

SKYEPHARMA PLC  
Form 6-K  
April 28, 2005

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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## FORM 6-K

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**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, 2005**

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## **SkyePharma PLC**

**(Translation of registrant's name into English)**

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**SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England**

**(Address of principal executive office)**

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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

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Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes                      No    X

If  Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

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**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: April 28, 2005

FOR IMMEDIATE RELEASE

28 APRIL, 2005

**SkyePharma PLC**

**Preliminary Results Announcement**

**for the year ended 31 December 2004**

**LONDON, UK, April 28, 2005** SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces the Company's preliminary results for the year-ended December 31, 2004.

**Operating highlights**

Agreement with GlaxoSmithKline for Paxil CR provides a \$10 million cash payment and a higher royalty rate and ensures royalty income received even while Paxil CR remains off the market

Pulmonary package: Heads of Terms with major global pharma company for Flutiform include up to \$160 million in milestone payments and reimbursement of development costs, with double digit royalties. Agreement still subject to contract

Conditional UK marketing authorisation for DepoDur

DepoBupivacaine licensed to Mundipharma outside North America and Japan

New agreements with Critical Therapeutics for zileuton and First Horizon for fenofibrate

Two products expected to be launched in 2005, four products to be filed for approval and four products to enter Phase III development

**Financial highlights**

Turnover up by 17% to £62.2m - excludes £5.5m of milestones received during 2004 (2003: £53.2m)

Royalty income increased by 39% to £26.0m (2003: £18.7m)

Gross profit up 33% to £31.0m (2003: £23.4m)

Exceptional items of £3.0m (2003: £9.5m)

Operating loss before exceptionals and amortisation fell by 59% to £9.7m (2003: £23.4m)

Operating loss after exceptionals and amortisation fell by 48% to £20.7m (2003: £39.5m)

Net loss fell by 44% to £24.3m (2003: £43.2m)

Loss per share 3.9p (2003: 7.1p)

End 2004 net cash £15.3m (2003: £22.0m)

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Ian Gowrie-Smith, Non-executive Chairman, said: A highly beneficial new agreement with GlaxoSmithKline for Paxil CR, significant advances for both our marketed products and our pipeline and important progress on the long-awaited pulmonary deal are the keynotes of our performance. We now have five key products on the market generating royalty income for us, with two more expected to be launched this year, and a well-stocked pipeline of products in late-stage development. Recent progress on corporate agreements brings us several powerful new partners. We face the future with confidence.

**For further information please contact:**

### **SkyePharma PLC**

Ian Gowrie-Smith, Non-executive Chairman

Michael Ashton, Chief Executive Officer

Peter Laing, Director of Corporate Communications

Today **+44 207 466 5000**

Thereafter **+44 207 491 1777**

Sandra Haughton, US Investor Relations **+1 212 753 5780**

**Buchanan Communications** **+44 207 466 5000**

Tim Anderson / Mark Court

### **CHAIRMAN'S STATEMENT**

A highly beneficial new agreement with GlaxoSmithKline for Paxil CR, significant advances for both our marketed products and our pipeline and important progress on the long-awaited pulmonary deal are the keynotes of our performance.

The current year brought an unwelcome surprise with news in March that the US FDA had halted distribution of GlaxoSmithKline's Paxil CR currently our major source of royalty income. Our partner is working with the FDA to expedite the return of this product to the market. Meanwhile I can report that GlaxoSmithKline has now agreed not only to increase the royalty rate due to us and make a \$10 million one-off payment but also to ensure that we will continue to receive royalty income even while the product remains off the market. We acknowledge our partner's willingness to support us in this way, a tribute to the strength of our relationship.

We have made encouraging progress with our pipeline in 2004. We currently have two products expected to be launched this year and four products that we expect to file for approval, with another four products poised to enter Phase III development. Our innovative pain control agent DepoDur was approved in the USA and launched by our partner Endo Pharmaceuticals. We have just heard that we have also received marketing authorisation for DepoDur in the UK (subject to some conditions), which will be used as the basis for wider approvals in Europe, where the product will be marketed by our partner Zeneus Pharma, appointed in 2004. Last year we also concluded new agreements with First Horizon Pharmaceuticals for fenofibrate and with Critical Therapeutics for zileuton. We have also recently granted Mundipharma (our European marketing partner for DepoCyte®) the rights outside North America and Japan for another pain control product, DepoBupivacaine, in a deal that will bring us up to \$80 million in milestone payments and a 35% share of sales.

Shareholders will be aware that our efforts to licence our package of pulmonary products have taken longer than we had initially hoped. However I am now delighted to report that we have negotiated Heads of Terms with a major global pharmaceutical company to develop and distribute our key pulmonary product Flutiform, a formoterol/fluticasone combination product in an HFA-powered metered-dose aerosol inhaler. The company combines strong primary care distribution in the key US market with the financial resources to commit to a clinical development programme designed to optimise the product profile. The outline terms include milestone payments and reimbursement of clinical development costs that in total could amount to \$160 million. In addition SkyePharma will receive double digit royalties, with an escalating royalty rate as sales achieve certain targets. SkyePharma will execute the clinical development programme. The agreement at this stage is non-binding and subject to contract finalisation and Board approvals.

We have now completed Phase II trials for Flutiform, with very encouraging top line results. We aim to file this product in 2007. Given the high potential value of a late-stage product in an important therapeutic area, we have been determined to maximise the return for ourselves. The terms that we have negotiated for Flutiform amply justify this policy and we hope that shareholders agree that it was worth waiting for.

## **Conclusion**

We now have five key products on the market generating royalty income for us, with two more expected to be launched this year, and a well-stocked pipeline of products in late-stage development. Recent progress on corporate agreements brings us several powerful new partners. We face the future with confidence.

**Ian Gowrie-Smith**

**Non-executive Chairman**

## **OPERATIONAL REVIEW**

### **Products on the market**

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During 2004, Paxil CR, our improved formulation of GlaxoSmithKline's Paxil, held about 6.5% of all new US prescriptions for SSRI antidepressants. This share has been gradually declining through the advent of new SSRI antidepressants but has been largely unaffected by US generic competition for the older version Paxil<sup>®</sup> from 2003. GlaxoSmithKline's total sales of Paxil CR were £396 million (\$725 million) in 2004, up by 13% in constant exchange rate terms. In March 2005, the FDA halted US distribution of Paxil CR and another unrelated product because of manufacturing problems at a GlaxoSmithKline plant in Puerto Rico. We have recently concluded an agreement with GlaxoSmithKline that not only provides us with a lump-sum payment of approximately \$10 million and an increased royalty rate on this product but also ensures that we will continue to receive royalty income while the product remains off the market.

Xatral<sup>®</sup> OD (Uroxatral<sup>®</sup> in the USA), our once-daily version of Sanofi-Aventis's Xatral<sup>®</sup> (alfuzosin), is a treatment for the urinary symptoms of benign prostatic hypertrophy. Xatral<sup>®</sup> OD has been on the market

outside the USA since April 2000 and has now largely replaced the older multidose versions of Xatral<sup>®</sup>. Uroxatral<sup>®</sup> was launched in the USA in November 2003 and by the end of 2004 had captured 9% of the combined prescriptions written for it and for its main competitor. Xatral<sup>®</sup> OD has now been approved in Europe for a second indication, acute urinary retention, with Phase III trials ongoing for the USA. Reported sales of all forms of Xatral<sup>®</sup> were 281 million in 2004, up by 28% in constant exchange rate terms.

Global sales of DepoCyt<sup>®</sup> doubled in 2004. Sales in the USA by our partner Enzon were \$6.6 million, up 61% on the prior year. Our European partner Mundipharma launched the product as DepoCyte<sup>®</sup> in February 2004 and has had an encouraging initial response with full year sales of \$1.5 million. Mundipharma shares our view that the market for DepoCyte<sup>®</sup> is largely under-developed. We have now completed enrolment in the Phase IV trial that will be used to support a filing for the most common form of neoplastic meningitis, associated with solid tumours. We have recently extended our relationship with Mundipharma by granting rights outside North America and Japan for DepoBupivacaine, a long-acting local anaesthetic that we believe complements DepoDur. DepoBupivacaine is currently in Phase II trials.

Solaraze<sup>®</sup>, our topical gel treatment for actinic keratosis, is now marketed in the US by Bradley Pharmaceuticals. Bradley, a fast-growing US specialty pharmaceuticals company, acquired the Bioglan dermatology unit of Quintiles in August 2004. This has more than doubled the number of sales representatives detailing Solaraze<sup>®</sup>. Combined sales by both partners in 2004 were \$12 million. The transfer of rights to market Solaraze<sup>®</sup> from Quintiles to Bradley required our consent and in August we received a \$5 million payment from Quintiles as part of this transaction. Solaraze<sup>®</sup> is marketed in Europe and certain other territories by Shire Pharmaceuticals. Total non-US sales were \$6 million in 2004. In Australia, Shire has now filed for approval using data from a clinical trial in patients with multiple actinic keratoses.

DepoDur (formerly known as DepoMorphine) is our new analgesic for the relief of acute post-operative pain. Our DepoFoam sustained-release injectable formulation delivers from a single epidural injection administered immediately before surgery a therapeutically effective level of morphine for up to 48 hours covering the typical period of peak pain after a major operation. There is widespread recognition that pain relief is an under-served therapeutic need and current approaches to control of postoperative pain leave much to be desired. In the USA, we filed DepoDur in July 2003. It was formally approved by the FDA in May 2004 the fastest approval time possible. Our North American partner Endo Pharmaceuticals launched DepoDur in the USA in December at a significant price premium to conventional approaches to post-operative analgesia and now has a team of 70 specialist sales representatives focused on hospitals. Initial acceptance has been encouraging.

DepoDur was filed with the UK regulatory authorities in November 2003 and we have recently received marketing authorisation subject to certain conditions. Once these conditions are met, this will be used as the basis for seeking approval throughout the European Union using the EU's mutual recognition procedure. Our European partner Zeneus Pharma (appointed in April 2004) has been eagerly awaiting approval of DepoDur to commence marketing. Zeneus has a pan-European hospital sales force of approximately 150 representatives.

### **Products in late-stage development**

Foradil<sup>®</sup> Certihaler<sup>®</sup> is a new version of Novartis long-acting bronchodilator Foradil<sup>®</sup> (formoterol). We developed not only the multidose dry-powder inhaler device but also the formulation technologies that ensure dose consistency regardless of storage conditions. These technologies are also involved in a new collaboration with Novartis to jointly develop another bronchodilator, QAB149. Novartis filed Foradil<sup>®</sup> Certihaler<sup>®</sup> with the FDA and European regulatory authorities in December 2002. The FDA issued a second approvable letter in December 2004 and Novartis is in discussions with the FDA about the conditions necessary for final approval. The product has now been approved in ten European and Latin American countries. Novartis is responsible for marketing Foradil<sup>®</sup> Certihaler<sup>®</sup> outside the USA. The US Foradil<sup>®</sup> franchise has been licensed to Schering-Plough Corporation.

We have now completed the Phase III trial of our once daily version of the Parkinson's drug Requip<sup>®</sup> which we are conducting for our partner GlaxoSmithKline. The product is expected to be filed later this year.



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We are developing several other asthma drugs in metered-dose aerosol inhalers (MDIs) powered by a hydrofluoroalkane (HFA) propellant gas. In 2004 we completed the Phase III trial of an HFA-MDI version

of AstraZeneca's inhaled steroid Pulmicort® (budesonide) and AstraZeneca is about to file for approval of this product in the first country in Europe. We will receive double-digit royalties on sales of Pulmicort® HFA-MDI.

Our own HFA-MDI version of the bronchodilator formoterol will commence Phase III trials in the autumn. Flutiform HFA-MDI (a fixed-dose combination of formoterol and the inhaled steroid fluticasone) has now completed its Phase II trial, with very encouraging headline results. Both products are on track for planned filing in 2007. As discussed in the Chairman's Statement, we have now negotiated Heads of Terms with a major global pharmaceutical company to develop and distribute Flutiform. The agreement, which is still subject to contract, will provide us with up to \$160 million in milestone payments and reimbursement of development costs and we will also be entitled to double-digit royalties on our partner's sales.

Propofol IDD-D is our novel formulation of propofol, a widely-used injectable anaesthetic and sedative. Our formulation has been designed not to support microbial growth, a recognised problem with current versions, and should provide uninterrupted sedation for 24 hours, ideal for the fast-growing intensive care market. In April 2004 the FDA completed its review of the Phase II trials, triggering a milestone payment from our North American partner Endo, and we are now in dialogue with the FDA on the design of the additional trials required for approval. We are also in current discussion with potential licensees for Europe and certain other markets.

#### **New corporate developments**

In 2004 we licensed fenofibrate, an oral treatment for elevated blood lipid disorders, in the USA to First Horizon Pharmaceutical Corporation. We will receive up to \$50 million in milestone payments, of which up to \$15 million is dependent on the timing and conditions of FDA approval, now anticipated in 2005. We will also receive 25% of First Horizon's net sales of this product in the form of royalty income and manufacturing revenues. We are also developing an improved formulation of First Horizon's lead product, the cardiovascular drug Sular (nisoldipine).

We also announced a collaboration with Critical Therapeutics to develop zileuton, an oral drug for asthma and COPD. We had previously developed a twice-daily version for Abbott Laboratories: this had completed Phase III development for asthma but was not filed. Critical Therapeutics has now licensed zileuton from Abbott. Critical Therapeutics is aiming to file the controlled release product with the FDA by the end of this year.

In April we licensed our dermatology products, pipeline and topical delivery technologies to a US dermatology company, Trigenesis Therapeutics. In a strategic review last year we concluded that we would gain a greater return by out-licensing this technology portfolio to a company with a development and market focus in this area. We retain our existing licences and can also continue to use the delivery technologies under certain conditions. If all the pipeline products reach the market, milestone payments will exceed US\$20 million. SkyePharma will also receive a 10% royalty on sales. Trigenesis is now part of the Indian pharmaceutical company, Dr Reddy's Laboratories.

In June we agreed a strategic alliance with the UK company Vectura for pulmonary delivery technologies. We obtained certain rights to Vectura's Aspira® dry-powder inhaler, which is particularly suitable for the delivery of macromolecules. We invested £2 million for a 4% equity stake in Vectura. We are gratified that Vectura subsequently completed a successful initial public offering on the AIM market and also recently concluded a major pulmonary deal with Novartis.

King Pharmaceuticals (at that time the target of a takeover offer from Mylan Laboratories, a leading US generic company) decided to terminate a 2003 agreement to develop a modified release formulation of Altace® (ramipril). This product was at an early stage of development.

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In 2004 our partner Astralis initiated US Phase II trials of its novel psoriasis treatment Psoraxine. Preliminary results announced recently were disappointing, with a placebo-like level of response. We are currently working with Astralis to investigate and resolve the possible reasons why the outcome of this trial should have been so different from the promising results of previous large-scale trials in Venezuela. We have recently acquired shares from two former directors of Astralis, taking our equity stake up to just under 50% and enabling us to exercise greater influence. Dr. Gordon Schooley, SkyePharma's Chief Scientific Officer, has also been appointed to the board of Astralis.

## **The future**

We are determined to maximise the long-term return from our products and to move away from reliance on one-off milestone payments, which historically have made up the majority of our revenues. This has meant a change in the structure of our agreements to optimise royalty rates and to increase milestone payments that are tied to product revenue targets. Inevitably this has brought a short-term penalty in terms of revenues and cashflow but we are confident that this is the correct long-term approach, which will greatly enhance the value of our products to the company.

**Michael Ashton**

**Chief Executive Officer**

## **FINANCIAL REVIEW**

### **Turnover**

Turnover for the year increased by 17% to £62.2 million, compared with £53.2 million in 2003. This is primarily due to higher royalty income together with an increase in manufacturing and distribution revenues, partly off-set by a fall in contract development and licensing revenues. This increase does not include milestone payments of £5.5 million (\$10 million) received during 2004 from Endo and First Horizon, which have not been included in turnover and have been fully deferred to later years. In April 2005 SkyePharma announced the licensing of DepoBupivacaine for Europe to Mundipharma.

Contract development and licensing revenue decreased by 11% to £26.3 million due primarily to the deferral of the above milestones received and the absence of anticipated milestones in the year from the expected approval of fenofibrate and the licensing of a package of products in the pulmonary field. As discussed in the review of operations both milestones are still anticipated. Revenues recognised from milestone payments and payments received on the signing of agreements amounted to £20.3 million compared with £24.2 million in 2003. The 2004 total included revenue from Endo upon the FDA approval of DepoDur in the USA, Zeneus (formerly Medeus) for the European marketing and distribution rights for DepoDur, Dr Reddy's (formerly Trigenesis) for the rights to certain dermatological assets and Quintiles for consenting to the transfer of the US, Canadian and Mexican marketing rights for Solaraze® to Bradley. In addition, £7.2 million of revenue was recognised from GlaxoSmithKline on the phase III clinical trials of Requip® (ropinirole), AstraZeneca on the phase III clinical trials of budesonide HFA and Novartis on the first European approval of Foradil® Certihaler® and the phase II clinical trials of QAB 149.

Royalty income increased by 39% to £26.0 million, compared with £18.7 million in 2003. Royalty income in 2004 derives principally from Paxil CR, Xatral® OD, DepoCyt® and Solaraze®. DepoDur was launched in December 2004 and is expected to contribute to royalty income in 2005.

Manufacturing and distribution revenues more than doubled to £9.9 million, compared with £4.8 million in 2003, mainly due to increased clinical and pre-launch production of the Foradil® Certihaler® for Novartis and Coruno for Therabel.

### **Deferred income**

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During 2004, the Group released a net £1.4 million from deferred income under its revenue recognition policy. Amounts received included the milestones from Endo and First Horizon noted above which have been fully deferred. The total deferral of £14.5 million at the end of 2004 comprises:

	31 December		31 December	
	2003	Received *	Recognised	2004
	£ million	£ million	£ million	£ million
Contract development and licensing revenue	7.1	26.6	(26.3)	7.4
Other operating income	8.8	(0.5)	(1.2)	7.1
	15.9	26.1	(27.5)	14.5

\* Includes exchange adjustments

Deferred contract development and licensing income will be released in later years as the related costs are incurred or as any associated obligations under the relevant contracts are satisfied. Other operating income deferred will no longer be recognised under International Financial Reporting Standards ( IFRS ).

### **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 5% to £31.2 million in 2004, compared with £29.8 million in 2003. This was mainly due to increased manufacturing and distribution costs on the higher production of the Foradil® Certihaler® for Novartis partly offset by a fall in contract development and licensing cost of sales. The resulting gross profit increased by 33% to £31.0 million, compared with £23.4 million in 2003.

### **Expenses**

Selling, marketing and distribution expenses decreased significantly by 60% to £1.7 million, reflecting the significant savings resulting from the Group reorganisation announced last year. Amortisation of intangible assets decreased slightly by £0.4 million to £6.3 million. Other administration expenses before exceptionals were £12.2 million in 2004, compared with £18.0 million in 2003, a fall of 32%. The decrease was mainly due to one-off charges in 2003, including the cost of reacquiring the DepoCyt® European rights from Elan and from administration savings resulting from the aforementioned reorganisation.

The exceptional charge of £4.7 million mainly relates to a write down in the value of fixed asset investments, and the continuing reorganisation of some research and development operations and other business functions which commenced during 2003. The reorganisation is expected to be completed during the first half of 2005.

SkyePharma's own research and development expenses in the year decreased by £2.6 million to £28.0 million, mainly due to a reduction in expenditure on DepoDur when compared with the significant expenditure incurred in the prior year in preparation for its July 2003 filing with the FDA.

### **Other operating income**

Under the Paul Capital agreements, other operating income recognised in 2004 was £1.2 million, compared with £6.1 million in 2003. All of the income under the first Paul Capital agreement has now been recognised, and there is £7.1 million of deferred income under the second Paul Capital agreement as at December 2004. Royalty payments to Paul Capital of £3.0 million (2003: £3.2 million) were expensed during the year.

### **Operating results**

The Group's operating loss before exceptionals fell by 59% to £9.7 million, compared with £23.4 million in 2003 due principally to the reduction in other administration expenses. The increased turnover and lower selling, marketing and distribution expenses together with lower research and development expenses have also contributed to the reduction of the operating loss before exceptionals. The operating loss after exceptionals also fell by 48% to £20.7 million. The net loss fell by 44% to £24.3 million in 2004, compared with £43.2 million in 2003. Earnings before interest, tax, depreciation and amortisation ( EBITDA ), a commonly used performance indicator, showed a 76% improvement to a loss of £6.4 million in 2004 compared with a loss of £26.6 million in 2003.

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The loss per share after exceptionals was 3.9 pence, which compares with 7.1 pence in 2003. Foreign exchange movements negatively impacted turnover by £2.8 million in the year. This was more than offset by exchange benefits in costs, primarily research and development costs. The total impact on the net loss for the year was a benefit of £1.6 million over 2003.

### **Cash balances and cash flow**

During 2004 the Group issued £20 million 6% convertible bonds, with a first right of conversion after five years by the holder of the bonds, and a final maturity of May 2024. In addition, the Group exchanged £49.6 million of its convertible bonds due 2005 for convertible bonds due 2024, leaving £9.8 million of the 2005 bonds outstanding. Unamortised issue costs of £0.3 million were written off on exchange of the convertible bonds. The £49.6 million 2024 convertible bonds were consolidated to form a single series with the £20 million 2024 bonds issued in 2004. The bonds are convertible at the option of the holder into SkyePharma Ordinary Shares at a conversion price of £1.00. This raised approximately £16.6 million net of expenses.

At 31 December 2004 SkyePharma had cash and short term deposits of £15.3 million. This compares with £22.0 million net of overdrafts at 31 December 2003 and £29.0 million net of overdrafts at 30 June 2004.

In 2004 there was a net cash outflow from operating activities of £10.7 million, compared with a net cash inflow of £6.6 million in 2003.

During the year the Group spent £7.9 million on capital expenditure and fixed asset investments, including £4.4 million on tangible fixed assets. The Group also recorded fixed asset investments of £2.0 million and intangible assets of £1.0 million relating to the strategic alliance with Vectura in the area of pulmonary delivery technologies. The proceeds on disposal of the Group's non-strategic holding of Transition Therapeutics shares were £2.7 million.

SkyePharma received £0.3 million of cash during the year from the issue of Ordinary Shares relating to the exercise of employee share options over Ordinary Shares. During 2004 the Group settled the £0.5 million Chiron promissory note.

### **Balance sheet**

The Group balance sheet at 31 December 2004 shows shareholders' funds of £63.6 million (2003: £84.9 million). Goodwill written off to the profit and loss account reserve remained at £147.6 million.

At 31 December 2004 SkyePharma had fixed asset investments totalling £20.1 million. The investments include Astralis Ltd, a US company; Micap plc, a UK company; Vectura Group plc, a UK company and Vital Living Inc, a US company. The investment in Astralis has been treated as an associated undertaking from December 2004, when SkyePharma announced a transaction to acquire a significant equity position and additional Board representation in Astralis so as to influence its future strategic direction. This has resulted in goodwill of £13.7 million.

The Group's fixed asset investments are primarily held in development stage pharmaceutical companies as long term investments associated with collaboration agreements or as part of SkyePharma's long term strategy. The Board continues to review the underlying performance of the individual companies and the investments have been recorded at the lower of cost or net realisable value. Vital Living has been written down by £3.5 million to the Directors' assessment of its net realisable value based on a number of considerations including the share price as at 31 December 2004. The Group will continue to monitor its investments and the underlying value of the companies closely.

Current asset investments comprise a £3.25 million 5% convertible loan note from GeneMedix plc. This has been recorded at £1.1 million at 31 December 2004, being the lower of cost and net realisable value assuming conversion of the note into GeneMedix ordinary shares.

At 31 December 2004 bank and other non-convertible debt amounted to £11.0 million (2003: £12.7 million) consisting primarily of a £7.4 million (2003: £7.5 million) property mortgage secured on the Swiss assets. In addition the company has 6% Convertible Bonds due June 2005 of £9.8 million (2003: £58.8 million) and 6% Convertible Bonds due May 2024 of £66.5 million (2003: £Nil). Net debt amounted to £72.0 million (2003: £49.5 million).

Throughout most of 2004 £30 million of the 6% Convertible Bonds were subject to an interest rate swap agreement, swapping a fixed rate obligation of 6% for a floating rate. The weighted average floating rate for the year was 6.82%, and the floating rate at 31 December 2004 was 7.14%. The swap is cancellable at the option of the bank. This will terminate in June 2005.



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During 2004 SkyePharma issued 3.25 million Ordinary Shares to the Research Development Foundation as a result of a restructuring of the historic arrangements with RDF existing at the time of the DepoTech acquisition in 1999.

### **International Financial Reporting Standards**

SkyePharma will be required to prepare consolidated financial statements under IFRS from 1 January 2005 and to restate the 2004 results for comparison.

The Group is completing a project to convert its comparative financial information from UK GAAP to IFRS and plans to announce the results during the first half of 2005. The first SkyePharma financial statements prepared under IFRS will be for the period ending 30 June 2005. The key differences that the Company expects to arise on the adoption of IFRS are summarised in this announcement in the Supplementary Information: IFRS.

**Subsequent events**

In April 2005 SkyePharma entered into an amendment agreement with GlaxoSmithKline ( GSK ) in respect of Paxil CR. Under the terms of the amendment agreement, GSK will make a one-time payment of approximately \$10 million. In addition, SkyePharma will also be entitled to an increase in the royalty rate from 3% to 4% on actual net sales of Paxil CR, with effect from 4 March 2005. As GSK has been unable to supply Paxil CR in the US since 4 March 2005, GSK has also agreed to pay SkyePharma the same level royalty on GSK's budgeted sales of Paxil CR from 4 March 2005 while the product remains off the market, subject to other terms of the agreement. Approximately £5.0 million has been recorded as royalty income in 2004.

**Donald Nicholson**

Finance Director

**CONSOLIDATED PROFIT AND LOSS ACCOUNT**

		Exceptional		Before			
	Notes	Before exceptional items and amortisation	Exceptional items and amortisation (note 4)	Year to 31 December 2004	exceptional items and amortisation	Exceptional items and amortisation	Year to 31 December 2003
		£ 000	£ 000	£ 000	£ 000	£ 000	£ 000
<b>Turnover</b>	2	<b>62,168</b>		<b>62,168</b>	53,152		53,152
Cost of sales	2	<b>(31,154)</b>		<b>(31,154)</b>	(29,786)		(29,786)
<b>Gross profit</b>		<b>31,014</b>		<b>31,014</b>	23,366		23,366
Selling, marketing and distribution expenses		(1,728)		(1,728)	(4,348)		(4,348)
Administration expenses			(6,314)	(6,314)		(6,669)	(6,669)
Amortisation		(12,226)	(4,711)	(16,937)	(17,987)	(9,487)	(27,474)
Other administration expenses		(12,226)	(11,025)	(23,251)	(17,987)	(16,156)	(34,143)
Research and development expenses		(27,961)		(27,961)	(30,520)		(30,520)
Other operating income	3	1,237		1,237	6,126		6,126
<b>Operating loss</b>		<b>(9,664)</b>	<b>(11,025)</b>	<b>(20,689)</b>	(23,363)	(16,156)	(39,519)
Profit on disposal of investment	7		2,021	2,021			
Share of loss in associate		(10)	(6)	(16)			
<b>Loss on ordinary activities before interest and taxation</b>		<b>(9,674)</b>	<b>(9,010)</b>	<b>(18,684)</b>	(23,363)	(16,156)	(39,519)
Interest receivable		758		758	1,029		1,029
Interest payable		(5,784)	(338)	(6,122)	(4,493)		(4,493)
<b>Loss on ordinary activities before taxation</b>	2	<b>(14,700)</b>	<b>(9,348)</b>	<b>(24,048)</b>	(26,827)	(16,156)	(42,983)
Taxation		(248)		(248)	(240)		(240)

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<b>Retained loss</b>		<b>(14,948)</b>	<b>(9,348)</b>	<b>(24,296)</b>	(27,067)	(16,156)	(43,223)
Basic and diluted loss per Ordinary share	5	<b>(2.4p)</b>	<b>(1.5p)</b>	<b>(3.9p)</b>	(4.4p)	(2.7p)	(7.1p)

There was no material difference between the loss on ordinary activities before taxation and the historical cost loss before taxation in 2004 and 2003. All results represent continuing activities.

See Notes to the Preliminary Announcement.

**CONSOLIDATED STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES**

	Year to 31 December 2004	Year to 31 December 2003
	£ 000	£ 000
<b>Loss attributable to shareholders</b>	<b>(24,296)</b>	<b>(43,223)</b>
Net currency translation effect	(531)	(175)
Unrealised gain on contract development	130	2,029
Unrealised interest receivable	42	
<b>Total recognised losses for the year</b>	<b>(24,655)</b>	<b>(41,369)</b>

**RECONCILIATION OF MOVEMENTS IN CONSOLIDATED SHAREHOLDERS FUNDS**

	Year to 31 December 2004	Year to 31 December 2003 (restated)
	£ 000	£ 000
<b>Shareholders funds at the beginning of the year as previously stated</b>	<b>84,870</b>	124,270
Restatement for UITF Abstract 38; Accounting for ESOP trusts		(1,028)
<b>Shareholders funds at the beginning of the year as restated</b>	<b>84,870</b>	123,242
Total recognised losses for the year	(24,655)	(41,369)
ESOP credit	1,278	558
Purchase of own shares for ESOP		(925)
Equity shares issued, net of expenses	1,869	2,560
Exercise of share options, net of expenses	261	765
Issue of warrants		39
<b>Net movement in the year</b>	<b>(21,247)</b>	<b>(38,372)</b>
<b>Shareholders funds at the end of the year</b>	<b>63,623</b>	84,870

**CONSOLIDATED BALANCE SHEET**

Notes	31 December	31 December
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		2004	2003
			(restated)
		£ 000	£ 000
<b>Fixed assets</b>			
Intangible assets	6	91,519	95,096
Tangible assets		40,628	42,615
Investments	7	20,104	22,024
		<u>152,251</u>	<u>159,735</u>
<b>Current assets</b>			
Stock		1,531	1,320
Debtors			
Due within one year		19,093	14,832
Due after more than one year		770	802
Investments		1,093	981
Cash and short-term bank deposits		15,337	23,240
		<u>37,824</u>	<u>41,175</u>
<b>Creditors: amounts falling due within one year</b>			
Convertible bonds due June 2005		(9,774)	
Deferred income		(14,291)	(12,926)
Other creditors		(24,486)	(26,394)
		<u>(48,551)</u>	<u>(39,320)</u>
<b>Net current (liabilities)/assets</b>		<u>(10,727)</u>	<u>1,855</u>
<b>Total assets less current liabilities</b>			
		141,524	161,590
<b>Creditors: amounts falling due after more than one year</b>			
Convertible bonds due May 2024		(66,478)	
Convertible bonds due June 2005			(58,791)
Deferred income		(250)	(2,948)
Other creditors		(10,462)	(12,860)
		<u>(77,190)</u>	<u>(74,599)</u>
<b>Provisions for liabilities and charges</b>		<u>(711)</u>	<u>(2,121)</u>
<b>Net assets</b>		<u>63,623</u>	<u>84,870</u>
<b>Capital and reserves</b>			
Called up share capital		63,440	63,067
Share premium account		320,980	319,223
Other reserves		9,350	9,350
Profit and loss account		(330,147)	(306,770)
<b>Shareholders funds</b>			
Attributable to equity interests		52,313	73,560
Attributable to non-equity interests		11,310	11,310
		<u>63,623</u>	<u>84,870</u>

See Notes to the Preliminary Announcement

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**CONSOLIDATED CASH FLOW STATEMENT**

	Notes	Year to 31 December 2004	Year to 31 December 2003
		£ 000	£ 000
<b>Net cash (outflow)/inflow from operating activities</b>	(b)	(10,715)	6,615
<b>Returns on investments and servicing of finance</b>			
Interest received		747	1,047
Interest paid		(5,880)	(4,013)
Interest element of finance lease payments		(9)	(70)
		<u>(5,142)</u>	<u>(3,036)</u>
<b>Taxation</b>		(248)	(227)
<b>Capital expenditure and financial investment</b>			
Purchase of intangible fixed assets		(1,308)	(2,530)
Purchase of tangible fixed assets		(4,432)	(4,021)
Purchase of fixed asset investments		(2,186)	(5,674)
Disposal of fixed asset investments		2,650	
		<u>(5,276)</u>	<u>(12,225)</u>
<b>Cash outflow before use of liquid resources and financing</b>		(21,381)	(8,873)
<b>Management of liquid resources</b>			
Net decrease in amounts held on short-term bank deposit		19,086	183
<b>Financing</b>			
Issue of Ordinary Share capital		261	1,437
Issue of warrants			39
Issue of convertible bonds due May 2024		20,000	
Expenses of convertible bonds issue and exchange		(3,399)	
Debt due within one year:			
Inception of new loan			770
Repayment of loans		(1,260)	
Debt due beyond one year:			
Inception of new loan			1,936
Repayment of loans		(264)	(286)
Capital element of hire purchase and finance lease payments		(223)	(1,078)
		<u>15,115</u>	<u>2,818</u>
<b>Increase/(decrease) in cash</b>		<u>12,820</u>	<u>(5,872)</u>

## NOTES TO THE CONSOLIDATED CASH FLOW STATEMENT

## (a) Reconciliation of movements in net debt

	Year to 31 December	Year to 31 December
	2004	2003
	£ 000	£ 000
<b>Increase/(decrease) in cash in the year</b>	<b>12,820</b>	<b>(5,872)</b>
Cash inflow from increase in debt and lease financing	(14,854)	(1,342)
Cash inflow from decrease in liquid resources	(19,086)	(183)
<b>Change in net debt resulting from cash flows</b>	<b>(21,120)</b>	<b>(7,397)</b>
Amortisation of issue costs on convertible bonds	(522)	(414)
Write off of issue costs on exchange of convertible bonds	(338)	
New finance leases		(46)
Translation difference	(489)	(24)
<b>Movement in net debt in the year</b>	<b>(22,469)</b>	<b>(7,881)</b>
<b>Net debt at beginning of the year</b>	<b>(49,482)</b>	<b>(41,601)</b>
<b>Net debt at end of the year</b>	<b>(71,951)</b>	<b>(49,482)</b>

Net debt is defined as cash and liquid resources less borrowings.

## (b) Reconciliation of operating loss to net cash (outflow)/inflow from operating activities

	Year to 31 December	Year to 31 December
	2004	2003
	£ 000	£ 000
Operating loss	(20,689)	(39,519)
Depreciation	5,994	6,294
Amortisation	6,314	6,669
Increase in stock	(211)	(64)
(Increase)/decrease in debtors	(4,207)	19,573
Decrease in deferred income excluding unrealised gain on contract development	(1,203)	(126)
Increase in other creditors	28	4,734
(Decrease)/increase in provisions	(1,410)	1,920
Provision for diminution in value of fixed asset investments	3,503	1,599
Impairment of intellectual property		2,673
Impairment of tangible fixed assets		1,324
Other	1,166	1,538
<b>Net cash (outflow)/inflow from operating activities</b>	<b>(10,715)</b>	<b>6,615</b>

## NOTES TO THE CONSOLIDATED CASH FLOW STATEMENT continued

## c) Analysis of net debt

	At				At
	1 January	Cash	Non-cash	Exchange	31 December
	2004	flow	changes	movements	2004
	£ 000	£ 000	£ 000	£ 000	£ 000
Cash at bank and in hand	3,052	11,653		(18)	14,687
Bank overdraft	(1,198)	1,167		31	
Short-term bank deposits	20,188	(19,086)		(452)	650
	<u>22,042</u>	<u>(6,266)</u>		<u>(439)</u>	<u>15,337</u>
Debt due within one year	(3,172)	1,260	(1,923)	34	(3,801)
Debt due after one year	(9,195)	264	1,923	(92)	(7,100)
Convertible bonds due June 2005	(58,791)		49,017		(9,774)
Convertible bonds due May 2024		(16,601)	(49,877)		(66,478)
Hire purchase and finance leases	(366)	223		8	(135)
	<u>(71,524)</u>	<u>(14,854)</u>	<u>(860)</u>	<u>(50)</u>	<u>(87,288)</u>
<b>Total</b>	<u>(49,482)</u>	<u>(21,120)</u>	<u>(860)</u>	<u>(489)</u>	<u>(71,951)</u>

Cash at bank and in hand and short-term bank deposits are aggregated on the balance sheet. Debt includes bank loans and a secured mortgage.



Non-cash changes relate to the exchange of £49.6 million convertible bonds due 2005 for bonds due 2024 in the same amount, amortisation of the issue costs on the convertible bonds, the write off of unamortised issue costs on the 2005 convertible bonds on exchange for 2024 convertible bonds and transfers between categories. See note 8; Convertible bonds.

## NOTES TO THE PRELIMINARY ANNOUNCEMENT

### 1 Accounting policies

#### Accounting convention and presentation

The unaudited results for the year ended 31 December 2004 have been prepared in accordance with the accounting policies applied in 2004. The Group has applied one new accounting standard during the period. During 2004 the Group has implemented UITF Abstract 38; Accounting for ESOP trusts and related amendments to Abstract 17; Employee share schemes. UITF 38 changes the presentation of an entity's own shares held in an ESOP trust from requiring them to be recognised as assets to requiring them to be deducted in arriving at shareholders' funds. UITF 17 (revised) requires that the minimum expense recognised in respect of an award should be the difference between the fair value of the shares at the date of award and the amount that an employee may be required to pay for the shares (i.e. the intrinsic value of the award). The prior year comparatives have been restated for the adoption of UITF Abstract 38. The effect of adoption of UITF 17 is not material. The financial information in this statement does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985.

The financial information for the year ended 31 December 2003 has been extracted from the Statutory Accounts for that period which have been delivered to the Registrar of Companies. The Auditors' Report on these Accounts was unqualified and did not contain a statement under Section 237 of the Companies Act 1985.

The financial information in this announcement has been prepared on a going concern basis which assumes that the Company will continue in operational existence for the foreseeable future. The Directors have reviewed the working capital requirements of the Group for the next twelve months. The Group's working capital requirements are sensitive to the timing and receipt of milestone payments and payments received on the signing of new contracts, particularly in the short-term the timing of FDA approval of Fenofibrate and the conclusion of a definitive agreement for the pulmonary licensing.

The Directors have a reasonable expectation that appropriate financing will be available, if required to cover any shortfall, and have therefore prepared the financial information contained herein on a going concern basis.

Until the above uncertainties are resolved 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.

#### Revenue recognition

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Turnover comprises contract development and licensing, royalty and manufacturing and distribution income. Contract development and licensing income represents amounts invoiced to customers for services rendered under development and licensing agreements, including milestone payments and technology access fees. Contract revenue is recognised when earned and non-refundable and to the extent that there are no future obligations pursuant to the revenue, in accordance with the contract terms. Refundable contract revenue is treated as deferred until such time as it is no longer refundable. Royalty income represents income earned as a percentage of product sales. Advance royalties received are treated as deferred income until earned, at which time they are recognised as income. Manufacturing and distribution revenues principally comprise contract manufacturing fees invoiced to third parties and income from product sales. Sales taxes are excluded from revenue.

### **Research and development costs**

Research and development costs are charged as an expense in the period in which they are incurred.

**NOTES TO THE PRELIMINARY ANNOUNCEMENT continued**

**1 Accounting policies (continued)**

**Foreign currency transactions**

Foreign currency transactions by Group companies are recorded in local currency at the exchange rate ruling on the date of transaction. Assets and liabilities expressed in foreign currencies are translated into sterling at the exchange rates ruling at the balance sheet date. Exchange differences which relate to the retranslation of net assets of overseas companies are taken directly to reserves. All other foreign exchange differences are taken to the profit and loss account in the year in which they arise. The Group uses the average exchange rates prevailing during the year to translate the results of overseas subsidiaries into sterling and year-end rates to translate the net assets of those undertakings.

**Fixed asset investments Investments in associates**

Investments in associated undertakings are recorded in the consolidated balance sheet at the Group's share of net assets at acquisition and of their post acquisition retained profits or losses, together with any goodwill arising on the acquisition net of amortisation. Goodwill is capitalised and amortised over a period of 20 years or less in line with the Directors' view of its useful economic life.

**Fixed asset investments - Unlisted investments**

Investments that are held for continuing use in the business are classified as fixed asset investments and recorded in the balance sheet at the lower of cost and net realisable value.

**Impairment of fixed assets**

The carrying values of fixed assets are reviewed for impairment when there is an indication that the assets may be impaired. First year impairment reviews are conducted for acquired goodwill and intangible assets. Impairment is determined by reference to the higher of net realisable value and value in use, which is measured by reference to discounted future cash flows. Any provision for impairment is charged to the profit and loss account in the year concerned.

**Convertible debt**

On issue, convertible debt is stated at the amount of net proceeds after deducting issue costs. On conversion, the amount recognised in shareholders' funds in respect of the shares issued is equal to the carrying value at the date of conversion. Issue costs on convertible debt and any discount on issue are charged to the profit and loss account at a constant rate over the term of the debt.

**Future requirements**

In June 2002, the Council of the European Union adopted a Regulation requiring listed companies in its Member States to prepare consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) from 1 January 2005.

The Group is completing a project to convert its principal financial reporting from UK GAAP to IFRS, and plans to announce the financial effect and status of the transition during the first half of 2005. The first SkyePharma financial statements prepared under IFRS will be for the interim period ending 30 June 2005.

## NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

## 2 Segmental analysis

The Group's operations relate wholly to one class of business, pharmaceuticals. Further analysis of turnover, loss on ordinary activities before taxation and net assets by geographical area is set out below, together with an analysis of cost of sales.

	Year to 31 December 2004	Year to 31 December 2003
	£ 000	£ 000
<b>(a) Turnover</b>		
By class of business:		
Pharmaceuticals		
Contract development and licensing		
Milestone payments	20,334	24,196
Research and development costs recharged	6,003	5,456
	<u>26,337</u>	<u>29,652</u>
Royalties receivable	25,959	18,701
Manufacturing and distribution	9,872	4,799
	<u>62,168</u>	<u>53,152</u>
By location of customer:		
UK	15,343	21,327
Europe	24,875	18,027
North America	17,195	10,289
Rest of the world	4,755	3,509
	<u>62,168</u>	<u>53,152</u>
By location of operation:		
Europe	47,525	42,503
North America	14,643	10,649
	<u>62,168</u>	<u>53,152</u>
	Year to 31 December 2004	Year to 31 December 2003
	£ 000	£ 000
<b>(b) Cost of sales</b>		
By class of business:		
Pharmaceuticals		
Contract development and licensing	(10,735)	(12,085)

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Royalties payable	(4,503)	(4,707)
Manufacturing and distribution	(15,916)	(12,994)
	<u>(31,154)</u>	<u>(29,786)</u>

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

2 Segmental analysis (continued)

	Year to	Year to
	31 December	31 December
	2004	2003
	<u>£ 000</u>	<u>£ 000</u>
<b>(c) Loss on ordinary activities before taxation</b>		
By class of business:		
Pharmaceuticals	(24,048)	(42,983)
By location of operation:		
UK	(7,505)	(5,825)
Europe	687	(3,424)
North America		
Operations	(11,856)	(30,270)
Associated undertakings	(10)	
Loss on ordinary activities before interest and taxation	(18,684)	(39,519)
Net interest payable	(5,364)	(3,464)
Loss on ordinary activities before taxation	<u>(24,048)</u>	<u>(42,983)</u>

### 3 Other operating income

The Group entered into two transactions with Paul Capital Royalty Acquisition Fund in 2000 and 2002. Under the first of these transactions Paul Capital provided a total of \$30 million between

2000 and 2002, in return for the sale of a portion of the potential future royalty and revenue streams from DepoDur, Xatral® OD, Solaraze® and DepoCyt®. No income was recognised under this agreement during 2004 (2003: £1.1 million) since all of the income had been recognised as at 31 December 2003. Royalty payments to Paul Capital of £1.3 million (2003: £1.0 million) have been expensed during the year.

Under the second transaction Paul Capital provided a further \$30 million during 2002 and 2003, in return for the sale of a portion of the potential future royalty and revenue streams from nine products from the Group's drug pipeline. Income of £1.2 million (2003: £5.0 million) was recognised as Other operating income under this agreement on a cost to complete basis. Royalty payments to Paul Capital of £1.7 million (2003: £2.2 million) have been expensed during the year.

### NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

### 4 Exceptional items

Exceptional items are categorised as follow:

	Year to 31 December 2004	Year to 31 December 2003
	£ 000	£ 000
Operating exceptional items:		
Restructuring costs	(1,208)	(2,673)
Provision for diminution in value of fixed asset investments	(3,503)	(1,599)
Impairment of intellectual property		(2,673)
Impairment of tangible fixed assets		(1,324)
Settlement of licensing dispute		(1,218)
	<u>(4,711)</u>	<u>(9,487)</u>
Non operating exceptional items:		
Profit on disposal of investment	2,021	
Write off unamortised issue costs on exchange of convertible bonds	(338)	
	<u>(3,028)</u>	<u>(9,487)</u>

Exceptional items include £1.2 million relating to the reorganisation of some research and development operations and other business functions commenced during 2003. The reorganisation is expected to be completed during 2005. A charge of £3.5 million was recorded for a provision for

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diminution in value of fixed asset investments (note 7; Fixed asset investments). In addition, £2.0 million relates to the profit on disposal of the Group's investment in Transition Therapeutics (note 7; Fixed asset investments). A further £0.3 million relates to the write off of unamortised issue costs on the 2005 convertible bonds on exchange for 2024 bonds (note 8; Convertible bonds). The exceptional items do not give rise to a taxation charge or credit.

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

5 Loss per Ordinary Share

	Year to 31 December 2004	Year to 31 December 2003
	£ 000	£ 000
Attributable loss before exceptional items and amortisation	(14,948)	(27,067)
Exceptional items	(3,028)	(9,487)
Amortisation	(6,320)	(6,669)
	<u>(24,296)</u>	<u>(43,223)</u>
	<b>000</b>	<b>000</b>
Basic and diluted weighted average number of shares in issue	<u>615,203</u>	<u>609,855</u>
Loss per Ordinary Share before exceptional items and amortisation	(2.4p)	(4.4p)
Exceptional items	(0.5p)	(1.6p)
Amortisation	(1.0p)	(1.1p)
	<u>(3.9p)</u>	<u>(7.1p)</u>



There is no difference between basic and diluted loss per Ordinary Share since in a loss making year all potential Ordinary 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 Intangible fixed assets

	<u>Goodwill</u>	<u>Intellectual property</u>	<u>Development costs</u>	<u>Total</u>
	£ 000	£ 000	£ 000	£ 000
<b>Cost</b>				
At 1 January 2004	82,730	36,127	1,712	120,569
Exchange adjustments		(89)	(19)	(108)
Additions		2,928		2,928
	<u>82,730</u>	<u>38,966</u>	<u>1,693</u>	<u>123,389</u>
<b>Amortisation</b>				
At 1 January 2004	14,025	10,436	1,012	25,473
Exchange adjustments		109	(26)	83
Charge for the year	4,136	1,980	198	6,314
	<u>18,161</u>	<u>12,525</u>	<u>1,184</u>	<u>31,870</u>
Net book value at 31 December 2003	<u>68,705</u>	<u>25,691</u>	<u>700</u>	<u>95,096</u>
Net book value at 31 December 2004	<u>64,569</u>	<u>26,441</u>	<u>509</u>	<u>91,519</u>

Intellectual property includes £1.2 million following a restructuring of the arrangements with RDF existing at the time of the DepoTech acquisition in 1999.

## NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

## 7 Fixed asset investments

	<u>Investments in associates</u>	<u>Unlisted investments</u>	<u>Total</u>
	£ 000	£ 000	£ 000
<b>Cost</b>			
At 1 January 2004 (as restated)		22,024	22,024
Reclassification of associate	14,217	(14,217)	
Additions	125	2,103	2,228
Disposals		(629)	(629)
Share of loss in associate and amortisation of associate goodwill	(16)		(16)
Provision for diminution in value (note 4)		(3,503)	(3,503)

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At 31 December 2004	14,326	5,778	20,104
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Shares held by the ESOP trust have been reclassified from fixed asset investments in own shares to reserves in accordance with UITF 38. The restatement has resulted in a reduction of the opening balance of £1,395,000.

### Associates

#### Astralis Limited

Astralis Limited is an emerging biotechnology company based and incorporated in the US, and engaged primarily in the research and development of novel treatments for immune system disorders and skin diseases. The company is currently developing two products. Its primary product, Psoraxine, is an innovative vaccine under development for the treatment of psoriasis. The company's second product is for the treatment of leishmaniasis.

In January 2004 SkyePharma converted all of its 2 million series A convertible preferred shares into 25 million common shares, 12.5 million of these being held in escrow. The resulting holding represented approximately 35.7% of the common shares. The investment was not regarded as an associated undertaking as the Directors concluded that the Group did not exert significant influence.

In December 2004 SkyePharma signed conditional stock purchase and assignment agreements with two former Astralis Directors to acquire 11,160,000 common shares and appoint a further two Directors representing SkyePharma to the Astralis Board. The Group also acquired 33,900 common shares of Astralis for approximately £12,000. As at 31 December 2004 the total SkyePharma holding was 25,233,900 common shares and 20,000 warrants, representing approximately 34.5% of the common shares. As a result of these events the investment has been treated as an associated undertaking from December 2004. Goodwill of £13.7 million arose on the acquisition as shown in note 9; Acquisitions. SkyePharma's share of the loss of Astralis for the period was £10,000 and the amortisation of the associate goodwill was £6,000.

In March 2005 Astralis announced that the phase II study of its product Psoraxine did not meet the primary study endpoint upon completion of the treatment phase of the study. The Company is currently working with Astralis to investigate and resolve the possible reasons for the result. Pending the outcome of these investigations the Directors have no basis to believe that the underlying value of the business has been affected.

In March 2005 SkyePharma acquired the 11,160,000 common shares from two former Astralis Directors.

#### **Unlisted investments**

##### **Micap plc**

Micap plc is a UK science-based technology company traded on the Alternative Investment Market. As at 31 December 2004 the total SkyePharma holding was 5,238,334 ordinary shares and 1,830,000 convertible shares, representing approximately 18.2% of the ordinary share capital. The ordinary shares and convertible shares are recorded at a cost of £2.1 million.

#### **NOTES TO THE PRELIMINARY ANNOUNCEMENT continued**

##### **7 Fixed asset investments (continued)**

##### **Transition Therapeutics Inc**

In May 2004 SkyePharma disposed of its investment in Transition Therapeutics for £2.6 million, resulting in a profit on disposal of £2.0 million (note 4; Exceptional items).

##### **Vectura Group plc**

Vectura is a UK emerging pharmaceutical company traded on the Alternative Investment Market from July 2004. Vectura is developing a range of inhaled drugs for the treatment of lung diseases and conditions where delivery via the lungs can provide significant benefits, such as rapid onset of action, improved efficacy and improved tolerability compared with current therapies.

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During the year the Group acquired 3.2 million ordinary shares, representing approximately 4.0% of the ordinary share capital. The ordinary shares are recorded at a cost of £2.0 million.

### **Vital Living Inc**

Vital Living primarily develops and markets evidence-based nutraceuticals. These are developed for incorporation by physicians into a standard physician/patient program, supported by a specially designed compliance regimen. Vital Living is based in the US.

During the year the Group received 687,629 Vital Living common shares with a value of £42,000 (\$80,000) in lieu of interest due on the 12% senior secured convertible notes. The shares do not represent qualifying consideration and have therefore been recorded in the statement of total recognised gains and losses. As at 31 December 2004 the total SkyePharma holding was 14,892,177 common shares, 1 million series D convertible preferred shares, \$1 million 12% senior secured convertible notes due 2008 and 1 million warrants expiring 2008, representing approximately 18.8% of the common shares. A provision for diminution in value of £3.5 million has been made such that the investment was recorded at £1.7 million as at 31 December 2004 based on the year end share price.

## **Cade Struktur Corp**

Cade Struktur was formerly a drug delivery company engaged in research and development and worldwide commercialisation of pharmaceutical formulations. The current business is the development, financing and completion of industrial and infrastructure projects in Europe.

As at 31 December 2004, the total SkyePharma holding of Cade Struktur, a Canadian company, was 869,086 shares, representing approximately 10.1% of the ordinary share capital. The shares were originally acquired consequent upon the acquisition of the assets of Hyal Pharmaceutical Corp. SkyePharma has not attributed a value to these shares and they have been recorded at zero cost.

## **NOTES TO THE PRELIMINARY ANNOUNCEMENT continued**

### **8 Convertible bonds**

In 2000, the Company issued £59.4 million 6% convertible bonds due June 2005. The bonds are convertible at the option of the holder into Ordinary Shares at a conversion price of 83 pence.

In April 2004, the Group issued £20 million 6% convertible bonds, with a first right of conversion after five years by the holder of the bonds, and a final maturity of May 2024. The bonds are convertible at the option of the holder into Ordinary Shares at a conversion price of £1.00.

In July 2004 the Group exchanged £49.6 million of the convertible bonds due 2005 for bonds due 2024 in the same amount, leaving £9.8 million 2005 bonds outstanding. No gain or loss arose on the exchange, however unamortised issue costs of £0.3 million were written off (note 4; Exceptional items). In September 2004 the £49.6 million 2024 convertible bonds were consolidated to form a single series with the £20 million 2024 bonds issued in May 2004.

As a result of these transactions there are £69.6 million convertible bonds due May 2024 issued by SkyePharma (Jersey) Limited and £9.8 million convertible bonds due June 2005 issued by the Company outstanding as at 31 December 2004.

## **NOTES TO THE PRELIMINARY ANNOUNCEMENT continued**

### **9 Acquisitions**

#### **Astralis Limited**

On 29 December 2004 SkyePharma signed conditional stock purchase and assignment agreements with two former Astralis Directors to acquire 11,160,000 common shares and appoint a further two Directors representing SkyePharma to the Astralis Board. As at 29 December 2004 the

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total SkyePharma holding was 25,233,900 common shares and 20,000 warrants, representing approximately 34.5% of the common shares. The investment has been treated as an associated undertaking from 29 December 2004. As of 29 December 2004 SkyePharma began to exert significant influence and therefore the equity method of accounting has been adopted from that date. Goodwill of £13.7 million arose on the acquisition. By consideration of the likely commercial life of the Astralis technology, the Directors have determined that a suitable period over which to amortise the goodwill is 20 years. See note 7; Fixed asset investments.

	Book values at 29 December 2004	Accounting policy alignment	Provisional fair values at 29 December 2004
	£ 000	£ 000	£ 000
<b>Fixed assets</b>			
Intangible assets	61		61
Tangible assets	112		112
Investments	14		14
	187		187
<b>Current assets</b>			
Stock	29		29
Debtors	37	521	558
Cash and short-term bank deposits	1,204		1,204
	1,270	521	1,791
<b>Creditors: amounts falling due within one year</b>			
Other creditors	(207)		(207)
	1,063	521	1,584
<b>Net current assets</b>			
	1,250	521	1,771
<b>Capital and reserves</b>			
Share capital	27,138		27,138
Profit and loss account	(25,888)	521	(25,367)
	1,250	521	1,771
<b>Shareholders funds</b>			
	1,250	521	1,771
Consideration			14,342
Share of net assets at fair value (34.5%)			(611)
<b>Goodwill</b>			13,731

The accounting policy alignment to the net assets of Astralis of £521,000 relates to an amount recorded as an expense by Astralis which would have been recorded as a prepayment according to SkyePharma's accounting policies.

During the period 29 to 31 December 2004 SkyePharma's share of the loss of Astralis was £10,000.

The loss of Astralis for the financial year was £10,939,000 (2003: £3,089,000).

#### **NOTES TO THE PRELIMINARY ANNOUNCEMENT continued**

##### **10 Subsequent events**

In April 2005 SkyePharma entered into an amendment agreement with GlaxoSmithKline ( GSK ) in respect of Paxil CR. Under the terms of the amendment agreement, GSK will make a one-time payment of approximately \$10 million. In addition, SkyePharma will also be entitled to an increase in the royalty rate from 3% to 4% on actual net sales of Paxil CR, with effect from 4 March 2005. As GSK has been unable to supply Paxil CR in the US market since 4 March 2005, GSK has also agreed to pay SkyePharma the same level royalty on GSK's budgeted sales of Paxil CR from 4 March 2005 while the product remains off the market, subject to other terms of the agreement. Approximately £5.0 million has been recorded as royalty income in 2004.

#### **SUPPLEMENTARY INFORMATION: INTERNATIONAL FINANCIAL REPORTING STANDARDS**

The 2004 consolidated financial statements have been prepared under UK Generally Accepted Accounting Principles ( UK GAAP ), SkyePharma's historic primary reporting GAAP. From 1 January 2005 SkyePharma is required to prepare its consolidated financial statements under International Financial Reporting Standards ( IFRS ). These standards represent a significant change from UK GAAP. While SkyePharma's first published IFRS financial statements will be its interim results for June 2005, guidance is provided below as to the key differences that the Group expects to arise on the adoption of IFRS. The Group intends to communicate further details of the impact of adopting IFRS on the 2004 results during the first half of 2005.

##### **Assumptions**

The financial impact of the transition to IFRS has been assessed based upon the assumption that all IFRS standards issued by the International Accounting Standards Board ( IASB ) that are effective for 2005 reporting are endorsed by the European Commission. At present, the European Commission has not endorsed all of these standards. Although the IASB has issued all standards that will be compulsory for the year ended 31 December 2005, some new standards may be available for early adoption, changes are still anticipated to others and the interpretation and application of certain recently revised standards is still being debated. Therefore the current position with respect to IFRS may be subject to change.

## Transition Date and Comparative Information

The IASB issued IFRS 1 First time adoption of international financial reporting standards in June 2003. This deals with how companies will have to apply IFRS for the first time. IFRS 1 requires that comparative information be restated for all years that a full set of comparatives is provided. Therefore, the Group's IFRS transition date is 1 January 2004.

## IFRS 1 Exemptions

In general a Group is required to determine its IFRS accounting policies and apply these retrospectively to determine its opening balance sheet, in our case at 1 January 2004, under IFRS at its transition date. However IFRS 1 permits those companies adopting IFRS for the first time to take some exemptions from the full requirements of IFRS in the transition period.

The key IFRS 1 transitional provisions the Group proposes to adopt are outlined below.

### IFRS 3: Business combinations

A first time adopter has the option not to restate most aspects of past business combinations and instead to apply IFRS 3 prospectively from the transition date. It is expected that SkyePharma will elect this option. In this case goodwill would remain largely as under UK GAAP and amortisation would stop at 1 January 2004, SkyePharma's proposed transition date.

### IFRS 2: Share based payments

IFRS 2 applies to unvested equity instruments, such as share options, granted since 7 November 2002 and not vested at 1 January 2005. However under the transitional arrangements of IFRS 1, there is the option to adopt full retrospective application of the standard where companies have previously publicly disclosed the fair value of those equity instruments determined at the measurement date. SkyePharma has previously disclosed those fair values in its US GAAP disclosures and expects to adopt full retrospective application.

### IAS 19: Employee benefits

In accordance with IFRS1, the Group expects to elect to fully recognise all actuarial gains and losses on its pension scheme in France at 1 January 2004, its transition date to IFRS. Subject to the endorsement by the European Union of IAS 19 (revised), ongoing actuarial gains and losses will be recognised in the Statement of Recognised Income and Expenditure.

## SUPPLEMENTARY INFORMATION: INTERNATIONAL FINANCIAL REPORTING STANDARDS continued



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### IAS 32 and IAS 39: Financial Instruments

One of the exemptions available under IFRS1 relaxes the requirement to present comparative information on financial instruments for 2004 in the 2005 financial statements. The Group does not anticipate utilising this exemption, and expects to retrospectively apply IAS 32 ( Financial Instruments: Disclosure and presentation ) and IAS 39 ( Financial Instruments: Recognition and Measurement ) which for many financial instruments will be fair value.

### IAS 21: The Effects of Changes in Foreign Exchange Rates

An exemption offered by IFRS 1 in respect of IAS 21 The Effects of Changes in Foreign Exchange Rates gives the Group the option to reset its cumulative translation differences to zero at 1 January 2004, its date of transition. The Group does not expect to take this exemption, and will continue to include its cumulative translation differences within equity. This is because the information is readily available and will be consistent with its reporting under US GAAP.

### **Key differences**

The key differences that the Group expects to arise on the adoption of IFRS are:

Revenue recognition differences in respect of up front payments

Accounting for the sale of royalty interests to Paul Capital

The inclusion of a fair value charge in respect of outstanding employee share options

The cessation of amortisation of goodwill

Accounting for Convertible Bonds

The capitalisation of certain research and development costs

### ***Revenue Recognition***

Under IFRS SkyePharma will adopt a revenue recognition policy in accordance with IAS 18 which is similar to that applied under US GAAP. Under UK GAAP Skye has generally recognised up front payments immediately in full where there are no material future obligations and the milestones are non-refundable, on the basis that the up front is a payment for past services. Under IFRS generally up front payments will be deferred and amortised on a systematic basis over the period of development to filing. This is similar to the treatment adopted under US GAAP. However, the accounting for each agreement will need to be determined on an individual basis.

### ***Sale of Royalty Interests***

Under IFRS SkyePharma will account for the sale of royalty interests to Paul Capital on a similar basis to that under US GAAP. Under IFRS the proceeds received from Paul Capital meet the definition of a financial liability under IAS 32, and will be treated as debt. No other operating income will be recognised under IFRS, royalties paid to Paul Capital will be treated as repayment of the debt and interest will be charged on the debt. Under UK GAAP the proceeds received from Paul Capital are treated as a sale and recorded as other operating income and royalties are expensed when incurred.

### ***Share Based Payments***

IFRS 2 requires that for share option awards to employees, the fair value of the employee services received should be measured by reference to the fair value of the share option at the grant date. This is significantly different from the current treatment in the UK where the charge to the profit and loss account is based on the difference between the fair value of the shares at the date of grant and the exercise price. Since SkyePharma has historically granted employee options where the share price at the date of grant equals the exercise price, there has been no charge to record. The charge under IFRS will be the same as that previously disclosed under US GAAP standard FAS 123.

### ***Goodwill Amortisation***

UK GAAP requires goodwill to be amortised over its estimated expected useful life which the Directors have determined is 20 years. Under IFRS, goodwill is considered to have an indefinite life and so is not amortised, but is subject to annual impairment testing. Therefore the annual

goodwill charge made under UK GAAP will not be recorded under IFRS from 1 January 2004, the IFRS transition date.

**SUPPLEMENTARY INFORMATION: INTERNATIONAL FINANCIAL REPORTING STANDARDS continued**

***Convertible Bond***

Under UK GAAP the net proceeds of the convertible bond issue were recorded as debt. Under IFRS the convertible bonds will be bifurcated and the conversion option deducted from the debt and classified as equity. This will lead to higher interest charges under IFRS than under UK GAAP. Furthermore the Group is likely to record a one off gain or loss on the exchange of the 2005 bonds for the 2024 bonds. No such gain or loss arises under UK GAAP.

***Research and Development***

Under IFRS the Group is required to capitalise research and development when the criteria as laid out in IAS 38 are met. The Group has reviewed its current projects and determined that the capitalisation of certain expenditure may be appropriate. Future projects may lead to the capitalisation of further expenditure.

**About SkyePharma**

SkyePharma PLC uses its world-leading drug delivery technology to develop easier-to-use and more effective formulations of drugs. The majority of challenges faced in the formulation and delivery of drugs can be addressed by one of the Company's proprietary technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit <http://www.skyepharma.com>.

*Except for the historical information herein, the matters discussed in this news release include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. These include without limitation risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for its products, other regulatory risks, risks relating to SkyePharma's ability to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning SkyePharma's ability to manage growth, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization and maintain or expand sales and market share for its products, risks relating to the ability to ensure regulatory compliance, risks related to the research, development and regulatory approval of new pharmaceutical products, risks related to research and development costs and capabilities, market acceptance of and continuing demand for SkyePharma's products and the impact of increased competition, risks associated with anticipated top and bottom line growth and the possibility that upside potential will not be achieved, competitive products and pricing, and risks associated with the ownership and use of intellectual property rights. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.*

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