SKYEPHARMA PLC
Form 6-K
April 29, 2004

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a 16 OR 15d 16 OF

THE SECURITIES EXCHANGE ACT OF 1934

For the month of April, 2004

SkyePharma PLC

(Translation of registrant s name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F x Form 40-F ¨

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

Yes ¨ No x

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: April 29, 2004

For Immediate Release **29 April, 2004**

SkyePharma PLC

Preliminary Results Announcement

for the year ended 31 December 2003

LONDON, ENGLAND, 29 April 2004

Financial Highlights

- Turnover down by 24% to £53.2m - mainly from delays to completion of new agreements
- Two new agreements completed since year-end, others still in negotiation
- Royalty income nearly tripled to £18.7m (2002: £6.8m)
- Exceptional items of £9.5m (2002: £nil)
- Operating loss after exceptionals of £39.5m (2002: £4.7m profit)
- Net loss after exceptionals of £43.2m (2002: £1.1m profit)
- Loss per share 7.1p (2002: earnings per share 0.2p)
- End 2003 net cash £22.0m (2002: £28.1m)
- Issue of £20m convertible bond announced today

Operating highlights

- Paxil CR US prescription share increases to 8%
- UroXatral® launched in USA
- DepoCyt® European rights reacquired and relicensed to Mundipharma
- FDA issues approvable letter for Foradil® Certihaler®
- New agreement with Novartis to jointly develop QAB149
- DepoMorphine filed for approval in US and Europe
- Agreement with King Pharmaceuticals to develop once-daily version of Altace®
- DepoMorphine European rights licensed to Medeus Pharma (April 2004)

Ian Gowrie-Smith, Executive Chairman, said: This year we expect two important new products, DepoMorphine and Foradil® Certihaler®, to reach the market, underpinning an expected further substantial increase in royalty income. This and the conclusion of recent deals and the status of those still pending make me confident in the outcome for the year.

For further information please contact:

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CHAIRMAN S STATEMENT

2003 was a very frustrating year for SkyePharma. While we made significant progress in a number of important areas (outlined in the Operational Review), for a number of reasons we did not complete several key new agreements by the end of the year and therefore our revenues fell short of the target we had set ourselves. Delaying completion of these deals also raised our costs since our budget had been based on the assumption of development funding by the partner. These two factors meant that we slipped back into losses after reporting an initial profit in 2002.

I wish to underscore the limited relevance of this in the context of the long-term growth of the company. Our business model involves revenues from both milestone payments and royalties on product sales. Royalty income is the key to future sustainable growth in profits. However to secure these royalties we need to enter into agreements with marketing partners. The timing and structure of these agreements by their nature cannot be predicted accurately. Therefore at our current stage of development, when milestone payments still represent a significant proportion of our income, there is bound to be a degree of uncertainty about our forecast revenues.

Attempting to complete negotiations on a new agreement within the rather artificial timeframe imposed by a financial reporting period is impractical - and can even be counter-productive. What is important for the company (and for shareholders) are deal structures that optimise long-term royalty income rather than ensuring that one-off payments are made by a certain date.

In our 5 January Trading Update, we reported that three key licence agreements which we had expected to conclude in 2003 were still in negotiation. These consisted of the European rights for DepoMorphine; an unnamed pipeline product; and a package of products in the pulmonary field. Of these, the latter was the largest licensing opportunity. We also indicated that, because of certain internal and external developments in the second half of 2003, we had decided to reject a substantial offer we had received for this package.

The first of the deals deferred from 2003 to be completed was finalised in April, when we announced that we had granted an exclusive licence for DepoMorphine in Europe to Medeus Pharma, on terms which we believe are highly satisfactory. These involve milestone payments in excess of 100 million (US$120 million) and a share of sales that varies between 35% and 50% depending on sales levels. These terms exemplify our strategic determination to maximize returns on our products and to prioritize royalty income or profit share over milestone payments.

The management of SkyePharma is now in advanced negotiations with our preferred partner for the pulmonary package. We expect this agreement to be completed in the near future. In addition to this negotiation, we are simultaneously conducting late-stage negotiations with a number of alternative partners for these products. We also remain in advanced negotiations with several potential partners for the unnamed oral pipeline product disclosed in the January Trading Update. This product was filed for approval with the FDA in March 2004.

We have now completed a reorganisation of our R&D units with the aim of removing some geographical inefficiencies arising from previous acquisitions. We now have a simplified structure that will improve our ability to develop products for partners and for ourselves. Regrettably this has involved a reduction of about 10% in our staff numbers. Although there was a cost of £2.7 million in 2003 and further costs in 2004, there will be significant savings going forward.

As previously indicated, I will be stepping down as Executive Chairman at the Annual General Meeting on 23 June and seeking reappointment in a Non-Executive capacity. Since founding SkyePharma in 1996, I have seen the company develop a strong internal organisation and I am confident that I can leave day-to-day management in the capable hands of Michael Ashton and his team. My particular area of expertise is in establishing new companies and I have a number of other interests where these skills can more appropriately be applied. However shareholders can be assured that my decision does not imply any loss of confidence in SkyePharma s potential and I shall continue to be closely involved with the company s progress.

Outlook

This year we expect two important new products, DepoMorphine and Foradil® Certihaler®, to reach the market, underpinning an expected further substantial increase in royalty income. This and the conclusion of recent deals and the status of those still pending make me confident in the outcome for the year.

Ian Gowrie-Smith

Executive Chairman

OPERATIONAL REVIEW

On the market

Paxil CR, an improved version of GlaxoSmithKline s selective serotonin reuptake inhibitor (SSRI) antidepressant Paxil® (paroxetine), continues to make encouraging progress. Paxil CR was designed to reduce the incidence of nausea, a troubling early side-effect of all SSRI antidepressants that contributes to poor

compliance with this class of drug. A recently published study of US prescription data for depression showed a significantly lower discontinuation rate with Paxil CR than with competing SSRI antidepressants. GlaxoSmithKline launched Paxil CR in the USA in April 2002 for treating depression and panic disorder and it has recently also been launched in Canada. Paxil CR has subsequently been approved by the FDA for two other depression-related indications, social anxiety disorder and the continuous and intermittent treatment of pre-menstrual dysphoric disorder (PMDD). Paxil® was never filed for the latter indication so Paxil CR is the only version approved for PMDD.

By the end of 2003, Paxil CR had captured approximately 8% of all new US prescriptions for SSRI antidepressants. This share has been largely unaffected by the commencement of generic competition for Paxil® in September 2003. A prescription written for Paxil CR cannot be substituted by generic paroxetine because Paxil CR is a clinically differentiated product. Finally, on our interpretation of the agreement between GlaxoSmithKline and ourselves, we are entitled to a significant enhancement in the rate of the royalty we receive on sales of Paxil CR from the date on which generic paroxetine entered the US market. Should we be unable to arrive at a mutually satisfactory agreement with our partner, we will resort to the binding arbitration procedure laid down in the original agreement.

Our second oral product on the market is a once-daily version of Sanofi-Synthélabo s Xatral® (alfuzosin), a treatment for the urinary symptoms of benign prostatic hypertrophy, a common condition affecting males in middle age. Xatral® OD has now been launched throughout Europe and also in Canada and other territories in Africa, Asia and Latin America. The older multi-dose versions of Xatral®, which had to be taken two or three times a day, have now been withdrawn from the market in some areas. The main event of 2003 was the November launch in the USA, where the product is marketed as Uroxatral®. The older versions of Xatral® had never been launched in that market so Uroxatral® is a new product in the US market. By the end of January 2004, Uroxatral® had captured an encouraging 8% of new US prescriptions for this class of drug. Our partner Sanofi-Synthélabo reports that combined global sales of all versions rose by 25% in constant exchange rate terms in 2003 to 222 million. Sanofi-Synthélabo continues to invest in the development of this product with Phase III trials ongoing for a second indication, acute urinary retention. This indication has now been approved in Europe, with a US filing planned for late next year.

DepoCyt® is our first sustained-release injectable product to reach the market. It is a treatment for lymphomatous meningitis, a serious complication of the later stages of non-Hodgkin s lymphoma. DepoCyt®, a long-acting formulation of the chemotherapy drug cytarabine, provides effective treatment and only needs an injection every two weeks against an infusion every two days for conventional cytarabine. We are close to completing a Phase IV trial, the results of which should provide the data required to expand the indication to neoplastic meningitis associated with solid tumours, a more common form of this distressing condition. DepoCyt® received FDA approval in 1999 as an orphan drug and is marketed in North America by Enzon Pharmaceuticals. Sales of DepoCyt® in North America in 2003 were around $5 million. Enzon and we believe that this is well below the peak market potential. In 2003, we reacquired European marketing rights for DepoCyt® from Elan Pharmaceuticals for an unspecified amount and relicensed the product to Mundipharma International Holdings (Mundipharma , part of the privately-owned Purdue/Mundipharma/Napp group of companies). Mundipharma has recently launched the product (as DepoCyte®) in Europe. We have also licensed DepoCyt to Pharmis for Brazil.

Solaraze® is a topical treatment for actinic keratosis, an increasingly common pre-cancerous skin condition caused by excessive exposure to the sun. Solaraze® is marketed by Quintiles Transnational in the USA and by Shire Pharmaceuticals in Europe. Sales in these territories were approximately $18 million in 2003. Shire has also acquired rights to Solaraze® in Australia and certain Pacific Rim territories. The incidence of actinic keratosis is exceptionally high in Australia so we expect the results of an ongoing clinical trial in that country (funded by Shire) will be helpful in supporting marketing efforts elsewhere.

Strategic developments

We invested £2.1 million to acquire an 18.2% stake in Micap plc, a small UK company developing a novel encapsulation technology based on yeast cells. Originally developed for use in the food industry, there are several potential applications of this technology to oral and topical drug delivery, including taste-masking for unpleasant-tasting medicines and enhanced uptake

through mucosal membranes. SkyePharma has an option over the pharmaceutical applications of Micap s technology. Micap successfully completed an initial public offering on the UK Alternative Investment market in August 2003. We also converted an existing investment in a private US

company (e-nutriceuticals) into a strategic stake of 24.4% in Vital Living Inc, a leader in the field of pharmaceutical-grade nutraceuticals. We also entered into a contract to develop certain products for Vital Living that incorporate our Geomatrix oral controlled-release technology. Finally our partner Astralis Ltd initiated the Phase I clinical trial in the USA of Psoraxine, its novel treatment for psoriasis. This has recently moved into Phase II trials. These strategic investments give us exposure to potentially valuable technologies that we would not be able to develop internally without diverting resources from our mainstream business.

On the way

Foradil® Certihaler is a new version of Novartis long-acting bronchodilator Foradil® (formoterol) for the relief of bronchoconstriction in asthma and chronic obstructive pulmonary disease (COPD). We developed the multi-dose dry-powder inhaler device and also the formulation that ensures dose consistency regardless of storage conditions. These technologies will also be employed in a new agreement we signed with Novartis last year to jointly develop a dry-powder formulation of another bronchodilator, QAB149, which Novartis currently has in Phase II development. QAB149 appears to be even longer-acting than formoterol and could be the first once-daily bronchodilator to enter the market. Novartis filed Foradil® Certihaler with the FDA and European regulatory authorities in December 2002 and the FDA issued an approvable letter in October 2003. On normal approval timelines, we would expect Foradil® Certihaler to begin to be approved during the second half of 2004. The product has also received its first European approval in Switzerland in March and has subsequently received additional approvals in Finland and Austria. Novartis will market Foradil® Certihaler in Europe but in the US the Foradil® franchise has been licensed to Schering-Plough Corporation a commercial decision we welcome given the latter s strong position in the US asthma market. The current version of Foradil®, using Novartis own single dose inhaler Aeroliser, had global sales in 2003 of approximately $300 million. SkyePharma will receive a royalty on product sales and will also manufacture for both parties. The role of formoterol in asthma therapy should be enhanced by the recent publication of a major independent study on its use as a routine rescue medication, showing that formoterol is superior to the widely used short-acting bronchodilator salbutamol.

DepoMorphine is our new analgesic for the relief of acute post-operative pain. Our sustained-release injectable technology means that a single epidural injection immediately before surgery maintains a therapeutically effective level of morphine for up to 48 hours the typical period of peak pain after a major operation. Results from Phase III trials in nearly one thousand patients in four different pain models (hip arthroplasty, major abdominal surgery, caesarean section and knee surgery) confirm that DepoMorphine is at least as safe and effective as conventional immediate-release morphine. Our clinical investigators also believe that DepoMorphine will bring significant advantages for patients arising from freedom from pain and faster recovery times and for hospitals in terms of savings in labour and equipment costs and improvements in resource utilisation. We filed DepoMorphine with the FDA in July and with the European regulatory authorities in November. We would expect to hear the first reaction from the FDA in May this year. North American rights to DepoMorphine and a second product, Propofol IDD-D, were licensed to Endo Pharmaceuticals in December 2002. In April 2004 we announced the appointment of Medeus Pharma as our European licensee for DepoMorphine, with additional licences in other territories still to come.

Propofol IDD-D is a novel formulation of a widely used injectable anaesthetic and sedative. Our proprietary microemulsion formulation is designed not to support microbial growth, a recognised problem with current versions, and should provide uninterrupted sedation for 24 hours, making it ideal for the fast-growing intensive care market. We completed a Phase II trial last year and we expect the Phase III trials to start by mid-year. Propofol IDD-D was licensed in December 2002 to Endo for North America. We expect to license Propofol IDD-D in Europe this year.

In trials

In the oral area, we are conducting clinical studies of our once-daily version of the oral Parkinson s disease drug Requip® (ropinirole) for our partner GlaxoSmithKline. Requip® is a dopamine agonist, a class of drug increasingly recommended as first-line treatment for Parkinson s, but the current version has to be taken three times a day. Our once-daily Geomatrix version is not only more convenient for patients but also reduces fluctuations in levels of the drug in the brain, which should bring therapeutic benefits. We commenced the Phase III trial in July and expect to file the product for approval towards the end of 2004.

We are also developing an undisclosed product for Merck KGaA. This project, involving our oral controlled-release technology, is about to commence Phase III development.

In addition to our collaboration with Novartis on dry-powder inhalers, we are also developing several asthma drugs in metered-dose aerosol inhalers (MDI). These widely-used MDIs have traditionally been powered by chlorofluorocarbon (CFC) propellant gases but the use of CFCs is being phased out on environmental concerns. Replacing CFCs with hydrofluoroalkane (HFA) alternatives is not straightforward and requires modification of virtually every component of the MDI device and of the formulation of the active drug. For AstraZeneca we have developed an HFA-MDI version of their inhaled steroid Pulmicort® (budesonide) for the European market (with US rights retained by SkyePharma). After successfully completing pharmacokinetic studies, Phase III pivotal trials started in the second half of 2003. SkyePharma has also developed at its own expense an HFA-MDI version of the long-acting bronchodilator formoterol. This completed Phase II trials in 2003, and Phase III trials will commence shortly.

We have also begun clinical trials of our own HFA-MDI containing a fixed-dose combination of formoterol with the inhaled steroid fluticasone. A single delivery device containing two separate agents with complementary therapeutic roles (steroids are anti-inflammatory whereas bronchodilators control those attacks that still occur) brings obvious convenience benefits for patients. GlaxoSmithKline s Advair® (combining fluticasone with salmeterol, another long-acting bronchodilator) has been very successful, with 2003 global sales of $3.7 billion. Advair® was only launched in the US in April 2001 and we believe our combination could be the third (or possibly even the second) such combination to enter the US market. Given the recent publication of a major study confirming the benefits of routine use of formoterol and the advantage that formoterol has over salmeterol in terms of time to onset of action, we are excited by the potential of our combination product.

Because of the growing interest in the respiratory field, we decided to out-license these three asthma products as a package. We had expected to conclude an agreement by the end of 2003 but the prospects for this group of products have justified extending negotiations into 2004. Several parties are competing for this package. Although negotiations of commercial terms have been completed, all parties are concluding due diligence. Under the draft terms of these agreements, SkyePharma will receive upfront milestone payments upon signature, additional milestone payments on achievement of various clinical and commercial targets and a premium royalty rate.

In early 2004 we also concluded an agreement on another asthma product, in this case an oral drug, zileuton. This is a potent anti-inflammatory agent but has the disadvantages of a short half-life coupled with liver toxicity, requiring patients to undergo regular monitoring of liver function. A four times daily version was marketed in the US as Zyflo® by Abbott Laboratories. We had developed a once-daily version for Abbott which has completed Phase III development for asthma but has not been filed. A new company, Critical Therapeutics, has now licensed zileuton from Abbott and we will work with Critical Therapeutics to develop the product for severe asthma and COPD, indications where the current dearth of other therapeutic options suggests the liver testing requirement will not be a major commercial drawback.

DepoBupivacaine is our sustained-release injectable version of bupivacaine, a widely-used local anaesthetic. The useful anaesthesia period has been extended from 12-18 hours for unmodified bupivacaine to 3-4 days. This should make the product suitable for the control of post-operative pain in patients who have undergone certain particularly painful out-patient procedures such as knee arthroscopy, laparoscopic surgery and facial plastic surgery. Currently many day surgery patients have to take extended time off work after discharge because of the level of post-operative pain. We initiated a Phase I study in September 2003. Our agreement with Endo for North American rights to DepoMorphine and Propofol IDD-D includes an option over DepoBupivacaine, on terms that will be negotiated at the conclusion of our Phase II studies. In Europe bupivacaine is the local anaesthetic most widely used in day surgery and we are confident of finding high interest in a licence for this product, not only in Europe but also in Japan.

In the lab

In 2003 we entered into a new agreement with King Pharmaceuticals to develop a once-daily version of its lead product, the antihypertensive Altace® (ramipril). Altace® is the leading US angiotensin converting enzyme (ACE) inhibitor, with 2003 sales of $527 million.

The delivery of protein drugs is an increasingly important challenge for the pharmaceutical industry. There are already over one hundred protein or peptide drugs on the market (with many hundreds more in clinical development) and this type of drug normally cannot be given orally because proteins will not survive passage through the digestive system. However, the short half-life of most protein drugs means that injections usually need to be given frequently and as injections are unpopular with patients, compliance tends to be poor. We have two complementary sustained release injectable technologies, DepoFoam® and Biosphere, making us well-

positioned to add value to currently marketed proteins and peptides and to new compounds. Our Biosphere version of human growth hormone has successfully completed proof of principle studies and is now in early-stage clinical trials.

Our 2001 strategic collaboration with Astralis Ltd (Astralis) covers the development of Psoraxine, a unique injectable treatment for psoriasis, a chronic skin disorder that affects approximately 3% of the world population. There is no approved cure for psoriasis and most approved treatments provide only temporary or incomplete relief and may also cause serious side effects. Given as a course of injections, Psoraxine is a protein that stimulates cells from the patient s immune system to reverse the inflammatory process responsible for psoriasis symptoms. Clinical studies in Venezuela using an early version of Psoraxine involved nearly 3,000 psoriasis patients, the vast majority of whom responded positively with a low level of side effects. We are working with Astralis to develop a second-generation product, now being produced in the USA, and to validate the promising results from Venezuela in US clinical studies that will be used as the basis for regulatory submissions and marketing approval. The US Phase I clinical trials commenced in September 2003 and the Phase II study has recently been initiated.

Conclusion

Our strategic goal remains the maximisation of returns on products we develop for ourselves and for our partners. The progress we have made in 2003 and in the current year has been very encouraging and we believe that we can continue to reduce our current dependence on milestone payments. Although it was disappointing not to complete the key deals we had expected to conclude in 2003, we have now licensed DepoMorphine in Europe on highly satisfactory terms. We look forward with confidence to future profitable growth.

Michael Ashton

Chief Executive Officer

FINANCIAL REVIEW

Turnover

As a result of delays in concluding a number of key deals in 2003, turnover for the year decreased by 24% to £53.2 million, compared with £69.6 million in 2002. The major transactions postponed from 2003 to 2004 included the licensing of a package of products in the pulmonary field, the licensing of DepoMorphine for Europe and the licensing of an unnamed pipeline product subsequently filed for approval with the FDA in March 2004. In April 2004 SkyePharma announced the licensing of DepoMorphine for Europe to Medeus Pharma.

Contract development and licensing revenue decreased by 47% to £29.7 million due primarily to the delay in the above licensing transactions. Revenues recognised from milestone payments and payments received on the signing of agreements amounted to £24.2 million compared with £47.7 million in 2002. The 2003 total included revenue from Endo upon the FDA formally accepting for filing a NDA for DepoMorphine, Mundipharma for the rights to market and distribute DepoCyt® in most European countries, King for developing and commercialising a modified-release formulation of Altace® (ramipril) and the signing of an option agreement in respect of an undisclosed pulmonary product. In addition, SkyePharma received milestones from GlaxoSmithKline and AstraZeneca on the initiation of phase III clinical trials of Requip® (ropinirole) and budesonide HFA respectively. Milestone payments and payments on signing are expected to continue to be an important component of turnover in the near term.

Royalty income almost tripled to £18.7 million, compared with £6.8 million in 2002, following a fourfold increase in 2002. Royalty income in 2003 derives principally from Paxil® CR, Xatral® OD, DepoCyt® and Solaraze®.

Manufacturing and distribution revenues decreased by 35% to £4.8 million, compared with £7.4 million in 2002, due principally to the way in which the revenue from the new licensing arrangements agreed with Enzon, signed in December 2002, is accounted for. Revenue from Enzon is split between royalty and manufacturing and distribution income in accordance with the contract. Under the previous arrangements with Chiron the Company recorded its 50% share of sales as manufacturing and distribution income. This category also includes £1.0 million from Kowa under our collaboration on NK-104 and £0.9 million in respect of Foradil® Certihaler® for Novartis.

Deferred income

During 2003, the Group released a net £2.1 million of turnover and other operating income under its revenue recognition policy, leaving a total deferral of £15.9 million at the end of 2003 comprising:

	31 December 2002 £ million	Received £ million	Recognised £ million	31 December 2003 £ million
Contract development and licensing revenue	10.2	26.6	(29.7)	7.1
Other operating income	7.8	7.1	(6.1)	8.8
	18.0	33.7	(35.8)	15.9

This deferred income will be released in later years in line with the related costs or as the associated obligations under the relevant contracts are satisfied.

In addition, the Group recognised £2.0 million of revenue through the statement of total recognised gains and losses rather than the profit and loss account, as the amount earned did not meet the definition of qualifying consideration.

Cost of sales

Cost of sales consists of 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 was £29.8 million in 2003, compared with £24.8 million in 2002. This was mainly due to increased royalty payments made to Paul Capital of £2.5 million and increased manufacturing and distribution costs. The resulting gross profit decreased by £21.4 million to £23.4 million, primarily as a result of the decreased milestone payments and payments received on the signing of agreements and a £4.8 million increase in manufacturing losses. The manufacturing losses arise primarily due to inadequate overhead recovery in the US and Lyon prior to the start of manufacture or increased sales of the Company s own products and licensee products.

Expenses

Selling, marketing and distribution expenses decreased marginally to £4.3 million, compared to £4.8 million in 2002. Other administration expenses before exceptionals were £18.0 million in 2003, compared with £13.7 million in 2002. The increase mainly relates to the cost of reacquiring the DepoCyt® European rights from Elan and writing down the Group s investment in GeneMedix plc to market value at the year-end.

Exceptional items and amortisation amounted to £16.2 million in 2003, comprising exceptional items of £9.5 million and amortisation of £6.7 million. Amortisation of intangible assets increased slightly by £0.2 million from £6.5 million. The exceptional charge includes £2.7 million cash costs relating to the reorganisation of some research and development operations and other business functions, involving reductions in staff at most sites. The remaining restructuring provision of approximately £1.8 million will be utilised in 2004. A further charge will be recognised in 2004.

A further non-cash charge of £4.0 million is in respect of the impairment of associated intellectual property and tangible fixed assets. In addition, £1.6 million of the charge relates to a write-down in the value of investments. A further £1.2 million of the charge relates to the settlement of a licensing dispute on favourable terms.

Our own research and development expenses in the year increased by £1.2 million to £30.5 million, as contrary to our previous expectations we were unable to transfer certain costs to our partners due to the delays to completion of new agreements.

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 DepoMorphine, Xatral® OD, Solaraze® and DepoCyt®. Income of £1.1 million (2002: £9.7 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 £1.0 million (2002: £Nil) have been expensed during the year.

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 £5.0 million (2002: £4.5 million) was recognised as Other operating income under this agreement on a cost to complete basis. Royalty payments to Paul Capital of £2.2 million (2002: £0.7 million) have been expensed during the year. Further details are provided in note 3; Other operating income.

Operating results

The delay in concluding a number of key new deals in 2003 was the most significant factor contributing to the Group s operating loss after exceptionals of £39.5 million, compared with an operating profit of £4.7 million in 2002. The exceptional charge of £9.5 million and the reduction in income being recognised under the Paul Capital agreements of £8.1 million have also contributed to the 2003 loss. The net loss was £43.2 million in 2003, compared with a net profit of £1.1 million in 2002. Earnings before interest, tax, depreciation and amortisation (EBITDA), a commonly used performance indicator, was a loss of £26.6 million in 2003 compared with a profit of £17.3 million in 2002. EBITDA before exceptionals was a loss of £17.1 million compared with a profit of £17.3 million in 2002.

Comparing the first half of 2003 with the second, the net loss for the second half of the year before exceptionals was less than that for the first half. The periods compare as follows:

	Six months to 30 June 2003 £ 000	Six months to 31 December 2003 £ 000
Net loss before exceptional items	(17,280)	(16,456)
Exceptional items	(1,409)	(8,078)
Net loss	(18,689)	(24,534)

The loss per share after exceptionals was 7.1 pence, which compares with a profit per share of 0.2 pence in 2002. Foreign exchange movements did not have a material impact on the results of operations in 2003 compared with 2002.

Cash balances and cash flow

At 31 December 2003 SkyePharma had cash and short term deposits of £23.2 million (£22.0 million net of overdrafts). The latter figure compares with £28.1 million at 31 December 2002 and £21.9 million at 30 June 2003.

In 2003 there was a net cash inflow from operating activities of £6.6 million for the full year, compared with £1.6 million in 2002.

During the year the Group spent £12.2 million on capital expenditure and fixed asset investments. Purchases of tangible fixed assets were £4.0 million and purchases of intangible assets amounted to £2.5 million. Purchases of fixed asset investments were £5.7 million, of which £2.1 million relates to Micap plc, £1.5 million to Astralis Ltd, £1.2 million to Vital Living Inc and £0.9 million was spent on the purchase of SkyePharma shares as part of the Group s hedging strategy for share scheme based remuneration.

SkyePharma received £1.4 million of cash during the year from the issue of Ordinary Shares, of which £0.8 million related to the exercise of employee share options over Ordinary Shares and £0.6 million was received in early 2003 in respect of the exercise of the B Warrants which expired at the end of 2002.

Balance sheet

The Group balance sheet at 31 December 2003 shows shareholders funds of £86.3 million (2002: £124.3 million). Goodwill written off to the profit and loss account reserve remained at £147.6 million.

At 31 December 2003 SkyePharma had fixed asset investments totalling £23.4 million. The investments include Astralis Ltd, a US company; Micap plc, a UK company listed on the Alternative Investment Market; Transition Therapeutics Inc, a Canadian company; and Vital Living Inc, a US company. Further details are provided in note 7; Fixed Asset Investments.

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 cost or Directors valuation less provision for permanent diminution in value. At the year end a provision of £1.6 million was made against the Group s fixed asset investments. 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 £1.0 million at 31 December 2003, being the lower of cost and net realisable value assuming conversion of the note into GeneMedix ordinary shares.

At 31 December 2003 bank and other non-convertible debt amounted to £12.7 million (2002: £11.3 million) consisting primarily of a £7.5 million (2002: £7.8 million) property mortgage secured on the Swiss assets and a £2.7 million loan agreed during 2003. In addition the company has 6% Convertible Bonds due 2005 of £58.8 million (2002: £58.4 million). Net of cash and short term deposits less overdrafts net debt amounted to £49.5 million (2002: £41.6 million).

Throughout most of 2003 £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 5.77%, and the floating rate at 31 December 2003 was 6.35%. The swap is cancellable at the option of the fixed rate payer.

As part of the 2001 RTP acquisition, deferred consideration of 3,690,211 SkyePharma Ordinary Shares were issued to the former RTP shareholders during the year.

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 expects to quantify the potential impact during 2004, and has a project team to manage its convergence to IFRS.

Donald Nicholson

Finance Director

CONSOLIDATED PROFIT AND LOSS ACCOUNT

	Notes	Before exceptional items and amortisation £ 000	Exceptional items and amortisation (note 4) £ 000	Year to 31 December 2003 £ 000
Turnover	2	**53,152**		**53,152**
Cost of sales	2	**(29,786)**		**(29,786)**
Gross profit		**23,366**		**23,366**
Selling, marketing and distribution expenses		**(4,348)**		**(4,348)**

Administration expenses				
Amortisation			**(6,669)**	**(6,669)**
Other administration expenses including exceptional impairments		**(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**
Operating (loss)/profit		**(23,363)**	**(16,156)**	**(39,519)**
Interest receivable		**1,029**		**1,029**
Interest payable		**(4,493)**		**(4,493)**
(Loss)/profit on ordinary activities before taxation	2	**(26,827)**	**(16,156)**	**(42,983)**
Taxation		**(240)**		**(240)**
Retained (loss)/profit		**(27,067)**	**(16,156)**	**(43,223)**
Earnings per Ordinary Share	5			
Basic		**(4.4p)**	**(2.7p)**	**(7.1p)**
Diluted		**(4.4p)**	**(2.7p)**	**(7.1p)**

CONSOLIDATED PROFIT AND LOSS ACCOUNT Continued

	Notes	Before amortisation £ 000	Amortisation £ 000	Year to 31 December 2002 £ 000
Turnover	2	69,573		69,573
Cost of sales	2	(24,830)		(24,830)
Gross profit		44,743		44,743
Selling, marketing and distribution expenses		(4,769)		(4,769)
Administration expenses				
Amortisation			(6,506)	(6,506)
Other administration expenses including exceptional impairments		(13,686)		(13,686)
		(13,686)	(6,506)	(20,192)
Research and development expenses		(29,285)		(29,285)
Other operating income	3	14,219		14,219
Operating (loss)/profit		11,222	(6,506)	4,716
Interest receivable		1,081		1,081
Interest payable		(4,464)		(4,464)
(Loss)/profit on ordinary activities before taxation	2	7,839	(6,506)	1,333
Taxation		(224)		(224)
Retained (loss)/profit		7,615	(6,506)	1,109
Earnings per Ordinary Share	5			
Basic		1.3p	(1.1p)	0.2p
Diluted		1.3p	(1.1p)	0.2p

There was no material difference between the (loss)/profit on ordinary activities before taxation and the historical cost (loss)/profit before taxation in 2003 and 2002. All results represent continuing activities.

See Notes to the Preliminary Announcement.

CONSOLIDATED STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES

	Year to 31 December 2003 £ 000	Year to 31 December 2002 £ 000
(Loss)/profit attributable to shareholders	**(43,223)**	1,109

Net currency translation effect	**(175)**	903
Unrealised gain on contract development	**2,029**	
Lapse of warrants		1,096
Total recognised gains and losses for the year	**(41,369)**	3,108

RECONCILIATION OF MOVEMENTS IN SHAREHOLDERS FUNDS

	Year to 31 December 2003 £ 000	Year to 31 December 2002 £ 000
Shareholders funds at the beginning of the year	**124,270**	95,145
Total recognised gains and losses for the year	**(41,369)**	3,108
Equity shares issued, net of expenses	**2,560**	43,816
Exercise of share options, net of expenses	**765**	700
Issue of warrants	**39**	311
Non-equity shares converted to equity shares		(11,310)
Goodwill adjustments on deferred consideration		4,837
Revaluation of shares and warrants to be issued		(4,837)
Decrease in shares and warrants to be issued		(5,780)
Exercise of warrants		(624)
Lapse of warrants		(1,096)
Net movement in the year	**(38,005)**	29,125
Shareholders funds at the end of the year	**86,265**	124,270

CONSOLIDATED BALANCE SHEET

	Notes	31 December 2003 £ 000	31 December 2002 £ 000
Fixed assets			
Intangible assets	6	**95,096**	100,015
Tangible assets		**42,615**	45,504
Investments	7	**23,419**	19,902
		161,130	165,421
Current assets			
Stock		**1,320**	1,256
Debtors		**15,634**	35,207
Investments		**981**	1,961
Cash and short-term bank deposits		**23,240**	28,061
		41,175	66,485
Creditors: amounts falling due within one year			
Deferred income		**(12,926)**	(15,069)
Other creditors		**(26,394)**	(19,402)
		(39,320)	(34,471)

Net current assets	**1,855**	32,014
Total assets less current liabilities	**162,985**	197,435
Creditors: amounts due after more than one year		
Convertible bonds due 2005	**(58,791)**	(58,377)
Deferred income	**(2,948)**	(2,960)
Other creditors	**(12,860)**	(11,627)
	(74,599)	(72,964)
Provisions for liabilities and charges	**(2,121)**	(201)
Net assets	**86,265**	124,270
Capital and reserves		
Share capital	**63,067**	62,546
Share premium	**319,223**	316,419
Other reserves	**9,350**	9,311
Profit and loss account	**(305,375)**	(264,006)
Shareholders funds		
Attributable to equity interests	**74,955**	112,960
Attributable to non-equity interests	**11,310**	11,310
	86,265	124,270

See Notes to the Preliminary Announcement.

CONSOLIDATED CASH FLOW STATEMENT

	Notes	**Year to 31 December 2003 £ 000**	Year to 31 December 2002 £ 000
Net cash inflow from operating activities	(b)	**6,615**	1,552
Returns on investments and servicing of finance			
Interest received		**1,047**	943
Interest paid		**(4,013)**	(3,913)
Interest element of finance lease payments		**(70)**	(130)
		(3,036)	(3,100)
Taxation		**(227)**	(224)
Capital expenditure and financial investment			
Purchase of intangible fixed assets		**(2,530)**	(3,035)
Purchase of tangible fixed assets		**(4,021)**	(3,238)
Purchase of fixed asset investments		**(5,674)**	(6,285)
		(12,225)	(12,558)
Acquisitions			
Purchase of drug delivery business of Bioglan AB			(3,595)
Cash outflow before use of liquid resources and financing		**(8,873)**	(17,925)
Management of liquid resources			
Net decrease/(increase) in amounts held on short-term bank deposit		**183**	(3,872)
Financing			
Issue of Ordinary Share capital		**1,437**	26,168
Issue of warrants		**39**	311
Debt due within one year:			
Inception of new loan		770	
Repayment of loans			(2,992)
Debt due beyond one year:			
Inception of new loan		1,936	
Repayment of loans		(286)	(929)
Capital element of finance lease payments		**(1,078)**	(937)
		2,818	21,621
Decrease in cash		**(5,872)**	(176)

NOTES TO THE CONSOLIDATED CASH FLOW STATEMENT

(a) Reconciliation of movements in net debt

	Year to 31 December 2003 £ 000	Year to 31 December 2002 £ 000
Decrease in cash in the year	**(5,872)**	(176)
Cash (inflow)/outflow from (increase)/decrease in debt and lease financing	**(1,342)**	4,858
Cash (inflow)/outflow from (decrease)/increase in liquid resources	**(183)**	3,872
Change in net debt resulting from cash flows	**(7,397)**	8,554
Amortisation of issue costs on convertible bonds	**(414)**	(415)
Finance leases acquired with subsidiary		(361)
New finance leases	**(46)**	(91)
Chiron promissory note		(621)
Translation difference	**(24)**	(1,505)
Movement in net debt in the year	**(7,881)**	5,561
Net debt at beginning of the year	**(41,601)**	(47,162)
Net debt at end of the year	**(49,482)**	(41,601)

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

NOTES TO THE CONSOLIDATED CASH FLOW STATEMENT continued

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

	Year to 31 December 2003 £ 000	Year to 31 December 2002 £ 000
Operating (loss)/profit	**(39,519)**	4,716
Depreciation	**6,294**	6,101
Amortisation	**6,669**	6,506
(Increase)/decrease in stock	**(64)**	1,022
Decrease/(increase) in debtors	**19,573**	(21,585)
(Decrease)/increase in deferred income excluding unrealised gain on contract development	**(126)**	6,339
Increase/(decrease) in other creditors	**4,734**	(313)
Increase in provisions	**1,920**	133
Impairment of intellectual property	**2,673**	
Impairment of tangible fixed assets	**1,324**	
Write down of fixed asset investments	**1,599**	
Other	**1,538**	(1,367)
Net cash inflow from operating activities	**6,615**	1,552

(c) Analysis of net debt

	At 1 January 2003 £ 000	Cash flow £ 000	Non-cash changes £ 000	Exchange movements £ 000	**At 31 December 2003 £ 000**
Cash at bank and in hand	**7,394**	(4,666)		324	**3,052**
Bank overdraft		(1,206)		8	**(1,198)**
Short-term bank deposits	**20,667**	(183)		(296)	**20,188**
	28,061	(6,055)		36	**22,042**
Debt due within one year	**(1,842)**	(770)	(559)	(1)	**(3,172)**
Debt due after one year	**(8,123)**	(1,650)	559	19	**(9,195)**
Convertible bonds	**(58,377)**		(414)		**(58,791)**
Finance leases	**(1,320)**	1,078	(46)	(78)	**(366)**
	(69,662)	(1,342)	(460)	(60)	**(71,524)**
Total	**(41,601)**	(7,397)	(460)	(24)	**(49,482)**

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

Non-cash changes relate to the amortisation of the issue costs on the convertible bonds, the inception of new finance leases and transfers between categories.

NOTES TO THE PRELIMINARY ANNOUNCEMENT

1 Accounting policies

Accounting convention and presentation

The unaudited results for the year ended 31 December 2003 have been prepared in accordance with the accounting policies applied in 2003. These are unchanged from those set out in the Report and Accounts for the year ended 31 December 2002. 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 2002 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.

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.

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 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.

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)/profit 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 2003 £ 000	Year to 31 December 2002 £ 000
(a)	**Turnover**		
	By class of business:		
	Pharmaceuticals		
	Contract development and licensing		
	Milestone payments	**24,196**	47,736
	Research and development costs recharged	**5,456**	7,705
		29,652	55,441
	Royalties receivable	**18,701**	6,751
	Manufacturing and distribution	**4,799**	7,381
		53,152	69,573
	By location of customer:		
	UK	**21,327**	21,000
	Europe	**18,027**	10,333
	North America	**10,289**	34,047
	Rest of the world	**3,509**	4,193
		53,152	69,573
	By location of operation:		
	Europe	**42,503**	34,449
	North America	**10,649**	35,124
		53,152	69,573
(b)	**Cost of sales**		
	By class of business:		
	Pharmaceuticals		
	Contract development and licensing	**(12,085)**	(12,649)
	Royalties payable	**(4,707)**	(1,374)
	Manufacturing and distribution	**(12,994)**	(10,807)
		(29,786)	(24,830)

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

2 Segmental analysis (continued)

		Year to 31 December 2003 £ 000	Year to 31 December 2002 £ 000
(c)	**(Loss)/profit on ordinary activities before taxation**		
	By class of business:		
	Pharmaceuticals	**(42,983)**	1,333
	By location of operation:		
	UK	**(5,825)**	(7,695)
	Europe	**(3,424)**	7,652
	North America	**(30,270)**	4,759
	Operating (loss)/profit	**(39,519)**	4,716
	Net interest payable	**(3,464)**	(3,383)
	(Loss)/profit on ordinary activities before taxation	**(42,983)**	1,333

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 DepoMorphine, Xatral® OD, Solaraze® and DepoCyt®. Paul Capital will receive 15% of the annual royalties and revenues from the stated products up to a predetermined ceiling for the period until 31 December 2014. Once the predetermined ceiling is reached, the percentage participation will fall to 3% for the remainder of the period until 31 December 2014. Income of £1.1 million (2002: £9.7 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 £1.0 million (2002: £Nil) have been expensed during the year.

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. Paul Capital will receive between 4% and 20% of the annual royalties and revenues from the nine products up to a predetermined ceiling for the period until 31 December 2015. The 20% rate applies first and the percentage then falls, when an agreed ceiling is reached, to 12.5% until a second ceiling is reached, before falling to 4% for the remainder of the period until 31 December 2015. During 2002 and 2003 the 20% rate was reduced based on the percentage of the total $30 million that had been provided. Income of £5.0 million (2002: £4.5 million) was recognised as Other operating income under this agreement on a cost to complete basis. Royalty payments to Paul Capital of £2.2 million (2002: £0.7 million) have been expensed during the year.

4 Exceptional items

The operating exceptional items included within administration expenses are categorised as follows:

	£ 000
Restructuring costs	(2,673)
Impairment of intellectual property	(2,673)
Impairment of tangible fixed assets	(1,324)
Write down of fixed asset investments	(1,599)
Settlement of licensing dispute	(1,218)
	(9,487)

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

4 Exceptional items (continued)

The exceptional charge includes £2.7 million relating to the reorganisation of some research and development operations and other business functions, involving some staff redundancies at most sites. The reorganisation is expected to be completed during 2004. A further £4.0 million is in respect of the impairment of associated intellectual property and tangible fixed assets. In addition, £1.6 million relates to a write down in value of fixed asset investments.

5 Earnings per Ordinary Share

	Year to 31 December 2003 £ 000	Year to 31 December 2002 £ 000
Attributable (loss)/profit before exceptional items and amortisation	**(27,067)**	7,615
Exceptional items	**(9,487)**	
Amortisation	**(6,669)**	(6,506)
Basic and diluted attributable (loss)/profit	**(43,223)**	1,109
	000	**000**
Basic weighted average number of shares in issue	**609,855**	577,018
Dilution for potential Ordinary Shares		20,077
Diluted weighted average number of shares in issue	**609,855**	597,095
Earnings per Ordinary Share before exceptional items and amortisation	**(4.4p)**	1.3p
Exceptional items	**(1.6p)**	
Amortisation	**(1.1p)**	(1.1p)
Basic earnings per Ordinary Share	**(7.1p)**	0.2p
Diluted earnings per Ordinary Share	**(7.1p)**	0.2p

In 2003 there is no difference between basic and diluted earnings per Ordinary Share since all potential Ordinary Shares including convertible bonds, warrants and options are anti-dilutive. For diluted earnings per Ordinary Share in 2002, the weighted average number of Ordinary Shares in issue is adjusted to assume conversion of all dilutive potential Ordinary Shares. Shares held by SkyePharma PLC General Employee Benefit Trust are excluded from the weighted average number of shares.

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

6 Intangible fixed assets

	Goodwill £ 000	Intellectual property £ 000	Development costs £ 000	Total £ 000
Cost				
At 1 January 2003	80,017	34,560	1,778	116,355
Exchange adjustments		(1,085)	(66)	(1,151)
Additions	2,713	2,652		5,365
At 31 December 2003	82,730	36,127	1,712	120,569
Amortisation				
At 1 January 2003	9,953	5,539	848	16,340
Exchange adjustments		(155)	(54)	(209)
Charge for the year	4,072	2,379	218	6,669
Impairment (note 4)		2,673		2,673
At 31 December 2003	14,025	10,436	1,012	25,473
Net book value at 31 December 2002	70,064	29,021	930	100,015
Net book value at 31 December 2003	68,705	25,691	700	95,096

The deferred consideration of 3,690,211 SkyePharma Ordinary Shares issued to the former RTP shareholders during the year has been recorded within goodwill.

The £2.2 million ($3.5 million) paid to Enzon for access to its PEG modification technology during the year has been recorded within intellectual property.

7 Fixed Asset Investments

	Unlisted investments £ 000	Own shares £ 000	Total £ 000
Cost			
At 1 January 2003	18,874	1,028	19,902
Exchange adjustments	(87)		(87)
Additions	4,836	925	5,761
Charge for the year		(558)	(558)
Write down (note 4)	(1,599)		(1,599)

At 31 December 2003	22,024	1,395	23,419

Astralis Limited

Astralis is an emerging biotechnology company based 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.

During the year the Group acquired 250,000 series A convertible preferred shares of Astralis for £1.5 million ($2.5 million). As at 31 December 2003 the total SkyePharma holding was 2 million series A convertible preferred shares, 200,000 common shares and 20,000 warrants, representing approximately 25.4% of the common shares assuming conversion of the preferred shares and warrants. The investment is not regarded as an associated undertaking as the Directors have concluded that the Group does not exercise significant influence. The convertible preferred shares, common shares and warrants are recorded at a cost of £14.2 million. As at 31 December 2003 Astralis had net assets of £3.5 million (31 December 2002: £4.9 million) and a retained loss for the year of £3.1 million (2002: £12.2 million).

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

7 Fixed Asset Investments (continued)

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.

Micap plc

Micap is a UK science-based technology company which was listed on the Alternative Investment Market in August 2003.

During the year the Group acquired 5,238,334 ordinary shares, representing approximately 18.2% of the ordinary share capital, and 1,830,000 convertible shares of Micap for £2.1 million. The shares are recorded at cost.

Transition Therapeutics Inc

Transition Therapeutics is a biopharmaceutical company based in Canada and engaged primarily in the business of developing products for the treatment of multiple sclerosis, diabetes and restenosis.

As at 31 December 2003, the total SkyePharma holding of Transition Therapeutics was 4,930,814 shares, representing approximately 6.6% of the ordinary share capital. The shares are recorded at a net cost of £0.6 million.

Vital Living Inc

Vital Living primarily develops and markets evidence-based nutriceuticals. 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.

At 31 December 2002 SkyePharma held 1 million convertible preference shares in e-nutriceuticals Inc, based in the US, representing approximately 14.2% of the ordinary share capital assuming conversion. In August 2003 e-nutriceuticals merged with Vital Living and as a result of the merger SkyePharma acquired 14,204,548 common shares in Vital Living.

During the year the Group acquired 1 million series D convertible preferred shares, $1 million of 12% senior secured convertible notes due 2008 and 1 million warrants expiring 2008 of Vital Living for £1.2 million ($2.0 million). As at 31 December 2003 the total SkyePharma holding was 14,204,548 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 24.4% of the ordinary share capital, 28.1% assuming conversion of the preferred shares, notes and warrants. The investment is not regarded as an associated undertaking as the Directors have concluded that the Group does not exercise significant influence. The investment is recorded at £5.1 million, comprising shares recorded at Directors valuation based on a number of considerations including comparable transactions and discounted future cash flows, and notes and warrants recorded at cost. The most recent accounts available are as at 30 September 2003 when Vital Living had net assets of £27.8 million and a retained loss for the nine month period of £10.1

million.

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 2003, 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.

Own shares

During 2001 the Company established an employee share ownership trust, the SkyePharma PLC General Employee Benefit Trust. The purpose of the trust is to hold shares in the Company, which may subsequently be awarded to Directors and employees under the Deferred Share Bonus Plan and Share Purchase Plans. During the year, the trust purchased

NOTES TO THE PRELIMINARY ANNOUNCEMENT continued

7 Fixed Asset Investments (continued)

2 million shares and approximately 1.1 million shares were allocated at an average price of 51 pence per share. As at 31 December 2003 the trust held approximately 2.7 million shares at a carrying value of £1.4 million and a market value of £2.1 million.

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.