

SKYEPHARMA PLC  
Form 6-K  
September 15, 2004

**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 September, 2004

**SkyePharma PLC**

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(Translation of registrant's name into English)

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

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(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.

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Yes  No

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

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**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: September 15, 2004

**SkyePharma PLC**

**Interim Financial Results**

**for the six months ended 30 June 2004**

**Financial Highlights**

Turnover up by 26% to £28.5 million (2003:£22.6 million)

Royalty income up by 28% to £10.3 million (2003: £8.0 million)

Gross profit up by 52% to £15.0 million (2003: £9.9 million)

R&D down 13% to £14.4 million (2003: £16.4 million)

Operating loss after exceptionals down by 44% to £9.6 million (2003: £17.0 million)

Deferred income up by £1.0 million to £16.9 million (as of 31 December 2003: £15.9 million)

Net loss after exceptionals down by 45% to £10.2 million (2003: £18.7 million)

Loss per share 1.7p (2003: 3.1p)

Net cash £29.0 million (as of 31 December 2003: £22.0 million)

Convertible bond refinancing completed, including raising £20 million of new money

**Operating Highlights**

FDA approves DepoDur - US marketing to commence before end-year

DepoDur licensed to Medeus Pharma for Europe

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Trigenesis licenses dermatology products, pipeline and topical delivery technologies

Discussions with potential partners for pulmonary package ongoing

Foradil® Certihaler® approved in Switzerland and certain other European countries

Paxil® CR (GlaxoSmithKline) holds US market share despite generic competition for Paxil®

Uroxatral® (Sanofi-Aventis) launched to primary care physicians in USA

Xatral OD approved in Europe for second indication, Acute Urinary Retention

DepoCyt® (Mundipharma) launched in Europe

DepoCyt® Phase IV trial patient enrolment completed

Pulmicort® HFA (AstraZeneca) completes Phase III trials

Requip OD (GlaxoSmithKline) Phase III trial patient enrolment completed

FDA completes review of Phase II trials of Propofol IDD-D

Ian Gowrie-Smith, SkyePharma's Non-Executive Chairman, said: The most important event in the first half of 2004 was the US Food & Drug Administration's approval of DepoDur (the new name for DepoMorphine) on 18 May. After taking the decision in 2001 to undertake full clinical development ourselves and completing the clinical studies and regulatory filings for DepoDur on time, it is highly gratifying to see this crowned by approval by the FDA. Importantly this was the first possible date on which the product could be approved. Few new drugs are approved by the FDA at the first opportunity so this achievement is a real tribute to both the quality of the product and the skill of our clinical and regulatory teams. DepoDur is the first product for which we have undertaken full development ourselves and we expect it to be a major contributor to the company's future.

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

#### **SkyePharma PLC**

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**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, SkyePharma's marketing partners' ability to market a pharmaceutical product on a large scale and manage their sales and marketing organisation 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.*

## **CHAIRMAN'S STATEMENT**

The most important event in the first half of 2004 was the US Food & Drug Administration's approval of DepoDur (the new name for DepoMorphine) on 18 May. After taking the decision in 2001 to undertake full clinical development ourselves and completing the clinical studies and regulatory filings for DepoDur on time, it is highly gratifying to see this crowned by approval by the FDA. Importantly this was the first possible date on which the product could be approved. Few new drugs are approved by the FDA at the first opportunity so this achievement is a real tribute to both the quality of the product and the skill of our clinical and regulatory teams. DepoDur is the first product for which we have undertaken full development ourselves and we expect it to be a major contributor to the company's future.

Apart from the exciting news about DepoDur, I am also pleased to report that Foradil® Certihaler® has received its first approvals in Europe. Following the FDA's approvable letter issued in October last year, a response has been filed. Our royalty income continues to grow rapidly, driven by continuing progress by Paxil CR and Xatral® OD/Uroxatral®. Our new partner Mundipharma launched DepoCyte® in Europe and US sales of Solaraze® are expected to benefit from an expanded sales force following the recent acquisition of Quintiles' Bioglan unit by Bradley Pharmaceuticals. In our pipeline, the HFA-MDI version of Pulmicort® we are developing for AstraZeneca has now completed its Phase III trials.

We have also completed some important new agreements. We appointed Medeus Pharma as our European licensee for DepoDur, on excellent terms, and also licensed to First Horizon a cardiovascular product currently under review by the FDA. Approval this year would bring us a substantial milestone payment and a very attractive royalty rate. We entered a collaboration with Critical Therapeutics to develop a controlled release version of zileuton for asthma. This is a near-term opportunity, with filing expected in 2005. We also licensed our entire dermatology portfolio to Trigenesis Therapeutics following a strategic review that concluded that we could obtain a greater return from this technology if we licensed the portfolio to a company focused in this therapeutic area.

For our package of pulmonary products, we are seeking to appoint a partner with proven marketing ability in the respiratory field. We have a short-list of partners (including our preferred candidate) who are completing their enquiries in this complex area. Although this has taken longer than we had hoped, potential partners have required very extensive due diligence investigations to satisfy themselves fully before committing to the project given the development cost and timescale involved. We remain confident of completing a satisfactory agreement.

Our revenues in the first half were 26% above the 2003 level even though, as in previous years, we expect the majority of our revenues to arise in the second half of the year. However I must point out that whether we make a profit for the second half, and for the year as a whole, will depend on the structure and timing of the signature of the above pulmonary deal and the timing of FDA approval of the cardiovascular pipeline product.

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Finally we are pleased to report that we have recently completed an exchange offer for our 2005 convertible bonds. Over 80% of holders accepted the offer to exchange their bonds for new bonds with a higher conversion price of £1.00 and first conversion in 2009. The remaining £10 million of 2005 bonds will either be redeemed next year or converted into ordinary shares. We also raised £20 million of new money in May, also at a conversion price of £1.00. These successful issues demonstrate belief in the value of Skyepharm and greatly enhance our financial flexibility.

**Ian Gowrie-Smith**

**Non-executive Chairman**

## **REVIEW OF OPERATIONS**

This has been a busy period for SkyePharma. The most important event was the exciting news of the FDA approval of DepoDur in May. We have also made encouraging progress with our other near-term pipeline products and announced a number of important new agreements. We are still in late-stage discussions with several parties wishing to license our package of pulmonary products, including our preferred partner, and remain confident of achieving a satisfactory agreement. Our total revenues increased by some 26% over the first half of the previous year and more importantly our royalty income has continued to grow rapidly, continuing the trend of the past few years.

### **Products on the market**

Paxil® CR, our improved formulation of GlaxoSmithKline's Paxil®, was launched in the USA in April 2002 and currently holds just under 8% of all new US prescriptions for SSRI antidepressants. This share has been largely unaffected by the onset of US generic competition for the older version Paxil®, which started in September last year. GlaxoSmithKline's total sales of Paxil® CR were £196 million (\$356 million) in the first half of 2004, up by 29% in constant exchange rate terms. As disclosed in the 2003 Annual Report, SkyePharma is in discussions with GlaxoSmithKline over the rate of the royalty we receive on sales of Paxil® CR.

Xatral® OD (Uroxatral® in the USA), our once-daily version of Sanofi-Aventis's Xatral® (alfuzosin), is a treatment for the urinary symptoms of benign prostatic hypertrophy. Xatral® OD has been on the market outside the USA since April 2000 and has now largely replaced the older multidose versions of Xatral®. Uroxatral® was launched in the USA in November 2003 and has already captured just under 10% of the combined new prescriptions written for it and for its main competitor, an encouraging start. Xatral® OD has now been approved in Europe for a second indication, acute urinary retention, with Phase III trials ongoing for the USA. Sales of all forms of Xatral® were £138 million in the first half of 2004, up by 35% in constant exchange rate terms. This included US sales of Uroxatral® of £14 million.

Our European partner Mundipharma launched DepoCyt® (known as DepoCyt® in the USA) in February at an oncology meeting in Barcelona and has had an encouraging initial response. Mundipharma shares our view that the market for DepoCyt® is largely under-developed. We have now completed enrolment in the Phase IV trial that will be used to support a filing for a more common form of neoplastic meningitis, associated with solid tumours.

Solaraze®, 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 will more than double the number of sales representatives detailing Solaraze®. The transfer of rights to market Solaraze® from Quintiles to Bradley required our consent and in August we received a \$5 million payment from Quintiles as part of this transaction. Solaraze® is marketed in Europe and certain other territories by Shire Pharmaceuticals. In Australia we have recently completed a clinical trial of patients with multiple actinic keratoses. This will be used as the pivotal trial for submission to the Australian regulatory authorities.

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



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On 18 May, we received the exciting news that the US FDA had formally approved DepoDur, our new injectable analgesic for the treatment of pain after surgery. DepoDur is the first product that we decided to develop ourselves. The recent FDA approval validates that decision and also bodes well for approval in Europe. Having now completed licensing deals in North America and Europe on excellent terms, we expect DepoDur to be a major contributor to the company's future.

In DepoDur we have used our DepoFoam sustained-release delivery technology to improve morphine for relief of post-surgical pain. Given as a single epidural injection before or during surgery, DepoDur provides highly effective pain relief for the following 48 hours – normally the period of peak post-operative pain. Our clinical trials, involving more than 1000 patients, convincingly demonstrated the potential of DepoDur to improve the treatment of pain after major surgery. There is widespread recognition that pain relief is an under-served market and current approaches to control of post-operative pain leave much to be desired.

We now look forward to the US launch of DepoDur by our partner Endo Pharmaceuticals later this year. We are now in the process of supplying full launch quantities to Endo, which will satisfy the conditions for receipt of a milestone payment due to us on US approval. DepoDur was filed with the UK regulatory authorities in November 2003 and on normal regulatory review timelines we would expect approval by the end of the year. This will be used as the basis for approval throughout European Union using the EU's mutual recognition procedure. Our new European partner Medeus Pharma (appointed in April) is eagerly awaiting approval of DepoDur to commence marketing.

Foradil® Certihaler® is a new version of Novartis' long-acting bronchodilator Foradil® (formoterol). We developed not only the multi-dose dry-powder inhaler device but also the formulation used in it that ensures 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® Certihaler® with the FDA and European regulatory authorities in December 2002. The FDA issued an approvable letter in October 2003 and Novartis has filed a response. In March this year the product received its first European approval, in Switzerland, and it has since been approved in several other countries. Novartis is responsible for marketing Foradil® Certihaler® outside the USA. The US Foradil® franchise has been licensed to Schering-Plough Corporation.

We have now completed the enrolment of patients for the Phase III trial of our once daily version of the Parkinson's drug Requip® which we are conducting for our partner GlaxoSmithKline. This is on track for the target filing planned for next year.

We are developing several other asthma drugs in metered-dose inhalers (MDIs) powered by a hydrofluoroalkane (HFA) propellant gas. We have now completed the Phase III trial of an HFA-MDI version of AstraZeneca's inhaled steroid Pulmicort® (budesonide). We expect AstraZeneca to file this for approval in the first country in Europe around the end of the year. We will receive double digit royalties on sales of Pulmicort® HFA-MDI. Our own HFA-MDI version of formoterol will commence Phase III trials around the end of this year and our fixed-dose combination product Flutiform (combining formoterol with the inhaled steroid fluticasone) will also start its Phase II trial in the autumn.

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 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**

Apart from the European licence for DepoDur with Medeus referred to above, we have also licensed a cardiovascular product in the US to First Horizon Pharmaceutical Corporation. This oral product is currently under review by the FDA. We will receive up to \$50 million in milestone payments, of which up to \$20 million is dependent on the timing and conditions of FDA approval, anticipated by the end of this year. We will also receive 25% of First Horizon's net sales of this product in the form of royalty income and manufacturing revenues.

In January we announced a collaboration with Critical Therapeutics to develop zileuton for asthma and COPD. We had developed a twice-daily version for Abbott Laboratories which completed Phase III development for asthma but has not been filed. Critical Therapeutics has now licensed zileuton from Abbott. We expect the controlled release product to be filed with the FDA by the end of next 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 outlicensing this technology portfolio to a

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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. Trigenesis is now part of the fast-growing Indian pharmaceutical company, Dr Reddy s Laboratories.

In June we agreed a strategic alliance with the UK company Vectura for pulmonary delivery technologies. We have obtained certain rights to Vectura's Aspira<sup>®</sup> dry-powder inhaler, which is particularly suitable for the delivery of macromolecules. We invested £2 million for a 4% equity stake in Vectura. Vectura has recently completed an initial public offering on the AIM market.

Finally King Pharmaceuticals (in the process of being acquired by Mylan Laboratories, a leading US generic company) has informed us that it wishes to terminate the agreement signed in May 2003 to develop a modified-release formulation of Altace<sup>®</sup> (ramipril). This product was in an early stage of development.

### **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 make milestone payments more tied to product revenue targets. Inevitably this will bring a short-term penalty in terms of revenues and cashflow but we are confident that this is the correct approach, which will greatly enhance the value of our products to the company.

**Michael Ashton**

**Chief Executive**

## **FINANCIAL REVIEW**

### **Turnover**

Revenues for the half year were 26% higher at £28.5 million compared with £22.6 million in the same period in 2003. This is primarily due to an increase in milestone payments as well as higher royalty income. This does not include milestone payments of £5.5 million received in the first half from Endo and First Horizon which have been fully deferred. Revenues have increased by a cumulative annual growth rate of 38% since 1996.

Contract development and licensing revenues increased 26% to £14.4 million for the period (H1 2003: £11.4 million). Revenues recognised from milestone payments and payments received on the signing of agreements in the period amounted to £11.5 million and included revenues from Medeus for the European marketing and distribution rights for DepoDur and Trigenesis for the rights to certain dermatological assets. In addition, £3.5 million of revenue was recognised from GlaxoSmithKline on the phase III clinical trials of Requip<sup>®</sup> (ropinirole); AstraZeneca on the phase III clinical trials of Budesonide HFA and Novartis on the first European approval of Foradil<sup>®</sup> Certihaler<sup>®</sup> and the phase II clinical trials of QAB 149.

Royalty income, principally from Paxil CR, Xatral<sup>®</sup> OD, DepoCyt<sup>®</sup> and Solaraze<sup>®</sup>, increased by 28% to £10.3 million compared with the first half of 2003.

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Manufacturing and distribution revenues increased by 22% to £3.8 million for the period mainly due to higher production of the Foradil® Certihaler® for Novartis, compared with £3.2 million in H1 2003.

### Deferred income

During the period, a further net £1.0 million of turnover and other income was deferred under SkyePharma's revenue recognition policy. Amounts received included the milestones from Endo and First Horizon noted above which have been fully deferred. Total deferred income of £16.9 million as at 30 June 2004 comprised:

	31 December 2003 £ million	Received * £ million	Recognised £ million	30 June 2004 £ million
Contract development and licensing revenue	7.1	16.7	(14.4)	9.4
Other operating income	8.8	(0.3)	(1.0)	7.5
	15.9	16.4	(15.4)	16.9

\* Includes exchange adjustments

Deferred income will be released in subsequent periods as the related costs are incurred or as any associated obligations under the relevant contracts are satisfied.

### 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 6% to £13.5 million in the first six months of 2004 (H1 2003: £12.7 million). This was mainly due to an increase of £0.6 million in royalty expenses due under our agreement with Paul Capital. The resulting gross profit increased 52% to £15.0 million compared with £9.9 million in the first half of 2003.

### Expenses

Selling, marketing and distribution expenses decreased to £1.1 million (H1 2003: £2.5 million), reflecting the significant savings resulting from the Group reorganisation announced last year.

Amortisation of intangible assets decreased slightly by £0.1 million to £3.1 million. Other administration expenses before exceptionals fell to £6.5 million in the first half, compared with £7.5 million in H1 2003. This reduction is mainly due to the release of a portion of a provision held against the Group's investment in GeneMedix plc, as well as the prior year expense of reacquiring the DepoCyt® European rights from Elan. The exceptional charge of £0.5 million relates to the continuing reorganisation of some research and development operations and other business functions which commenced during 2003. No further significant reorganisation expenses are anticipated, and the reorganisation is expected to be completed during 2004.

SkyePharma's own research and development expenses in the period decreased by £2.1 million to £14.4 million mainly due to a reduction in expenditure on DepoDur when compared with the significant expenditure incurred in the prior period in preparation for its July 2003 filing with the FDA.

### Other operating income

Under the Paul Capital agreements, other operating income recognised in the first half was £1.0 million (H1 2003: £4.2 million). All of the income under the first Paul Capital agreement has now been recognised, and there is £7.5 million of deferred income under the second Paul Capital agreement as at June 2004. Royalty payments to Paul Capital of £1.9 million (H1 2003: £1.3 million) were expensed during the period.

### Operating results

The increase in revenue mentioned above is the most significant factor contributing to the Group's 44% reduction in operating loss after exceptionals to £9.6 million (H1 2003: £17.0 million) in the first six months of 2004. The reduction in operating loss before exceptionals amounted to 52%. Other factors, including the decrease in the Group's own research and development of £2.1 million also contributed to the reduced loss. The Group made an exceptional £2.0 million profit on disposal of its entire holding of Transition Therapeutics shares. Similarly, the retained loss for the period decreased by 45% to £10.2 million (H1 2003: £18.7 million), after net interest payable of £2.5 million (H1 2003: £1.6 million). Earnings before interest, tax, depreciation and amortisation (EBITDA), a commonly used indicator, improved by 85% to a loss of £1.6 million in the period (H1 2003: £10.5 million loss).

The loss per share for the period was 1.7 pence, which represents a 45% reduction compared with a loss of 3.1 pence for the same period in 2003.

Foreign currency movements did not have a material impact on the results of operations in 2004 compared with 2003.

**Cash balances and cash flow**

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. This raised approximately £18.9 million net of expenses. The bonds are convertible at the option of the holder into SkyePharma Ordinary Shares at a conversion price of £1.00.

At 30 June 2004 SkyePharma had cash and short-term deposits of £29.9 million and a bank overdraft of £0.9 million, compared with £23.2 million cash and a £1.2 million bank overdraft at 31 December 2003.

There was a net cash outflow from operating activities of £5.1 million for the half year (H1 2003: £7.0 million inflow). During the first half of 2004 purchases of tangible fixed assets were £2.8 million. Purchases of intangible fixed assets of £1.2 million mainly relate to the strategic alliance with Vectura in the area of pulmonary delivery technologies. The proceeds on disposal of the Group's holding of Transition Therapeutics shares were £2.6 million. The resulting cash outflow before financing for the period was £10.4 million (H1 2003: £4.5 million).

**Balance sheet**

The balance sheet at 30 June 2004 shows shareholders' funds of £77.2 million, with cumulative goodwill written off to the profit and loss account reserve of £147.6 million.

In May 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. In addition, the Group settled the £0.5 million Chiron promissory note in June 2004.

In July 2004 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. Accordingly the unamortised issue costs on the exchanged 2005 convertible bonds were written off during the period. 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.

Bank and other non-convertible debt amounted to £11.3 million at 30 June 2004, consisting principally of a £7.2 million property mortgage secured by the assets of Jago. Net debt amounted to £60.4 million (31 December 2003: £49.5 million).

### International Financial Reporting Standards

SkyePharma will be required to prepare consolidated financial statements under International Financial Reporting Standards ( IFRS ) from 1 January 2005 and to restate the 2004 results for comparison.

The transition to IFRS could have a material impact on the Group's financial position and reported results from this date. The Group's project team is managing its conversion to IFRS and is in the process of assessing the potential impact.

**Donald Nicholson**

**Finance Director**

### CONSOLIDATED PROFIT AND LOSS ACCOUNT

for the six months ended 30 June 2004

	Notes	Unaudited 6 months to 30 June 2004 £ 000	Exceptional items and amortisation (note 4) £ 000	Unaudited 6 months to 30 June 2004 £ 000
<b>Turnover</b>	2	28,523		28,523
Cost of sales	2	(13,507)		(13,507)
<b>Gross profit</b>		15,016		15,016
Selling, marketing and distribution expenses		(1,133)		(1,133)
Administration expenses				
Amortisation			(3,072)	(3,072)
Other administration expenses		(6,526)	(537)	(7,063)
		(6,526)	(3,609)	(10,135)
Research and development expenses		(14,362)		(14,362)



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Other operating income	3	<b>1,016</b>		<b>1,016</b>
<b>Operating loss</b>		<b>(5,989)</b>	<b>(3,609)</b>	<b>(9,598)</b>
Profit on disposal of investment			<b>2,021</b>	<b>2,021</b>
<b>Loss on ordinary activities before interest and taxation</b>		<b>(5,989)</b>	<b>(1,588)</b>	<b>(7,577)</b>
Interest receivable		<b>370</b>		<b>370</b>
Interest payable		<b>(2,554)</b>	<b>(338)</b>	<b>(2,892)</b>
<b>Loss on ordinary activities before taxation</b>	2	<b>(8,173)</b>	<b>(1,926)</b>	<b>(10,099)</b>
Taxation		<b>(95)</b>		<b>(95)</b>
<b>Retained loss</b>		<b>(8,268)</b>	<b>(1,926)</b>	<b>(10,194)</b>
<b>Earnings per Ordinary Share</b>	5			
Basic		<b>(1.4p)</b>	<b>(0.3p)</b>	<b>(1.7p)</b>
Diluted		<b>(1.4p)</b>	<b>(0.3p)</b>	<b>(1.7p)</b>

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 Interim Financial Statements

**CONSOLIDATED PROFIT AND LOSS ACCOUNT Continued**

for the six months ended 30 June 2004

	Notes	Unaudited 6 months to 30 June 2003 £ 000	Exceptional items and amortisation £ 000	Unaudited 6 months to 30 June 2003 £ 000
<b>Turnover</b>	2	22,586		22,586
Cost of sales	2	(12,702)		(12,702)
<b>Gross profit</b>		9,884		9,884
Selling, marketing and distribution expenses		(2,518)		(2,518)
Administration expenses				
Amortisation			(3,226)	(3,226)
Other administration expenses		(7,478)	(1,409)	(8,887)
		(7,478)	(4,635)	(12,113)
Research and development expenses		(16,420)		(16,420)
Other operating income	3	4,173		4,173
<b>Operating loss</b>		(12,359)	(4,635)	(16,994)
Profit on disposal of investment				
<b>Loss on ordinary activities before interest and taxation</b>		(12,359)	(4,635)	(16,994)
Interest receivable		512		512
Interest payable		(2,131)		(2,131)
<b>Loss on ordinary activities before taxation</b>	2	(13,978)	(4,635)	(18,613)
Taxation		(76)		(76)
<b>Retained loss</b>		(14,054)	(4,635)	(18,689)
<b>Earnings per Ordinary Share</b>	5			
Basic		(2.3p)	(0.8p)	(3.1p)
Diluted		(2.3p)	(0.8p)	(3.1p)

**CONSOLIDATED PROFIT AND LOSS ACCOUNT continued**

for the six months ended 30 June 2004

	Notes	Audited 12 months to 31 December 2003 £ 000	Exceptional items and amortisation £ 000	Audited 12 months to 31 December 2003 £ 000
Turnover	2	53,152		53,152
Cost of sales	2	(29,786)		(29,786)
<b>Gross profit</b>		23,366		23,366
Selling, marketing and distribution expenses		(4,348)		(4,348)
Administration expenses				
Amortisation			(6,669)	(6,669)
Other administration expenses		(17,987)	(9,487)	(27,474)
		(17,987)	(16,156)	(34,143)
Research and development expenses		(30,520)		(30,520)
Other operating income	3	6,126		6,126
<b>Operating loss</b>		(23,363)	(16,156)	(39,519)
Profit on disposal of investment				

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<b>Loss on ordinary activities before interest and taxation</b>		(23,363)	(16,156)	(39,519)
Interest receivable		1,029		1,029
Interest payable		(4,493)		(4,493)
<b>Loss on ordinary activities before taxation</b>	2	(26,827)	(16,156)	(42,983)
Taxation		(240)		(240)
<b>Retained loss</b>		(27,067)	(16,156)	(43,223)
<b>Earnings per Ordinary Share</b>	5			
Basic		(4.4p)	(2.7p)	(7.1p)
Diluted		(4.4p)	(2.7p)	(7.1p)

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

for the six months ended 30 June 2004

	Unaudited 6 months to 30 June 2004 £ 000	Unaudited 6 months to 30 June 2003 £ 000	Audited 12 months to 31 December 2003 £ 000
<b>Loss attributable to shareholders</b>	(10,194)	(18,689)	(43,223)
Net currency translation effect	75	(37)	(175)
Unrealised gain on contract development	128	1,645	2,029
<b>Total recognised gains and losses for the period</b>	(9,991)	(17,081)	(41,369)

**RECONCILIATION OF MOVEMENTS IN SHAREHOLDERS FUNDS**

for the six months ended 30 June 2004

	Unaudited 6 months to 30 June 2004 £ 000	Unaudited 6 months to 30 June 2003 (restated) £ 000	Audited 12 months to 31 December 2003 (restated) £ 000
<b>Shareholders funds at the beginning of the period as previously stated</b>	84,870	124,270	124,270
Restatement for UITF Abstract 38; Accounting for ESOP trusts		(1,028)	(1,028)
<b>Shareholders funds at the beginning of the period as restated</b>	84,870	123,242	123,242
Total recognised gains and losses for the period	(9,991)	(17,081)	(41,369)
Purchase of own shares for ESOP		(925)	(925)
ESOP credit	271	201	558
Equity shares issued, net of expenses	1,869		2,560
Exercise of share options, net of expenses	181	61	765
Increase in shares and warrants to be issued		2,565	
Issue of warrants			39
Net movement in the period	(7,670)	(15,179)	(38,372)
<b>Shareholders funds at the end of the period</b>	77,200	108,063	84,870

**CONSOLIDATED BALANCE SHEET**

as at 30 June 2004

	Notes	Unaudited 30 June 2004 £ 000	Unaudited 30 June 2003 (restated) £ 000	Audited 31 December 2003 (restated) £ 000
<b>Fixed assets</b>				
Intangible assets	6	94,688	101,572	95,096
Tangible assets		40,349	44,533	42,615
Investments	7	21,563	22,446	22,024
		156,600	168,551	159,735

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<b>Current assets</b>				
Stock		1,372	1,156	1,320
Debtors		16,658	21,973	15,634
Investments		1,625	1,905	981
Cash and short-term bank deposits		29,921	22,181	23,240
		49,576	47,215	41,175
<b>Creditors: amounts falling due within one year</b>				
Convertible bonds due 2005	8	(59,336)		
Deferred income		(12,705)	(17,310)	(12,926)
Other creditors		(20,627)	(18,520)	(26,394)
		(92,668)	(35,830)	(39,320)
<b>Net current (liabilities)/assets</b>				
		(43,092)	11,385	1,855
<b>Total assets less current liabilities</b>				
		113,508	179,936	161,590
<b>Creditors: amounts falling due after more than one year</b>				
Convertible bonds due 2005	8		(58,584)	(58,791)
Convertible bonds due 2024	8	(18,874)		
Deferred income		(4,164)	(1,843)	(2,948)
Other creditors		(11,917)	(10,840)	(12,860)
		(34,955)	(71,267)	(74,599)
<b>Provisions for liabilities and charges</b>				
	11	(1,353)	(606)	(2,121)
<b>Net assets</b>				
		77,200	108,063	84,870
<b>Capital and reserves</b>				
Share capital	12	63,424	62,559	63,067
Share premium		320,916	316,467	319,223
Shares and warrants to be issued			2,565	
Other reserves		9,350	9,311	9,350
Profit and loss account		(316,490)	(282,839)	(306,770)
<b>Shareholders funds</b>				
Attributable to equity interests		65,890	96,753	73,560
Attributable to non-equity interests		11,310	11,310	11,310
		77,200	108,063	84,870

See Notes to the Interim Financial Statements

**CONSOLIDATED CASH FLOW STATEMENT**

for the six months ended 30 June 2004

	Notes	Unaudited 6 months to 30 June 2004 £ 000	Unaudited 6 months to 30 June 2003 (restated) £ 000	Audited 12 months to 31 December 2003 (restated) £ 000
<b>Net cash (outflow)/inflow from operating activities</b>	9	(5,084)	6,975	6,615
<b>Returns on investments and servicing of finance</b>				
Interest received		316	473	1,047
Interest paid		(4,107)	(3,752)	(4,013)
Interest element of finance lease payments		(5)	(15)	(70)
		(3,796)	(3,294)	(3,036)
<b>Taxation</b>		(95)	(5)	(227)
<b>Capital expenditure and financial investment</b>				
Purchase of intangible fixed assets		(1,168)	(2,239)	(2,530)
Purchase of tangible fixed assets		(2,760)	(2,385)	(4,021)
Purchase of fixed asset investments		(168)	(3,573)	(4,749)
Disposal of fixed asset investments		2,650		
		(1,446)	(8,197)	(11,300)
Cash outflow before use of liquid resources and financing		(10,421)	(4,521)	(7,948)
<b>Management of liquid resources</b>				
Net (increase)/decrease in amounts held on short-term bank deposit		(598)	1,734	183
<b>Financing</b>				
Issue of Ordinary Share capital		181	61	1,437
Issue of 2024 convertible bonds		20,000		
Expenses of convertible bonds issue		(1,135)		
Issue of warrants			672	39
Purchase of own shares			(925)	(925)
Debt due within one year:				
Inception of new loan				770
Repayment of Chiron promissory note		(549)		
Debt due beyond one year:				
Inception of new loan				1,936
Repayment of loans		(592)	(137)	(286)
Capital element of finance lease payments		(176)	(550)	(1,078)
		17,729	(879)	1,893
<b>Increase/(decrease) in cash</b>	10	6,710	(3,666)	(5,872)

See Notes to the Interim Financial Statements

## NOTES TO THE INTERIM FINANCIAL STATEMENTS

for the six months ended 30 June 2004

### 1 Accounting policies and the basis of preparation

The interim financial statements have been prepared using accounting policies consistent with those adopted by the Group in its financial statements for the year ended 31 December 2003 except as noted below.

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 interim report is unaudited and does not constitute statutory financial statements within the meaning of section 240 of the Companies Act 1985. The results for the period to 30 June 2004 have been formally reviewed and reported upon by the auditors on page 21 to this report. The figures for the year ended 31 December 2003 are an extract from the audited financial statements for that period which have been delivered to the Registrar of Companies and on which the auditors have issued an unqualified report which contained no statement therein under section 237(2) or section 237(3) of the Companies Act 1985.

### Consolidation

The consolidated financial information includes the financial statements for the Company and its subsidiary undertakings. Intra-group sales and profits are eliminated fully on consolidation. The results of subsidiaries sold or acquired are included in the consolidated profit and loss account up to the date of their sale or from their date of acquisition respectively.

### Revenue recognition

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, when they are recognised as income. Manufacturing and distribution revenues principally comprise contract manufacturing fees invoiced to third parties and income from product sales.

### Research and development costs

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

**Intangible fixed assets**

Intangible fixed assets comprise goodwill, intellectual property and capitalised development costs. Goodwill, being the difference between the fair value of the purchase consideration and the Group's share of the fair value of the net assets acquired, is capitalised and amortised over a period of 20 years or less in line with the Directors' view of its useful economic life. Prior to the introduction of FRS 10; Goodwill and intangible assets, the policy adopted was to write off goodwill to reserves. As permitted by FRS 10 goodwill written off to reserves in previous years has not been reinstated on the balance sheet and adjustments to such goodwill have been taken directly to reserves. Goodwill previously written off to reserves is charged to the profit and loss account in the event of disposal of the related business.

Intellectual property comprises acquired patents, trade marks, know-how and other similarly identified rights. These are recorded at their fair value at acquisition date and are amortised in equal instalments over their estimated useful economic lives, from the date when the transfer of technology is complete. The period over which the Group expects to derive economic benefits does not exceed 20 years. Costs associated with internally developed intellectual property are generally treated as research and development costs.



**Fixed asset investments**

Investments that are held for continuing use in the business are classified as fixed asset investments and recorded in the balance sheet at cost or Directors' valuation, less provision for permanent diminution in 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.

**2 Segmental analysis**

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

	Unaudited 6 months to 30 June 2004 £ 000	Unaudited 6 months to 30 June 2003 £ 000	Audited 12 months to 31 December 2003 £ 000
<b>(a) Turnover</b>			
<b>By class of business:</b>			
Pharmaceuticals			
Contract development and licensing			
Milestone payments	11,511	8,581	24,196
Research and development costs recharged	2,889	2,793	5,456
	14,400	11,374	29,652
Royalties receivable	10,271	8,027	18,701
Manufacturing and distribution	3,852	3,185	4,799
	28,523	22,586	53,152
<b>By location of customer:</b>			
North America	6,129	4,618	10,289
UK	8,489	7,103	21,327
Europe	12,276	8,222	18,027
Rest of the world	1,629	2,643	3,509
	28,523	22,586	53,152
<b>By location of operation:</b>			

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Europe	24,737	19,019	42,503
North America	3,786	3,567	10,649
	28,523	22,586	53,152
<b>(b) Cost of sales</b>			
<b>By class of business:</b>			
Pharmaceuticals			
Contract development and licensing	(4,529)	(4,076)	(12,085)
Royalties payable	(2,452)	(1,737)	(4,707)
Manufacturing and distribution	(6,526)	(6,889)	(12,994)
	(13,507)	(12,702)	(29,786)
<b>(c) Loss on ordinary activities before taxation</b>			
<b>By class of business:</b>			
Pharmaceuticals			
	(10,099)	(18,613)	(42,983)
<b>By location of operation:</b>			
UK	(3,680)	(5,198)	(5,825)
Europe	4,379	3,317	(3,424)
North America	(8,276)	(15,113)	(30,270)
Loss on ordinary activities before interest and taxation	(7,577)	(16,994)	(39,519)
Net interest payable	(2,522)	(1,619)	(3,464)
Loss on ordinary activities before taxation	(10,099)	(18,613)	(42,983)

### 3 Other operating income

Paul Capital Royalty Acquisition Fund 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. Income of £Nil million (2003: £1.2 million) was recognised as Other operating income under this agreement on a cost to complete basis. All of the income under this agreement has now been recognised. Royalty payments to Paul Capital of £0.5 million (2003: £0.4 million) have been expensed during the period.

Under a 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 £1.0 million (2003: £3.0 million) was recognised as Other operating income under this agreement on a cost to complete basis. Royalty payments to Paul Capital of £1.4 million (2003: £0.9 million) have been expensed during the period.

### 4 Exceptional items

Exceptional items include a charge of £0.5 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 2004 (note 11; Provisions for liabilities and charges). 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).

### 5 Earnings per ordinary share

	Unaudited 6 months to 30 June 2004 £ 000	Unaudited 6 months to 30 June 2003 £ 000	Audited 12 months to 31 December 2003 £ 000
Attributable loss before exceptional items and amortisation	(8,268)	(14,054)	(27,067)
Exceptional items	1,146	(1,409)	(9,487)
Amortisation	(3,072)	(3,226)	(6,669)
Attributable loss	(10,194)	(18,689)	(43,223)
	<b>000</b>	<b>000</b>	<b>000</b>
Basic and diluted weighted average number of shares in issue	614,209	609,177	609,855
Earnings per Ordinary Share before exceptional items and amortisation	(1.4p)	(2.3p)	(4.4p)
Exceptional items	0.2p	(0.2p)	(1.6p)
Amortisation	(0.5p)	(0.6p)	(1.1p)
Basic earnings per Ordinary Share	(1.7p)	(3.1p)	(7.1p)
Diluted earnings per Ordinary Share	(1.7p)	(3.1p)	(7.1p)

There is no difference between basic and diluted earnings per Ordinary Share since in a loss making period all potential Ordinary Shares are anti-dilutive. Shares held by the SkyePharma PLC General Employee Benefit Trust are excluded from the weighted average number of shares.

### 6 Intangible fixed assets

	Goodwill £ 000	Intellectual property £ 000	Development costs £ 000	Total £ 000
<b>Cost</b>				
At 1 January 2004	82,730	36,127	1,712	120,569
Exchange adjustments		(396)	(62)	(458)
Additions		2,859		2,859
At 30 June 2004	82,730	38,590	1,650	122,970
<b>Amortisation</b>				
At 1 January 2004	14,025	10,436	1,012	25,473
Exchange adjustments		(233)	(30)	(263)
Charge for the period	2,067	907	98	3,072
At 30 June 2004	16,092	11,110	1,080	28,282
Net book value at 31 December 2003	68,705	25,691	700	95,096
Net book value at 30 June 2004	66,638	27,480	570	94,688

**7 Fixed asset investments**

	Unlisted investments £ 000
<b>Cost</b>	
At 1 January 2004	22,024
Additions	168
Disposals	(629)
At 30 June 2004	21,563

**Astralis Limited**

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 represents approximately 35.7% of the common shares. The investment is not regarded as an associated undertaking as the Directors have concluded that the Group does not exert significant influence.

**Transition Therapeutics**

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).

**8 Convertible bonds**

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 SkyePharma Ordinary Shares at a conversion price of £1.00. Unless previously redeemed or converted, the bonds will be redeemed by the Group at their principal amount in May 2024.

In July 2004 the Group exchanged £49.6 million convertible bonds due 2005 for bonds due 2024 in the same amount, leaving £9.8 million 2005 bonds outstanding. The unamortised issue costs on the exchanged 2005 convertible bonds have been written off accordingly (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 2024 convertible bonds and £9.8 million 2005 bonds outstanding.

**9 Reconciliation of operating loss to net cash (outflow)/inflow from operating activities**

Unaudited 6 months to	Unaudited 6 months to	Audited 12 months to 31 December
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	30 June 2004 £ 000	30 June 2003 £ 000	2003 £ 000
<b>Operating loss</b>	(9,598)	(16,994)	(39,519)
Depreciation	2,929	3,225	6,294
Amortisation	3,072	3,226	6,669
Increase in stock	(52)	(100)	(64)
(Increase)/decrease in debtors	(1,024)	13,234	19,573
Increase/(decrease) in deferred income excluding unrealised gain on contract development	1,123	2,769	(126)
(Decrease)/increase in other creditors	(393)	953	4,734
(Decrease)/increase in provisions	(768)	405	1,920
Impairment of intellectual property			2,673
Impairment of tangible fixed assets			1,324
Write down of fixed asset investments			1,599
Other	(373)	257	1,538
<b>Net cash (outflow)/inflow from operating activities</b>	<b>(5,084)</b>	<b>6,975</b>	<b>6,615</b>

**10 Analysis of net debt**

	<b>At 1 January 2004 £ 000</b>	<b>Cash flow £ 000</b>	<b>Non-cash changes £ 000</b>	<b>Exchange movements £ 000</b>	<b>At 30 June 2004 £ 000</b>
Cash at bank and in hand	3,052	6,441		(78)	9,415
Bank overdraft	(1,198)	269		35	(894)
Short-term bank deposits	20,188	598		(280)	20,506
	22,042	7,308		(323)	29,027
Debt due within one year	(3,172)	549		(58)	(2,681)
Debt due after one year	(9,195)	592		205	(8,398)
Convertible bonds due 2005	(58,791)		(545)		(59,336)
Convertible bonds due 2024		(18,865)	(9)		(18,874)
Finance leases	(366)	176		19	(171)
	(71,524)	(17,548)	(554)	166	(89,460)
<b>Total</b>	<b>(49,482)</b>	<b>(10,240)</b>	<b>(554)</b>	<b>(157)</b>	<b>(60,433)</b>

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

Non cash changes relate to the amortisation of the issue costs on the convertible bonds.

**11 Provisions for liabilities and charges**

	<b>Restructuring £ 000</b>	<b>Pension £ 000</b>	<b>National Insurance £ 000</b>	<b>Total £ 000</b>
At 1 January 2004	1,829	285	7	2,121
Exchange adjustments	(69)	(23)	(2)	(94)
Charge for the period	537	52	5	594
Utilised	(1,268)			(1,268)
At 30 June 2004	1,029	314	10	1,353

**Restructuring Provision**

The restructuring provision relates to the reorganisation of research and development operations and other business functions involving reductions in staff at most sites. The remaining provision of approximately £1.0 million is expected to be fully utilised in 2004 (note 4; Exceptional items).

**12 Share capital****Equity share capital**

	<b>Ordinary Shares of 10p each Number</b>	<b>Nominal value £ 000</b>
<b>Issued, allotted and fully paid</b>		
At 1 January 2004	618,669,940	61,867
Exercise of share options	323,597	32
Issue of shares to Research Development Foundation	3,250,000	325
At 30 June 2004	622,243,537	62,224

During the period the Group issued 3,250,000 Ordinary Shares to Research Development Foundation as a result of a restructuring of the arrangements with RDF existing at the time of the DepoTech acquisition in 1999.

**Non-equity share capital**

	<b>Deferred B Shares of 10p each Number</b>	<b>Nominal value £ 000</b>
<b>Authorised and issued</b>		
At 1 January 2004 and 30 June 2004	12,000,000	1,200

END