World sales of Paxil CR™ were \$231 million in 2005, of which US sales were \$209 million, 70% below the 2004 level in constant exchange rate terms.

In late 2005 we and our partner GlaxoSmithKline received notification from Mylan Pharmaceuticals Inc. that it had filed an Abbreviated New Drug Application (ANDA) with the FDA for a version of paroxetine hydrochloride extended release tablets. The ANDA contains a Paragraph IV certification that certain of the patents listed in the FDA's Orange Book by GlaxoSmithKline for Paxil CRä (paroxetine hydrochloride Controlled Release tablets) are not infringed. These patents include SkyePharma's US patent 5,422,123. The certification does not challenge GlaxoSmithKline's basic active ingredient patent covering paroxetine hydrochloride hemihydrate, which protects the product until June 2007. GlaxoSmithKline has decided not to exercise its right to file suit for patent infringement within the 45-day period permitted by the Hatch-Waxman Act (the Act) and therefore there will be no 30-month stay of approval for this product pursuant to the Act. SkyePharma has a number of issued patents covering technology incorporated in Paxil CR™ and our policy is to enforce our intellectual property wherever possible.

### Requip Once-a-day

In December 2005, SkyePharma's collaborator GlaxoSmithKline submitted Requip Once-a-day, a once-daily dosage formulation of Requip® (ropinirole), for approval by US and European regulatory authorities for the treatment of Parkinson's disease. The FDA has raised some administrative issues that were identified in the preliminary initial review and which led GlaxoSmithKline to withdraw the US filing. SkyePharma has been informed that it is the intention of GlaxoSmithKline to resubmit as soon as possible. It is not expected that the European regulatory review process will be affected by these issues. This new once-daily oral formulation of Requip® incorporates SkyePharma's Geomatrix oral controlled-release delivery technology. SkyePharma will receive royalties on the product sales.

### Triglide

Following FDA approval in May 2005, First Horizon Pharmaceutical Corporation launched Triglide (fenofibrate) on the US market in July. First Horizon, which licensed Triglide in 2004, has a 500-strong representative force focused on cardiovascular physicians and high-prescribing primary care practitioners and has a proven ability to capture market share in the cardiovascular therapeutic area. We and First Horizon see a substantial opportunity for Triglide, 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), increasingly recognized as a major cardiovascular risk factor. In Triglide the problem of variable uptake arising from the low solubility of fenofibrate has been overcome by our proprietary IDD-P solubilization technology. Triglide has comparable absorption under both fed and fasting conditions and therefore allows patients to take the drug at any time, improving compliance and simplicity for both patients and prescribers. First Horizon's 2005 sales of Triglide in the 5 months since launch were just under \$5 million but we and First Horizon expect a significant increase in the current year.

SkyePharma has now received \$20 million in milestone payments from First Horizon (\$15 million of which was due on FDA approval, obtained in May 2005) and could receive up to \$30 million more in sales-based milestone payments. In addition we receive 25% of First Horizon's net sales, out of which we pay for manufacturing and supply. In 2005 we also agreed to contribute towards the marketing costs incurred by First Horizon to establish the product in its first two years after launch, the aim being

to enhance market penetration and thereby optimize revenues. Originally we agreed to contribute up to \$5 million towards First Horizon's marketing costs through 2007 and to provide samples. In January 2006 this arrangement was modified in order to emphasise its intent as a marketing contribution. SkyePharma will now make a contribution of up to \$11.3 million towards First Horizon's marketing costs (of which \$3.1 million was paid in 2005) and First Horizon will pay SkyePharma for the supply of product samples. There is no change in the net cost to SkyePharma.

#### **Xatral® OD**

Xatral® OD (Uroxatral® in the USA) is our once-daily version of Sanofi-Aventis's Xatral® (alfuzosin), a treatment for the urinary symptoms of benign prostatic hypertrophy. Xatral® OD has been on the market outside the USA since April 2000 and the older multidose versions of Xatral® have now largely been withdrawn. Uroxatral®, launched in the US in November 2003, currently holds over 11% of the combined prescriptions written for it and for its principal competitor Flomax (tamsulosin, jointly marketed in the US by Boehringer Ingelheim and Astellas). Xatral® OD has now been approved in more than 50 countries, including 24 in Europe, for a second indication, acute urinary retention. However Sanofi-Aventis is no longer pursuing US approval for this indication. In 2005, global sales of all forms of Xatral® reported by Sanofi-Aventis were 328 million (\$410 million), up by 18% in constant exchange rate terms. Included in this total were US sales of Uroxatral® of 53 million (\$66 million), up by 121% in constant exchange rate terms. We estimate that Xatral® OD now accounts for more than 90% of the sales of Xatral® reported by Sanofi-Aventis.

#### **Zyflo® CR**

SkyePharma's partner Critical Therapeutics, Inc. announced in January 2006 that it had initiated two studies designed to support a New Drug Application for a twice-daily version of Zyflo® (zileuton), an oral leukotriene synthesis inhibitor for the treatment of asthma. The current version of Zyflo® has to be taken four times a day and the CR version is expected to improve convenience for patients and therefore compliance. The controlled release formulation employed in the CR version was developed by SkyePharma. Critical Therapeutics expects to file the CR version with the FDA in the third quarter of 2006.

#### **OTHER PRODUCTS**

##### **Solaraze®**

Solaraze® is our topical gel treatment for actinic keratosis and our proprietary hyaluronic acid formulation ensures that a high concentration of the active ingredient is maintained in the upper layers of the skin. Solaraze® is now marketed in the US by the Doak Dermatology unit of Bradley Pharmaceuticals. Bradley has recently reported that sales in the first nine months of 2005 were just under \$10 million and SkyePharma estimates that full year sales were approximately \$15 million. Sales in 2004 were only \$6 million, reflecting the fact that product rights were not acquired by Bradley until August 2004. Solaraze® is marketed in Europe and certain other territories by Shire Pharmaceuticals. In 2005 Shire's total non-US sales of Solaraze were \$12.5 million, up by 32%.

#### **INJECTABLE PRODUCTS (TO BE DIVESTED)**

##### **Biologicals portfolio**

There has been encouraging progress with the Company's portfolio of versions of protein drugs with enhanced delivery profiles, based on its two complementary sustained-release injectable technologies DepoFoam and Biosphere. The objective of the work has been to develop different protein formulations to provide a range of durations from 7 up to 28 days of activity. The DepoFoam system has the benefit of neither altering the native protein during the formulation process nor the way in which it acts upon release into the body. SkyePharma has now successfully formulated seven different protein drugs, including major commercial products such as G-CSF, EPO, HGH, IFN- $\alpha$  and IFN- $\beta$ . In the second half of 2005 the Company entered into three new feasibility study agreements with third parties for enhanced biologics. It is anticipated that several of these products will enter Phase I clinical trials in 2007.

---

## DepoBupivacaine™

We are pleased to report that we have now completed the Phase II trial programme for DepoBupivacaine, a long-acting local anaesthetic for use in the treatment of post-operative pain. DepoBupivacaine is SkyePharma's novel sustained-release injectable formulation of the local anaesthetic bupivacaine, currently widely used as a local or regional anaesthetic during surgery, either in a hospital in-patient setting or in ambulatory (or day ) surgery in which the patient is discharged from the hospital or clinic shortly after surgery to recover at home. DepoBupivacaine employs SkyePharma's proprietary DepoFoam technology and was shown in Phase I and Phase II studies to provide local relief of pain for more than 48 hours after a single injection instead of 8-12 hours for conventional immediate-release bupivacaine. Superior control of pain after discharge is expected to reduce the need for other analgesics and to improve patient recovery and rehabilitation. The Phase III trial programme is expected to commence in the first half of 2006.

We have extended our relationship with Mundipharma, our European marketing partner for DepoCyt<sup>®</sup>, by granting rights outside North America and Japan for DepoBupivacaine™. Under the terms of the agreement we could receive up to \$80 million in milestone payments and a 35% share of sales (30% in markets outside Europe). The milestone payments include a contribution of up to \$20 million towards the cost of the Phase III trial once Mundipharma agrees to the design of the trial.

DepoBupivacaine has also been licensed to the Japanese pharmaceutical company Maruho for the Japanese market. Maruho will pay SkyePharma up to \$18 million in milestone payments and conduct at its own cost the clinical development of DepoBupivacaine required for regulatory approval in Japan. Additionally, SkyePharma will receive a share of Maruho's sales in Japan, out of which SkyePharma will bear the cost of manufacture.

Endo Pharmaceuticals, our North American partner for DepoDur, which had a right of first negotiation for commercial rights to DepoBupivacaine™ for North America, has now relinquished this right, thereby providing a buyer of the injectables business with unencumbered US rights to this product. Subject the terms of this sale, we may seek to retain an economic interest in the sales of DepoBupivacaine™, which we believe has major commercial potential.

## DepoCyt<sup>®</sup>

DepoCyt<sup>®</sup> is an oncology drug for the treatment of lymphomatous meningitis. It consists of cytarabine in our proprietary DepoFoam formulation to avoid the need for frequent intrathecal (spinal) injections. Sales of DepoCyt<sup>®</sup> in the USA in 2005 by our partner Enzon were \$8 million, up 26% on the prior year. Our European partner Mundipharma, which launched the product as DepoCyt<sup>®</sup> in February 2004, had sales of \$6 million (against \$1.5 million in 2004) and is forecasting a further substantial increase in 2006. We have completed the Phase IV trial required by the FDA when granting approval for this product and will be submitting the results to the FDA shortly. We have also filed in Europe for the additional indication of the most common form of neoplastic meningitis, associated with solid tumours. A response is expected in mid-2006.

## DepoDur

In December 2004 our US marketing partner Endo Pharmaceuticals launched DepoDur, our sustained-release injectable version of the analgesic morphine for the treatment of post-operative pain. Sales in 2005 were \$4 million, which was a disappointment both to us and to Endo. The product is still in the launch phase but has now been accepted on more than 400 hospital formularies, the first gateway to routine hospital use. Given the length of time typically needed to establish hospital products, we are confident that this initial sales level does not reflect the full potential of the product.

In the UK, we were informed last year by the UK regulatory agency, the CSM, that it would recommend approval for DepoDur, subject to certain conditions being satisfied. We have been in discussions with the CSM about these conditions (which did not require further clinical trials) and final UK approval is expected shortly. This will be used as the basis for seeking approval throughout the European Union under the EU's Mutual Recognition procedure. Zeneus Pharmaceuticals, SkyePharma's European licensee for DepoDur announced on 6 December 2005 that it had reached agreement to be acquired by the US company Cephalon Inc. SkyePharma has regained the European rights for DepoDur and is now seeking a new sales and distribution partner for the EU and other territories outside North America.

---

## **Propofol IDD-D™**

Propofol IDD-D™ is our novel formulation of propofol, a widely-used injectable anaesthetic and sedative. Our formulation was designed not to support microbial growth, a recognised problem with current versions, and to provide uninterrupted sedation for 24 hours. This product has satisfactorily completed Phase II trials. We are conducting additional toxicology studies as required by the FDA to determine the continued viability of the development programme. Pending resolution of the Phase III trial design, and a further evaluation of the commercial potential, this project is under strategic review.

## **The Future**

In the immediate future, we will be concentrating on two tasks: the divestment of our injectables business and securing a marketing and co-development partner (or partners) for Flutiform™. Once these tasks have been completed, we will be able to focus our management and financial resources on the new SkyePharma, consisting of our core inhalation and oral product business. We will drive for sustainable profitability. At the same time, however, we will invest in our inhalation and oral product pipeline to make sure that we bring forward the growth drivers of tomorrow. We have a longer term goal of forward integration into marketing and sales of our own products in selected specialty therapeutic areas. I believe that this new focus will create exciting opportunities for SkyePharma and increase investor confidence in our future.

## **Frank Condella**

### **Chief Executive**

## **FINANCIAL REVIEW**

### *Turnover*

The Group's revenues continue to be sensitive to the timing and receipt of milestone payments and payments received on the signing of new contracts. Revenues for 2005, at £61.3 million, were 18% below the £75.2 million reported in 2004. This was primarily due to the absence of a licensing transaction on Flutiform, continuing Paxil CR supply problems and slower overall market penetration of Triglide and DepoDur by marketing partners, partly offset by an increase in manufacturing and distribution revenues. In addition the Company undertook a strategic shift away from licence terms that prioritise upfront payments on signature towards deal structures with higher royalty rates and increased milestone payments tied to product revenue targets. Despite the decline in 2005, revenues have nevertheless increased at a cumulative annual growth rate of 24% since 1996.

The absence of a licensing agreement on Flutiform had a double negative impact on SkyePharma in 2005. First, revenues suffered from the absence of the anticipated milestone payment and of a partner's contribution towards continuing development costs of Flutiform. Secondly, SkyePharma's R&D costs exceeded budget expectations because of the need to press ahead with the development programme without a partner in order to avoid the risk of impairment to the commercial potential of this key product if development was delayed.

Contract development and licensing revenue decreased 30% to £27.6 million, compared with £39.4 million in 2004. This was primarily due to the absence of an anticipated milestone from the licensing of Flutiform and the change in the structure of our licence agreements described above. Revenues recognised from milestone payments and payments received on the signing of agreements amounted to £22.1 million in 2005 compared with £33.4 million in 2004. The 2005 total included revenues from First Horizon for the US marketing and distribution rights for Triglide triggered by FDA approval in May 2005 from Mundipharma for the licensing of DepoBupivacaine for Europe and from Maruho for the licensing of DepoBupivacaine for Japan. In addition, £5.7 million of revenue was recognised from GlaxoSmithKline on the phase III clinical trials of Requip (ropinirole), from AstraZeneca on the phase III clinical trials of Pulmicort HFA and from Novartis on the phase II clinical trials of QAB 149. Research and development costs recharged fell by 8% to £5.5 million, compared with £6.0 million in 2004. This was mainly due to a fall in the costs recharged to Micap plc in respect of the development of their microencapsulation technology which has now been completed.

Royalty income decreased by 16% to £21.7 million, compared with £25.9 million in 2004. Royalty income in 2005 derives principally from Paxil CR, Xatral OD, DepoCyt, Solaraze, DepoDur and Triglide. Although the Company was able to negotiate an increase in the royalty rate it receives on GlaxoSmithKline's sales of Paxil CR from 3% to 4% with effect from March 2005 and also received royalties based on budgeted sales while the product was temporarily off the US market, royalties were

still negatively impacted by the continuing supply problems experienced by GlaxoSmithKline. Excluding Paxil CR, royalties for the balance of SkyePharma's other products grew by 38%. In addition royalty growth was less than anticipated due to slower overall market penetration of Triglide and DepoDur by marketing partners during the year.

Manufacturing and distribution revenue increased by 21% to £12.0 million, compared with £9.9 million, mainly due to higher production of clinical trial material and launch quantities for Novartis in respect of QAB 149 and Foradil Certihaler.

### *Deferred income*

During 2005, there was a net reduction in deferred income of £3.5 million under SkyePharma's revenue recognition policy. The movement in deferred income was:

|  | 31 December<br>2004<br>£ m | Received *<br>£ m | Recognised<br>£ m | 31 December<br>2005<br>£ m |
|--|----------------------------|-------------------|-------------------|----------------------------|
| Contract development and licensing revenue | 14.1                       | 24.1              | (27.6)            | 10.6                       |

\* Includes exchange adjustments

### *Cost of sales*

Cost of sales comprises research and development expenditures, including the costs of certain clinical trials incurred on behalf of our collaborative partners; the direct costs of contract manufacturing; direct costs of licensing arrangements and royalties payable. Cost of sales increased by 4% to £29.2 million in 2005, compared with £28.2 million in 2004. This was mainly due to an increase in manufacturing and distribution expenses ahead of the approval and launch of Triglide. The resulting gross profit decreased 32% to £32.1 million, compared with £47.0 million in 2004.

### *Expenses*

Selling, marketing and distribution expenses increased significantly to £5.9 million, compared with £1.7 million in 2004. This mainly reflected SkyePharma's contribution towards the initial launch and marketing costs of DepoDur and Triglide. No further marketing contributions are due in respect of DepoDur and contributions on Triglide will terminate in 2007. The Company's total costs in respect of Triglide in 2005 amount to approximately £4.6 million.

Amortisation of intangible assets decreased slightly to £2.1 million, compared with £2.2 million in 2004.

Other administration expenses before exceptionals were £13.8 million in 2005, 12% lower than the £15.6 million reported in 2004, reflecting the first full year of cost savings following the restructuring started in 2004. The exceptional charge of £21.4 million comprises non-cash impairment charges of £19.4 million and abortive transaction costs of £2.0 million. Following the Strategic Review and the Group's decision to focus on its core oral and pulmonary products and to divest its injectable business, the Group no longer views its collaborations with Astralis, Vital Living and Micap as strategic and these investments have therefore been impaired. In addition, as an injectable project, SkyePharma's entitlement to negotiate for commercial rights for Psoraxine, Astralis' key product, is being offered with the injectable business interests. The remaining £2.0 million exceptional charge relates to legal and professional fees relating to an aborted transaction, as outlined in the Chairman's statement. Other administration expenses including exceptional items increased by £14.9 million to £35.2 million.

SkyePharma's own research and development expenses in the year decreased by £2.0 million to £26.0 million, mainly due to a reduction in expenditure on Pulmicort HFA, DepoDur and other injectable products, partly off set by an increase in expenditure on Flutiform and DepoBupivacaine in advance of their commencement of phase III clinical trials.

The other expense of £0.4 million comprises a £0.7 million loss due to the movement in the fair value of the Group's investment in GeneMedix plc, partly off set by a £0.3 million profit on disposal of part of the Group's holding of Vectura Group plc shares.

## Results

The operating loss before exceptional items was £16.1 million, compared with £0.4 million in 2004, due principally to the reduction in revenue and to increased marketing contributions. The operating loss after exceptionals increased by £34.4 million to £37.5 million, mainly due to the higher exceptional charges and fall in revenue.

The finance costs of £22.3 million (2004: £23.9 million) mainly comprise notional interest on the Paul Capital funding liabilities as well as interest on the convertible bonds. Finance income includes £9.0 million (2004: £6.0 million) in respect of a change in the estimated future payments to Paul Capital.

The Group's share of the losses of Astralis was £0.8 million for 2005, compared with £10,000 in 2004.

The retained loss after exceptionals increased by £32.3 million to £50.9 million, also due to the higher exceptional charges and fall in revenue.

Earnings before interest, tax, depreciation amortisation and exceptionals showed a loss of £8.5 million in 2005, compared with a profit of £7.8 million in 2004.

The loss per share after exceptionals was 8.1 pence, which compares with 3.0 pence in 2004.

Foreign currency movements did not have a material impact on the results of operations in 2005 compared with 2004.

## Segment information

Segmental information on revenue and operating loss before exceptionals is as follows:

|   | Year ended<br>31 December 2005<br>£m | Year ended<br>31 December 2004<br>£m |
|---|--------------------------------------|--------------------------------------|
| <b>Revenue</b>                              |                                      |                                      |
| Injectable                                  | 10.5                                 | 25.6                                 |
| Oral and Inhalation                         | 50.8                                 | 49.6                                 |
|   | <b>61.3</b>                          | <b>75.2</b>                          |
| <b>Operating loss pre exceptional items</b> |                                      |                                      |
| Injectable                                  | (18.6)                               | (1.4)                                |
| Oral and Inhalation                         | 2.5                                  | 1.0                                  |
|   | <b>(16.1)</b>                        | <b>(0.4)</b>                         |

Business segment data includes an allocation of corporate costs to each segment.

## Balance sheet

The Group balance sheet at 31 December 2005 shows shareholders' equity of £31.9 million (2004: £36.5 million).

In September 2005 the Group raised £34.8 million net of expenses by means of a rights issue of 125,627,357 new Ordinary Shares on the basis of one new share for every five held.

In July 2004 the Group exchanged £49.6 million of its convertible bonds due June 2005 for convertible bonds due May 2024, leaving £9.8 million of the 2005 bonds outstanding. The £49.6 million 2024 convertible bonds were consolidated to form a single series with the £20 million 2024 bonds issued in May 2004. In 2005 the Group issued £20 million 8% convertible bonds due June 2025. In June 2005 the company repaid the £9.8 million balance on the convertible bonds due June 2005. As a result of these transactions the Group has £69.6 million convertible bonds due May 2024 and £20 million convertible bonds due June 2025 outstanding as at 31 December 2005. On the balance sheet these are reflected as £63.6 million in liabilities and £28.4 million in equity.

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

In addition the Group has Other Borrowings at 31 December 2005 of £44.6 million due to Paul Capital Royalty Acquisition Fund. Whilst the contractual arrangements contemplate the payment of royalties to Paul Capital as outlined in note 8, IAS 39 requires the Company to record a liability equal to the net



present value of the royalties the Company expects to pay Paul Capital over the term of the agreement.

Financial assets held at fair value comprise a £3.25 million 5% convertible loan note from GeneMedix plc. This has been recorded at £0.4 million at 31 December 2005, being the lower of cost and net realisable value assuming conversion of the note into GeneMedix ordinary shares.

### **Liquidity and capital resources**

At 31 December 2005 SkyePharma had cash and short term deposits of £34.3 million and no bank overdraft, compared with £15.3 million net cash at 31 December 2004. Bank and other non convertible debt amounted to £9.9 million at 31 December 2005 (2004: £11.1 million), consisting principally of a £6.9 million property mortgage secured on the assets of Jago (2004: £7.4 million). In addition the Company has 6% convertible bonds due May 2024 of £69.6 million (2004: £69.6 million) and 8% convertible bonds due June 2025 of £20.0 million (2004: £Nil). Net debt (excluding the Paul Capital funding liabilities) amounted to £39.2 million (2004: £55.6 million).

In 2005 there was a net cash outflow from operating activities of £7.6 million, compared with £3.7 million in 2004. During the year the Group spent £2.6 million on property, plant and equipment and expenditure on intangible assets of £2.3 million mainly relates to the purchase of licenses to intellectual property in the area of pulmonary delivery. The proceeds on disposal of the Group's non strategic holding of Vectura shares were £1.6 million.

Cash inflows from financing in were £30.6 million (2004: £2.9 million). The Group raised £34.8 million net of expenses by means of a rights issue of 125,627,357 new Ordinary Shares. During the year the Group issued £20 million 8% convertible bonds raising £18.8 million net of expenses. In addition the company repaid the £9.8 million balance on the convertible bonds due June 2005.

Borrowings of £7.4 million were repaid in the period (2004: £8.6 million). This primarily comprises Paul Capital's share of the Company's royalty income.

The Group paid £2.0 million of costs relating to an aborted strategic transaction during the year.

### **International Financial Reporting Standards**

The financial information for the year ended 31 December 2005 has been prepared for the first time in accordance with IFRS. In preparing the financial information certain first-time adoption provisions have been applied. The Group's accounting policies and adjustments made on the implementation of IFRS were disclosed in the interim results announcement issued on 28 September 2005 and the IFRS restatement announcement issued on 3 August 2005 and can be found on the Group's corporate web site ([www.skyepharma.com](http://www.skyepharma.com)). Since the publication of these results the Group has changed its interpretation of the application of IAS 39 to the Paul Capital funding liabilities. The restatement resulted in a decrease in the 2004 net interest expense of £5.2 million and in the liability at 31 December 2004 of £4.3 million.

### **Forward looking statements**

The foregoing discussions contain certain forward looking statements and are made in reliance on the safe harbour provisions of the US 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 materialise. 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 Preliminary Announcement 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 Preliminary Announcement.

Donald Nicholson

Finance Director

## CONSOLIDATED INCOME STATEMENT

for the year ended 31 December 2005

|  | Notes | Year to 31 December 2005   |                               |               | Year to 31 December 2004   |                               |               |
|--|-------|----------------------------|-------------------------------|---------------|----------------------------|-------------------------------|---------------|
|  |       | Pre -<br>Exceptional<br>£m | Exceptional<br>(note 3)<br>£m | Total<br>£m   | Pre -<br>Exceptional<br>£m | Exceptional<br>(note 3)<br>£m | Total<br>£m   |
| Revenue                                      | 2     | 61.3                       |                               | 61.3          | 75.2                       |                               | 75.2          |
| Cost of sales                                |       | (29.2)                     |                               | (29.2)        | (28.2)                     |                               | (28.2)        |
| <b>Gross profit</b>                          |       | <b>32.1</b>                |                               | <b>32.1</b>   | <b>47.0</b>                |                               | <b>47.0</b>   |
| Selling, marketing and distribution expenses |       | (5.9)                      |                               | (5.9)         | (1.7)                      |                               | (1.7)         |
| Administration expenses                      |       |                            |                               |               |                            |                               |               |
| Amortisation of other intangibles            |       | (2.1)                      |                               | (2.1)         | (2.2)                      |                               | (2.2)         |
| Other administration expenses                |       | (13.8)                     | (21.4)                        | (35.2)        | (15.6)                     | (4.7)                         | (20.3)        |
|  |       | (15.9)                     | (21.4)                        | (37.3)        | (17.8)                     | (4.7)                         | (22.5)        |
| Research and development expenses            |       | (26.0)                     |                               | (26.0)        | (28.0)                     |                               | (28.0)        |
| Other expense                                |       | (0.4)                      |                               | (0.4)         | 0.1                        | 2.0                           | 2.1           |
| <b>Operating loss</b>                        |       | <b>(16.1)</b>              | <b>(21.4)</b>                 | <b>(37.5)</b> | <b>(0.4)</b>               | <b>(2.7)</b>                  | <b>(3.1)</b>  |
| Finance costs                                | 4     | (22.3)                     |                               | (22.3)        | (17.7)                     | (6.2)                         | (23.9)        |
| Finance income                               | 4     | 10.0                       |                               | 10.0          | 8.6                        |                               | 8.6           |
| Share of loss in associate                   | 6     | (0.8)                      |                               | (0.8)         |                            |                               |               |
| <b>Loss before income tax</b>                |       | <b>(29.2)</b>              | <b>(21.4)</b>                 | <b>(50.6)</b> | <b>(9.5)</b>               | <b>(8.9)</b>                  | <b>(18.4)</b> |
| Income tax expense                           |       | (0.3)                      |                               | (0.3)         | (0.2)                      |                               | (0.2)         |
| <b>Loss for the year</b>                     |       | <b>(29.5)</b>              | <b>(21.4)</b>                 | <b>(50.9)</b> | <b>(9.7)</b>               | <b>(8.9)</b>                  | <b>(18.6)</b> |
| <b>Basic and diluted earnings per share</b>  | 5     | <b>(4.7p)</b>              | <b>(3.4p)</b>                 | <b>(8.1p)</b> | <b>(1.6p)</b>              | <b>(1.4p)</b>                 | <b>(3.0p)</b> |

All results represent continuing activities.

See Notes to the Preliminary Announcement.

**CONSOLIDATED BALANCE SHEET**

as at 31 December 2005

|   | Notes | 31 December<br>2005<br>£m | 31 December<br>2004<br>£m |
|---|-------|---------------------------|---------------------------|
| <b>ASSETS</b>   |       |                           |                           |
| <b>Non-current assets</b>                             |       |                           |                           |
| Goodwill  |       | 68.7                      | 68.7                      |
| Other intangible assets                               |       | 26.8                      | 26.7                      |
| Property, plant and equipment                         |       | 37.1                      | 40.9                      |
| Investments in associates                             | 6     | 0.2                       | 14.3                      |
| Available for sale financial assets                   | 7     | 1.6                       | 5.2                       |
|   |       | <b>134.4</b>              | <b>155.8</b>              |
| <b>Current assets</b>                                 |       |                           |                           |
| Inventories   |       | 3.6                       | 1.5                       |
| Trade and other receivables                           |       | 14.2                      | 18.2                      |
| Financial assets at fair value through profit or loss |       | 0.4                       | 1.1                       |
| Cash and cash equivalents                             |       | 34.3                      | 15.3                      |
|   |       | <b>52.5</b>               | <b>36.1</b>               |
| <b>Total Assets</b>                                   |       | <b>186.9</b>              | <b>191.9</b>              |
| <b>LIABILITIES</b>                                    |       |                           |                           |
| <b>Current liabilities</b>                            |       |                           |                           |
| Trade and other payables                              |       | (21.0)                    | (20.6)                    |
| Convertible bonds                                     | 8,9   | (9.4)                     | (9.4)                     |
| Other borrowings                                      | 8     | (14.3)                    | (10.7)                    |
| Derivative financial instruments                      |       | (0.2)                     | (0.2)                     |
| Deferred income                                       |       | (7.7)                     | (11.8)                    |
| Provisions  |       | (0.3)                     | (0.3)                     |
|   |       | <b>(43.0)</b>             | <b>(53.0)</b>             |
| <b>Non current liabilities</b>                        |       |                           |                           |
| Convertible bonds                                     | 8,9   | (63.6)                    | (50.4)                    |
| Other borrowings                                      | 8     | (40.2)                    | (45.1)                    |
| Deferred income                                       |       | (2.9)                     | (2.3)                     |
| Other non current liabilities                         |       | (3.4)                     | (2.9)                     |
| Provisions  |       | (1.9)                     | (1.7)                     |
|   |       | <b>(112.0)</b>            | <b>(102.4)</b>            |
| <b>Total Liabilities</b>                              |       | <b>(155.0)</b>            | <b>(155.4)</b>            |
| <b>Net Assets</b>                                     |       | <b>31.9</b>               | <b>36.5</b>               |
| <b>SHAREHOLDERS EQUITY</b>                            |       |                           |                           |
| Share capital   | 10    | 76.6                      | 63.4                      |
| Share premium   |       | 345.6                     | 321.0                     |
| Translation reserve                                   |       | (1.2)                     | (3.3)                     |
| Fair value reserve                                    |       | 0.2                       | (0.5)                     |
| Retained losses                                       |       | (427.1)                   | (376.5)                   |

Edgar Filing: SKYEPHARMA PLC - Form 6-K

|                                   |             |             |
|-----------------------------------|-------------|-------------|
| Other reserves                    | 37.8        | 32.4        |
| <b>Total Shareholders' Equity</b> | <b>31.9</b> | <b>36.5</b> |

See Notes to the Preliminary Announcement.

**CONSOLIDATED CASH FLOW STATEMENT**

for the year ended 31 December 2005

|  |       | Year to      | Year to      |
|--|-------|--------------|--------------|
|  |       | 31 December  | 31 December  |
|  |       | 2005         | 2004         |
|  | Notes | £m           | £m           |
| <b>Cash flow from operating activities</b>                       |       |              |              |
| Cash used in operations  | (a)   | (7.6)        | (3.7)        |
| Income tax paid  |       | (0.3)        | (0.2)        |
| <b>Net cash used in operating activities</b>                     |       | <b>(7.9)</b> | <b>(3.9)</b> |
| <b>Cash flows from investing activities</b>                      |       |              |              |
| Purchases of property, plant and equipment                       |       | (2.6)        | (4.4)        |
| Purchases of intangible assets                                   |       | (2.3)        | (1.4)        |
| Purchase of shares in associates                                 |       | (0.2)        |              |
| Purchase of available for sale investments                       |       |              | (2.2)        |
| Purchase of own shares   |       | (0.4)        |              |
| Proceeds from disposal of available for sale investments         |       | 1.6          | 2.7          |
| <b>Net cash used in investing activities</b>                     |       | <b>(3.9)</b> | <b>(5.3)</b> |
| <b>Cash flows from financing activities</b>                      |       |              |              |
| Gross proceeds from rights issue                                 |       | 37.7         |              |
| Expenses of rights issue   |       | (2.9)        |              |
| Proceeds from issue of ordinary share capital                    |       | 0.1          | 0.3          |
| Proceeds from issue of convertible bonds due June 2025           |       | 20.0         |              |
| Proceeds from issue of convertible bonds due May 2024            |       |              | 20.0         |
| Expenses of issue of convertible bonds due June 2025             |       | (1.2)        |              |
| Expenses of issue and exchange of convertible bonds due May 2024 |       |              | (3.4)        |
| Repayment of convertible bonds due June 2005                     |       | (9.8)        |              |
| Repayments of borrowings   |       | (7.4)        | (8.6)        |
| Repayment of finance lease principal                             |       |              | (0.2)        |
| Interest paid  |       | (6.7)        | (5.9)        |
| Interest received  |       | 0.8          | 0.7          |
| <b>Net cash generated from financing activities</b>              |       | <b>30.6</b>  | <b>2.9</b>   |
| <b>Effect of exchange rate changes</b>                           |       | <b>0.2</b>   | <b>(0.4)</b> |
| <b>Net increase/ (decrease) in cash and cash equivalents</b>     |       | <b>19.0</b>  | <b>(6.7)</b> |
| Cash and cash equivalents at beginning of the year               |       | 15.3         | 22.0         |
| <b>Cash and cash equivalents at end of the year</b>              |       | <b>34.3</b>  | <b>15.3</b>  |

See Notes to the Preliminary Announcement.

**NOTES TO THE CONSOLIDATED CASH FLOW STATEMENT****(a) Cash flow from operating activities**

Edgar Filing: SKYEPHARMA PLC - Form 6-K

|   | Year to             | Year to                |
|---|---------------------|------------------------|
|   | 31 December<br>2005 | 31 December<br>2004 £m |
|   | £m                  |                        |
| <b>Loss for the year</b>  | (50.9)              | (18.6)                 |
| Adjustments for:  |                     |                        |
| Tax   | 0.3                 | 0.2                    |
| Depreciation  | 6.2                 | 6.0                    |
| Amortisation  | 2.1                 | 2.2                    |
| Impairments   | 19.4                | 3.5                    |
| Fair value (gain)/ loss on derivative financial instruments     | (0.3)               | 0.5                    |
| Finance costs   | 22.3                | 23.9                   |
| Finance income  | (10.0)              | (6.8)                  |
| Share of loss in associate                                      | 0.8                 |                        |
| Profit on disposal of available for sale financial assets       | (0.3)               | (2.0)                  |
| Other non-cash changes  | 3.2                 | 4.0                    |
| <b>Operating cash flows before movements in working capital</b> | (7.2)               | 12.9                   |
| <b>Changes in working capital</b>                               |                     |                        |
| Increase in inventories   | (2.1)               | (0.2)                  |
| Decrease/ (increase) in trade and other receivables             | 4.2                 | (5.9)                  |
| Increase in trade and other payables                            | 1.2                 | 4.0                    |
| Decrease in deferred income                                     | (3.4)               | (13.0)                 |
| Decrease in provisions  | (0.3)               | (1.5)                  |
| <b>Cash used in operations</b>                                  | (7.6)               | (3.7)                  |

**Notes to the Preliminary Announcement**

**1 Basis of preparation**

The unaudited preliminary announcement for the year ended 2005 has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU. The Group's accounting policies and adjustments made on the implementation of IFRS were disclosed in the

interim results announcement issued on 28 September 2005 and the IFRS restatement announcement issued on 3 August 2005 and can be found on the Group's corporate web site (www.skyepharma.com). Since the publication of these results the Group has made the following change to the application of IFRS, reflecting the endorsement by the EU of amended standards and emerging industry practice.

The Group had previously treated the proceeds received from Paul Capital as a floating rate financial liability in accordance with the guidance in paragraph AG7 of IAS 39; Financial instruments: Recognition and measurement. This was also consistent with the treatment under US GAAP. The Group has now concluded that the Paul Capital funding liabilities should be treated in accordance with the guidance in paragraph AG8 of IAS 39, not AG7 as previously used. This has the effect that the estimated payments to Paul Capital are discounted using each contract's original effective interest and any adjustment is recognised as income or expense in the income statement. Under the previous accounting (and US GAAP) such fluctuations were effectively spread forward and reflected in a reduced implicit interest cost in future years. The restatement resulted in a decrease in the 2004 net interest expense of £5.2 million and in the liability at 31 December 2004 of £4.3 million. There are no implications for cash flow or operating loss.

The financial information in this statement does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985. Statutory accounts for the year ended 31 December 2004, which were prepared under UK GAAP, have been filed with the Registrar of Companies. The auditors' report on those accounts was unqualified and did not contain a statement under Section 237 of the Companies Act 1985.

The Company's working capital requirements continue to be affected by the timing and receipt of milestone payments and payments received on the signing of new contracts. The Company's future cash flows will also be impacted by the Company's change in strategy as outlined in the EGM notice dated 16 February 2006, principally its stated aim of moving to sustainable profitability in the shortest possible time and its refocus to concentrate on oral and pulmonary products. Consequently the Group's near term working capital requirements are uncertain and sensitive to the timing of a number of initiatives required to provide the financial flexibility to implement the new strategy. These initiatives include the licensing of Flutiform, the divestment of its injectable business interests, which is expected to require shareholder approval, and the delay of certain licensing discussions, such as US licensing for DepoBupivacaine pending the divestment of its injectables business.

The Directors have reviewed the working capital requirements of the Group for the next twelve months and have a reasonable expectation that sufficient funds will be raised from these initiatives and have therefore prepared the financial information contained herein on a going concern basis which assumes that the Company will continue in operational existence for the foreseeable future.

Given the above uncertainties the auditors have indicated that their report may contain a reference to going concern relating to these matters. The financial information in this announcement does not reflect any adjustments that would be required to be made if it was to be prepared on a basis other than the going concern basis.

## 2 Segment information

Based on the risks and returns of the various segments, the Directors consider that the Group's primary reporting format is by business segment with geographical reporting being the secondary format. The Group is a speciality pharmaceutical company, using its multiple drug delivery technologies to create a product pipeline for out-licensing to marketing partners. The business segments consist of the Injectable business and the Oral and Inhalation business. Business segment data includes an allocation of corporate costs to each segment on an appropriate basis. There are no material inter-segment transfers. All Group activities are continuing operations.

### Revenue by business segment:

|                     | Year ended<br>31 December 2005<br>£m | Year ended<br>31 December 2004<br>£m |
|---------------------|--------------------------------------|--------------------------------------|
| Injectable          | 10.5                                 | 25.6                                 |
| Oral and Inhalation | 50.8                                 | 49.6                                 |
|                     | <b>61.3</b>                          | <b>75.2</b>                          |

Revenue earned can be analysed as:

|   |      |      |
|---|------|------|
| Contract development and licensing Milestone payments | 22.1 | 33.4 |
| Research and development costs recharged              | 5.5  | 6.0  |

Edgar Filing: SKYEPHARMA PLC - Form 6-K

|                                |             |             |
|--------------------------------|-------------|-------------|
|                                | 27.6        | 39.4        |
| Royalties                      | 21.7        | 25.9        |
| Manufacturing and distribution | 12.0        | 9.9         |
|                                | <b>61.3</b> | <b>75.2</b> |



**Operating profit/ (loss) by business segment:**

|   | Year ended<br>31 December 2005<br>£m | Year ended<br>31 December 2004<br>£m |
|---|--------------------------------------|--------------------------------------|
| Injectable                                  | (18.6)                               | (1.4)                                |
| Oral and Inhalation                         | 2.5                                  | 1.0                                  |
| <b>Operating loss pre exceptional items</b> | <b>(16.1)</b>                        | <b>(0.4)</b>                         |
| Exceptional items                           | (21.4)                               | (2.7)                                |
| <b>Operating loss</b>                       | <b>(37.5)</b>                        | <b>(3.1)</b>                         |
| Share of loss in associate                  | (0.8)                                |                                      |
| Net interest                                | (12.3)                               | (15.3)                               |
| Tax   | (0.3)                                | (0.2)                                |
| <b>Loss after tax</b>                       | <b>(50.9)</b>                        | <b>(18.6)</b>                        |

**3 Exceptional items**

|   | Year ended<br>31 December 2005<br>£m | Year ended<br>31 December 2004<br>£m |
|---|--------------------------------------|--------------------------------------|
| Impairments   | (19.4)                               | (3.5)                                |
| Abortive transaction costs                          | (2.0)                                |                                      |
| Restructuring costs                                 |                                      | (1.2)                                |
| Profit on disposal of available-for-sale investment |                                      | 2.0                                  |
| Convertible bonds exchange                          |                                      | (6.2)                                |
|   | (21.4)                               | (8.9)                                |

Following the Strategic Review and the Group's decision to focus on its core oral and pulmonary products and to divest its injectable business, the Group no longer views its collaborations with Astralis, Vital Living and Micap as strategic and these investments have therefore been impaired resulting in an exceptional charge of £19.4 million.

During the year the Group incurred £2.0 million legal and professional fees relating to an aborted strategic transaction.

**4 Finance costs and income**

|  | Year ended<br>31 December 2005<br>£m | Year ended<br>31 December 2004<br>£m |
|--|--------------------------------------|--------------------------------------|
| <b>Interest and similar expense:</b>             |                                      |                                      |
| Interest:  |                                      |                                      |
| - bank borrowings                                | (0.5)                                | (0.7)                                |
| - Paul Capital arrangements                      | (12.7)                               | (11.3)                               |
| - interest on convertible bonds                  | (5.8)                                | (5.7)                                |
|  | <b>(19.0)</b>                        | <b>(17.7)</b>                        |
| Foreign exchange on Paul Capital arrangements    | (3.3)                                |                                      |
| Fair value losses on financial instruments:      |                                      |                                      |
| - loss on exchange of convertible bonds          |                                      | (6.2)                                |
| <b>Total interest and similar expense</b>        | <b>(22.3)</b>                        | <b>(23.9)</b>                        |
| <b>Interest and similar income:</b>              |                                      |                                      |
| Paul Capital change in estimated future payments | 9.0                                  | 6.0                                  |
| Other interest income                            | 1.0                                  | 0.8                                  |
| Foreign exchange on Paul Capital arrangements    |                                      | 1.8                                  |
| <b>Total interest and similar income</b>         | <b>10.0</b>                          | <b>8.6</b>                           |

**5 Earnings per share**

|  | Year to<br>31 December 2005<br>£m | Year to<br>31 December 2004<br>£m |
|--|-----------------------------------|-----------------------------------|
| Attributable loss before exceptional items                   | (29.5)                            | (9.7)                             |
| Exceptional items  | (21.4)                            | (8.9)                             |
| <b>Basic and diluted attributable loss</b>                   | <b>(50.9)</b>                     | <b>(18.6)</b>                     |
|  | <b>Number<br/>m</b>               | <b>Number<br/>m</b>               |
| Basic and diluted weighted average number of shares in issue | 624.9                             | 615.2                             |
| Loss per Ordinary Share before exceptional items             | (4.7p)                            | (1.6p)                            |
| Exceptional items  | (3.4p)                            | (1.4p)                            |
| <b>Basic and diluted loss per Ordinary Share</b>             | <b>(8.1p)</b>                     | <b>(3.0p)</b>                     |

There is no difference between basic and diluted loss per share since in a loss making year all potential shares from convertible bonds, stock options, warrants and contingent issuance of shares are anti dilutive.

Shares held by the SkyePharma PLC General Employee Benefit Trust have been excluded from the weighted average number of shares.

**6 Investments in associates**

|   | As at<br>31 December 2005 | As at<br>31 December 2004 |
|---|---------------------------|---------------------------|
|   | £m                        | £m                        |
| Beginning of the year                       | 14.3                      |                           |
| Reclassification of investment as associate |                           | 14.2                      |
| Additions                                   | 3.0                       | 0.1                       |
| Share of loss                               | (0.8)                     |                           |
| Impairment                                  | (16.3)                    |                           |
| <b>End of the year</b>                      | <b>0.2</b>                | <b>14.3</b>               |

The investment in Astralis Limited was recorded at £0.2 million at 31 December 2005 (2004: £14.3 million) and had a market value of £0.4 million (2004: £9.6 million). Following the Strategic Review and the Group's decision to focus on its core oral and pulmonary products and to divest its injectable business, the Group no longer views its collaboration with Astralis as strategic. This combined with the current uncertainties concerning Astralis' financial position resulted in the Group impairing its investment to its estimated fair value.

**7 Available for sale financial assets**

|   | As at<br>31 December 2005 | As at<br>31 December 2004 |
|---|---------------------------|---------------------------|
|   | £m                        | £m                        |
| Beginning of the year                   | 5.2                       | 22.0                      |
| Exchange                                | 0.1                       |                           |
| Reclassification as associate           |                           | (14.2)                    |
| Additions                               | 0.1                       | 2.0                       |
| Disposal                                | (1.8)                     | (0.6)                     |
| Impairments                             | (2.6)                     | (3.5)                     |
| Revaluation surplus/ (deficit) transfer | 0.6                       | (0.5)                     |
| End of the year                         | 1.6                       | 5.2                       |

Available for sale financial assets comprise the following unlisted securities:

**Vectura Group plc**

During 2005 the Group sold 2 million ordinary shares in Vectura for £1.6 million. As at 31 December 2005 the remaining holding was 1.2 million ordinary shares. The investment was recorded at £1.0 million at 31 December 2005 (2004: £2.0 million). In January 2006 the Group sold the remaining 1.2 million ordinary shares.

**Vital Living Inc**

The investment in Vital Living was recorded at £0.4 million at 31 December 2005 (2004: £1.7 million). Following the Strategic Review and the Group's decision to focus on its core oral and pulmonary products and to divest its injectable business, the Group no longer views its collaboration with Vital Living as strategic and this investment has therefore been impaired.

**Micap plc**

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

The investment in Micap recorded at £0.2 million at 31 December 2005 (2004: £1.5 million). Following the Strategic Review and the Group's decision to focus on its core oral and pulmonary products and to divest its injectable business, the Group no longer views its collaboration with Micap as strategic and this investment has therefore been impaired.

**8 Borrowings**

|                                     | As at<br>31 December 2005 | As at<br>31 December 2004 |
|-------------------------------------|---------------------------|---------------------------|
|                                     | £m                        | £m                        |
| <b>Current</b>                      |                           |                           |
| Convertible bonds due June 2005     |                           | <b>9.4</b>                |
| Bank borrowings                     | 2.3                       | 3.5                       |
| Property mortgage                   | 0.3                       | 0.3                       |
| Paul Capital funding liabilities    | 11.6                      | 6.8                       |
| Finance lease liabilities           | 0.1                       | 0.1                       |
| Other current borrowings            | <b>14.3</b>               | <b>10.7</b>               |
| <b>Total current borrowings</b>     | <b>14.3</b>               | <b>20.1</b>               |
| <b>Non-current</b>                  |                           |                           |
| Convertible bonds due May 2024      | 50.8                      | 50.4                      |
| Convertible bonds due June 2025     | 12.8                      |                           |
|                                     | <b>63.6</b>               | <b>50.4</b>               |
| Bank borrowings                     | 0.6                       |                           |
| Property mortgage                   | 6.6                       | 7.1                       |
| Paul Capital funding liabilities    | 33.0                      | 37.9                      |
| Finance lease liabilities           |                           | 0.1                       |
| Other non-current borrowings        | <b>40.2</b>               | <b>45.1</b>               |
| <b>Total non-current borrowings</b> | <b>103.8</b>              | <b>95.5</b>               |
| <b>Total borrowings</b>             | <b>118.1</b>              | <b>115.6</b>              |

**Bank Borrowings**

At 31 December 2005 bank borrowings include two amounts due to the Basellandschaftliche Kantonbank of £0.9 million (CHF 2 million) and £0.7 million (CHF 1.5 million) (2004: £0.9 million (CHF 2 million) and £0.7 million (CHF 1.5 million)). Both loans can be terminated with six weeks notice by either party and bear interest at 6.5% and 6.0% respectively. Both loans are secured on the assets of Jago and the £0.7 million (CHF 1.5 million) loan is guaranteed by SkyePharma PLC.

The Group had a loan as at 31 December 2005 with GE Capital Corp of £1.4 million (\$2.4 million) (2004: £1.9 million (\$3.7 million)). The loan is secured by certain assets of SkyePharma Inc, SkyePharma US Inc and SkyePharma PLC. The loan bears interest at 8.0% and is repayable by installments until September 2007.

**Property Mortgage**

At 31 December 2005, the Group had a property mortgage facility with the Basellandschaftliche Kantonbank of £6.9 million (CHF 15.5 million) (2004: £7.4 million (CHF 16.1 million)). The mortgage is in two tranches, both secured by the assets of Jago. The first tranche of £2.7 million (CHF 6.2 million) bears interest at 2.75% and is repayable by installments over 20 years semi-annually. The second tranche of £4.1 million (CHF 9.3 million) bears interest at 2.75% and is repayable by installments over 50 years semi-annually.

**Paul Capital Funding Liabilities**

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

The Group entered into two transactions with Paul Capital Royalty Acquisition Fund ( Paul Capital ) in 2000 and 2002. Under these transactions Paul Capital provided a total of \$60 million in return for the sale of a portion of the potential future royalty and revenue streams on a selection of the Group s products.

Whilst the contractual arrangement with Paul Capital is a royalty agreement under which royalties are payable on revenues earned and payments received, the proceeds received from Paul Capital meet the definition of a financial liability under IAS 39, and are treated as a financial liability. Royalties paid to Paul Capital are treated as repayment of the liability and notional interest is charged on the liability. The estimated future payments to Paul Capital are discounted using each contract s original effective interest and any adjustment is recognised as income or expense in the income statement.

**9 Convertible Bonds**

In June 2005 the Group issued £20 million 8% convertible bonds, with a first put after five years by the holder of the bonds, and a final maturity of June 2025. The bonds are convertible at the option of the holder into SkyePharma Ordinary Shares at an initial conversion price of 77 pence at any time prior to maturity. The bond contains a price reset feature such that if on 3 June 2006 the Company's average share price for the preceding 10 days (reset price) is less than the conversion price, then the conversion price shall be adjusted to the reset price subject to a maximum reduction of 25% in the conversion price. Unless previously redeemed or converted, the bonds will be redeemed by the Group at their principal amount in June 2025. The convertible bonds existing at 31 December 2005, due in May 2024, were not affected by this transaction.

On 19 June 2005 £9.8 million of convertible bonds due June 2005 were redeemed in full by the Company at their principal amount.

As a result of these transactions the Group has £69.6 million convertible bonds due May 2024 at a conversion price of 95 pence, and £20 million convertible bonds due June 2025 at a conversion price of 77 pence.

**10 Share capital**

|  | Ordinary      |               | Deferred B    |               | Total nominal value |
|--|---------------|---------------|---------------|---------------|---------------------|
|  | Shares of 10p | Nominal value | Shares of 10p | Nominal value |                     |
|  | each          |               | each          |               |                     |
|  | Number        | £m            | Number        | £m            | £m                  |
| <b>At 1 January 2004</b>                           | 618,669,940   | 61.9          | 12,000,000    | 1.2           | 63.1                |
| Exercise of share options                          | 478,803       |               |               |               |                     |
| Issue of shares to Research Development Foundation | 3,250,000     | 0.3           |               |               | 0.3                 |
| <b>At 1 January 2005</b>                           | 622,398,743   | 62.2          | 12,000,000    | 1.2           | 63.4                |
| Rights issue                                       | 125,627,357   | 12.6          |               |               | 12.6                |
| Acquisition of shares in Astralis                  | 5,482,238     | 0.6           |               |               | 0.6                 |
| Exercise of share options                          | 255,808       |               |               |               |                     |
| <b>At 31 December 2005</b>                         | 753,764,146   | 75.4          | 12,000,000    | 1.2           | 76.6                |

The Group raised £34.8 million net of expenses by means of a rights issue of 125,627,357 new ordinary shares.

The Group also issued 5,482,238 Ordinary Shares to two former Astralis Directors to acquire 11,160,000 common shares in Astralis.

**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 twelve 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 <http://www.skyepharma.com/>.