

SKYEPHARMA PLC  
Form 6-K  
September 28, 2006

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a - 16 OR 15d - 16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of September, 2006**

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**SkyePharma PLC**

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

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

**(Address of principal executive office)**

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

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Form 20-F  Form 40-F

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

Yes No

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

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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: 28 September, 2006

For Immediate Release

28 September, 2006

SkyePharma PLC

**Interim Results Announcement for the Six Months Ended 30 June 2006**

LONDON, ENGLAND, 28 September 2006 SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces today financial results for the six months ended 30 June 2006.

**Operating highlights**

**Marketed products:**

Sales of royalty-earning products reported by SkyePharma's partners have largely met or exceeded our expectations

**Pipeline progress:**

DepoDur approved in UK

DepoCyt® approved in Australia

zileuton CR filed by Critical Therapeutics

Lodotra filed by Nitec

Foradil® Certihaler successfully modified and modifications filed with the FDA

Flutiform commenced Phase III trials

**New corporate agreements:**

Flutiform licensed to Kos Pharmaceuticals for USA

Flutiform licensed to Mundipharma for Europe

DepoBupivacaine rights regained from Mundipharma

Development of nisoldipine CR for Sciele Pharma

Negotiations ongoing to divest the Injectables unit

**Financial highlights**

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Revenue £25.6m (2005: £36m)

Royalties £11.5m (2005: £12m)

R&D spend £19.2m (2005: £10.9m)

Gross Profit £12m (2005: £21.4m)

Loss before tax £26.4m (2005: £12.8m)

Loss per share 3.5p (2005: 2.1p)

Net cash £21.8m (2005: £19.0m)

**Frank Condella, Chief Executive, commented:**

SkyePharma has made significant progress on the strategic objectives put forward this year. With our new management team in place, we have licensed Flutiform, our major pipeline asset, in both the USA and Europe. We have also expanded our development pipeline while improving our operational efficiency. Throughout the remainder of this year we look forward to continue executing on our strategic plan, including the divestiture of our injectables unit as an outright sale or under the possible alternative scenario of the out-licensing of DepoBupivacaine.

We continue to believe that if we deliver on our strategic objectives we will reach sustainable profitability and create value for shareholders.

**For further information please contact:**

**SkyePharma PLC**

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**Notes for editors**

**About SkyePharma**

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now eleven approved products incorporating SkyePharma's technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit <http://www.skyepharma.com/>.

*Certain statements in this news release are forward-looking statements and are made in reliance on the safe harbour provisions of the U.S. Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that these expectations will materialize. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward-looking statements based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. Factors that could cause differences between actual results and those implied by the forward-looking statements contained in this news release include, without limitation, risks related to the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.*

**CHAIRMAN'S STATEMENT**

SkyePharma has made substantial progress on executing our strategic plan announced earlier this year.

**1. Appoint new leadership**

SkyePharma's founder Ian Gowrie-Smith resigned from the Board in January and I was appointed Non-executive Chairman in his place. A new executive management team has also been appointed with Frank Condella as Chief Executive and Dr Ken Cunningham as Chief Operating Officer. Both have now joined the Board.

**2. Divest the injectables unit**

This is a stand-alone operation in San Diego with its own management team, manufacturing facilities for marketed products (DepoCyt® and DepoDur), and R&D activities with a pipeline of products including DepoBupivacaine and several therapeutic proteins. We retained UBS as our investment bank to manage the divestment process. We are in active negotiations with several parties interested in acquiring the entire business unit, with terms likely to include a combination of upfront and milestone payments and royalties on product sales. In addition a number of parties have expressed their interest in licensing DepoBupivacaine, the major pipeline asset. We are therefore in parallel negotiations regarding a potential licence. Under this option, we would expect an upfront payment and full funding of further development of DepoBupivacaine, milestone payments and a longer term royalty stream. Should we pursue the licence option, we would plan to reduce the size of the unit, minimizing the ongoing cash burn, and pursue the future divestment of the remaining components of this business unit. We aim to complete a transaction before the end of the year.

**3. Continue Phase III for Flutiform and out-license this year**

Phase III trials started in February as planned, and represents our major R&D expenditure until anticipated completion in mid-2007. The 12 month safety study is ongoing and the three pivotal studies have also commenced recently, all on track for our target of filing with the FDA in the second half of 2007 and in Europe in 2008. In May, we granted exclusive US marketing rights for Flutiform to Kos Pharmaceuticals, a US specialty pharmaceutical company with a highly successful sales record and experience in the respiratory market. We are convinced that Kos has an ideal profile to optimise sales of Flutiform in the key US market and we are gratified by their obvious commitment to the product. We have recently announced a partnership with Mundipharma for Europe and other territories.

**4. Focus on core oral/inhalation unit and expand pipeline**

In June SkyePharma's Business Review day disclosed two new projects about to enter clinical trials: a treatment for pain and inflammation and a novel approach to the treatment of sleep disorders. We also announced one new partnered project (a controlled release version of Sular® (nisoldipine), the lead product of Sciele Pharma, our US partner for Triglide), and two late-stage products that have now been filed: a controlled

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release version of the oral asthma drug Zyflo<sup>®</sup> for Critical Therapeutics and Lodotra, a delayed release formulation of an anti-inflammatory drug for rheumatoid arthritis for Nitec. We are seeking additional complementary projects to reinforce our pipeline.

### **5. Improve operational efficiency**

We have been reviewing all costs, but remain committed to prudent R&D expenditure as it is the future of the company. Having completed a survey of the London market, we have found the rent of our existing offices to be highly competitive. Regardless, we have reduced our space requirements and halved the costs of our London head office. Also, we are vacating our US office in New York which will further reduce overheads. We have reviewed overall staffing levels and reduced the number of personnel at our plant in Lyon. Finally, we have restructured our investor relations, legal and company secretarial functions.

We are confident that the strategy we have adopted will enable the Company to maximise the potential of Flutiform and other pipeline products, to become profitable and to deliver long-term value for shareholders.

**Dr Jerry Karabelas**

**Non-Executive Chairman**

## REVIEW OF OPERATIONS

### Inhalation Products

For Foradil® Certihaler® (formoterol) we developed not only the multidose dry-powder inhaler device but also the formulation technologies designed to ensure dose consistency regardless of storage conditions. This product has now been approved in 26 countries in Europe, the Middle East, Latin America, South Africa and New Zealand. After launch in two European markets in late 2005, the product was voluntarily withdrawn by Novartis early this year because a small number of patients received an incorrect dose after mishandling the device. We have now successfully made modifications to the inhaler to ensure proper handling that we hope will allow Foradil® Certihaler® to be returned to the market in Europe and to obtain approval in the USA. We have filed modifications to the Certihaler® with the FDA and we expect a decision on this in late 2006.

### Inhalation pipeline

AstraZeneca has now received the first approvals in Europe, in Finland and Latvia, for the inhaled steroid Pulmicort® (budesonide) in a metered-dose aerosol inhaler (MDI) powered by a hydrofluoroalkane (HFA) propellant gas.

Flutiform HFA-MDI (a fixed-dose combination of formoterol and the inhaled steroid fluticasone) commenced its Phase III trial in February, on target, and remains on track for a target US filing date of H2 2007.

In May we announced that we had entered into an agreement with Kos Pharmaceuticals, Inc. to jointly develop Flutiform, our novel combination product for asthma and chronic obstructive pulmonary disease ( COPD ). In September we announced a parallel agreement with Mundipharma International to develop Flutiform for Europe. Both Kos and Mundipharma share our belief in the high potential of Flutiform as a superior product concept, differentiated from competing combination asthma products, and poised to take advantage of a clear window of opportunity.

Kos will have exclusive rights to market Flutiform in the US and a right of first negotiation for Canada. SkyePharma could receive up to \$165 million in milestone payments on achievement of all regulatory and revenue targets (of which \$25 million was paid upfront) together with royalties starting in mid-teens on sales by Kos. We will share with Kos the development of Flutiform for asthma and COPD: we will manage and fund the trials needed for approval of Flutiform in adult asthma while Kos will manage and fund the trials needed for all other indications and all marketing and post-approval studies. The US represents the largest market opportunity for Flutiform, forecast to exceed \$6 billion by 2009 when we expect Flutiform to be launched.

Mundipharma will have exclusive rights in Europe and other territories. We received an upfront payment of 15 million (\$19 million) on signature and could receive additional milestone payments of up to a further 70 million (\$90 million) on attainment of various development and revenue targets, together with double digit royalties. Mundipharma will have access to data from the trials we are conducting for FDA approval, which will be used as the basis for obtaining European approval. Mundipharma will also conduct, at its own expense, an additional clinical study needed for regulatory approval in Europe and also the studies needed to extend the indication to paediatric patients and to a higher dose strength. The costs of these studies will be recouped from future royalty and milestone payments to SkyePharma.

In a second collaboration with Novartis, the Certihaler and related formulation technology have been applied to QAB149 (indacaterol), which has completed Phase II development in both asthma and COPD. While Novartis has progressed to Phase III with another device, the QAB149 Certihaler project is on hold, pending finalization by Novartis of development plans for this formulation and full implementation of the device modifications.



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## Oral and Topical Products

US marketing of Paxil CR was suspended for four months in 2005 because of manufacturing problems at GlaxoSmithKline's plant in Puerto Rico. Even after returning to the market, new administrative procedures, introduced as part of a consent decree with the FDA, have resulted in continuing supply constraints and sales have not returned to the pre-withdrawal level. In the first half of 2006 sales were up by 22% in the US on the prior year period to \$141 million, on which we earned a royalty of 4%. However, royalty income was down since during the first half of 2005 we were paid royalties based on higher budgeted sales. The first US generic competitor for Paxil CR could enter the market in the second half of 2007.

Xatral® OD (Uroxatral® in the USA) is our once-daily version of Sanofi-Aventis's Xatral® (alfuzosin), a treatment for the urinary symptoms of benign prostatic hypertrophy. European sales have started to be affected by generic competition after the expiry of a key European patent in May, however the impact was offset by strong growth in the US. In the first half of 2006, reported sales of all forms of Xatral® were 186 million (\$229 million), up by 16% on the prior year period.

Solaraze®, our topical gel treatment for actinic keratosis, is marketed in the US by Bradley Pharmaceuticals. Sales in the first half of 2006 more than doubled to \$10.0 million. Sales in Europe and certain other territories by Shire Pharmaceuticals were \$6.9 million, up by 28% on the prior year period. Both partners are actively involved in campaigns to raise awareness of the risks posed by this common condition, an early form of skin cancer. Although Solaraze® has been approved and marketed in the USA and Europe for several years, we have recently been informed by the Australian regulatory authority that it will not approve the product.

Triglide (fenofibrate) is marketed in the US by Sciele Pharma, Inc. (formerly known as First Horizon Pharmaceutical Corporation). Triglide, an oral treatment for elevated blood lipid disorders, was launched in July 2005. By mid-2006, Triglide had captured 1.8% of new prescriptions for fenofibrate and 1.4% of total prescriptions and was one of the key drivers in Sciele's strong first half revenue growth.

## Oral pipeline

Requip Once-a-day tablets for Parkinson's disease, developed in partnership with GlaxoSmithKline, was filed at the end of 2005 in Europe and is expected to receive pan-European approval in the second half of 2007. The US NDA filing was withdrawn for technical reasons but is expected to be resubmitted in the fourth quarter of 2006.

We have developed an improved formulation of the oral asthma drug zileuton for Critical Therapeutics. Zileuton is a highly potent anti-inflammatory drug for treating severe asthma but the current version (marketed as Zyflo®) has to be taken four times a day. Our twice-daily version was filed with the FDA at the end of July. Our partner expects it to reach the market in the second half of 2007.

Lodotra, developed for Nitec, is a novel modified-release formulation of a widely-used anti-inflammatory drug for treating the pain and stiffness caused by rheumatoid arthritis. With our Geoclock delivery system the drug can be taken at bedtime but released in the early hours of the morning, the optimum time. Nitec has now filed the product in Europe. Merck KGaA has marketing rights for Germany and Austria. Nitec is currently in negotiations with potential licensees for other markets.

In May we entered into an agreement with Sciele Pharma (our US licensee for Triglide) to develop an improved version of Sciele's leading product Sular® (nisoldipine), a calcium channel blocker antihypertensive. This product is expected to be filed in the first half of 2007 and to enter the US market in the first half of 2008.

## Injectable products

Sales of DepoCyt® in the USA by our partner Enzon were \$4.0 million, up 15% on the prior year. Our European partner Mundipharma had sales of \$4.6 million, more than double the 2005 level. DepoCyt® is currently approved for the treatment of lymphomatous meningitis, a very rare condition. As a condition of US approval SkyePharma was required to conduct a Phase IV study: data from this trial has been filed with the FDA and we expect a decision in April 2007. We are seeking to expand the current indication to the most common form of neoplastic meningitis, associated with solid tumours. We have recently decided to withdraw our European filing in order to incorporate data from additional patients. Encouragingly, we have recently received approval for the treatment of all forms of neoplastic meningitis in Australia, where we are in the process of appointing a licensee.

DepoDur is our sustained-release injectable morphine analgesic for the treatment of pain after surgery. Sales by our US marketing partner Endo Pharmaceuticals in the first half of 2006 were \$1.6 million. Endo considers that the product is still in its launch phase. In the UK, we received approval in May which will be used as the basis for seeking approval throughout the European Union under the EU's Mutual Recognition procedure.

**Injectable pipeline**

Our long-acting local anaesthetic DepoBupivacaine is expected to commence Phase III trials later this year. In July we regained European rights from Mundipharma. This allows us to offer rights to this product in both the US and Europe as part of our divestment plans. We believe that DepoBupivacaine, for the relief of pain after surgery, has significant market potential.

In April we agreed with our US partner Endo Pharmaceuticals to halt development of Propofol IDD-D, an injectable anaesthetic and sedative.

**Frank Condella**

**Chief Executive Officer**

## Financial Review

### Revenue

The Group's revenues are sensitive to the timing and recognition of milestone payments and up-front payments received on the signing of new agreements. Revenues for the first six months of 2006, at £25.6 million, were 29% below the £36.0 million reported in the first half of 2005, primarily due to the phasing of recognition of up-front revenues received in 2006 for the US marketing and distribution rights for Flutiform.

Contract development and licensing revenue in the half year decreased by £9.3 million to £10.2 million, compared with £19.5 million in 2005. Revenues recognised from milestone payments and up-front payments received on the signing of agreements amounted to £8.3 million in the first half of 2006 compared with £17.6 million in 2005, primarily due to differences in revenue recognition for up-front payments received. Under SkyePharma's accounting policy for revenue recognition, up-front payments are generally deferred and recognised over the period of development up to filing. Consequently, while SkyePharma received £13.4 million (\$25 million) in May 2006 from Kos for the US marketing rights to Flutiform, only £2.9 million was recognised in the first half of 2006. By contrast in the first half of 2005 we were able to recognise £10.7 million from the payment from Sciele Pharma for the approval of Triglide. Research and development costs recharged remained constant at £1.9 million.

The recent up-front payment of £10.1 million (£15.0 million) received on signature of a licensing transaction with Mundipharma for European rights to Flutiform will result in a significant increase in the total revenue in respect of Flutiform that can be recognised in the second half of 2006, compared with the £2.9 million recognised in the first half of 2006.

Royalty income decreased slightly to £11.5 million, compared with £12.0 million in the first half of 2005. During the early part of 2005 the Company received royalties based on GlaxoSmithKline's budgeted sales of Paxil CR while the product was temporarily off the market as a result of GSK's suspension of production at their Cidra plant in Puerto Rico. The slight decrease in 2006 was due to a 48% fall in Paxil CR royalty income: although the product returned to the market in June 2005, continuing supply constraints mean that sales have not fully recovered to the pre-withdrawal level. This was largely offset in 2006 by an increase in royalty income from DepoCyt®, Triglide, Xatral® and Coruno®. Excluding Paxil CR, royalties for the balance of SkyePharma's other products grew by 50% in the first half of 2006 compared with the first half of 2005.

Manufacturing and distribution revenue decreased by £0.6 million in the first half to £3.9 million, compared with £4.5 million in the first half of 2005, primarily due to a fall in the production of clinical trial material for Novartis in respect of QAB 149 following the withdrawal of Foradil® Certihaler from the market.

### Deferred income

During the first half of 2006, there was a net increase in deferred income of £3.8 million under SkyePharma's revenue recognition policy. The movement in deferred income was as follows:

	31 December 2005 £m	Received * £m	Recognised/ Transferred £m	30 June 2006 £m
Contract development and licensing revenue	10.6	16.8	(13.0)	14.4

\* Includes exchange adjustments

### Cost of sales

Cost of sales comprises expenditure on research and development conducted for third parties, primarily 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 decreased by £1.0 million to £13.6 million in the first half of 2006, mainly due to the aforementioned fall in the production of clinical trial material for Novartis in respect of QAB 149. The resulting gross profit decreased 44% to £12.0 million, compared with £21.4 million in the first half of 2005.

**Expenses**

Selling, marketing and distribution expenses increased to £1.6 million in the first half of 2006, compared with £0.5 million in the first half of 2005, due primarily to SkyePharma's contribution towards the marketing costs of Triglide. The expenses for the 2005 calendar year of £5.9 million included a contribution towards the marketing costs of DepoDur which SkyePharma is no longer obliged to make.

Amortisation of intangible assets increased slightly to £1.1 million in the first half 2006, compared with £1.0 million in the first half of 2005. Other administration expenses were £10.0 million in 2006, £0.9 million higher than the £9.1 million reported in 2005, mainly due to the additional costs of the Strategic Review and the EGM.

SkyePharma's own research and development expenses in the period increased by £8.3 million to £19.2 million, mainly due to the development expenditure incurred on the start of the Flutiform phase III clinical trials.

The other income of £0.4 million is mainly due to the profit on disposal of the Group's holding in Vectura Group plc and certain Vital Living Inc securities.

**Results**

The operating loss was £19.5 million in the half year 2006, compared with £0.3 million in the comparable period in 2005, due principally to the reduction in revenue, the increased R&D costs for Flutiform phase III clinical trials and the additional costs of the Strategic Review and EGM.

The finance costs of £9.3 million (first half of 2005: £12.3 million) mainly comprise notional interest on the Paul Capital funding liabilities as well as the interest payable on the convertible bonds. The finance income of £2.6 million in 2006 includes £1.8 million of foreign exchange gains (first half of 2005: loss of £3.1 million) relating to the Paul Capital funding liabilities which are denominated in US dollars. As at 31 December 2005 the Paul Capital obligations were revised to reflect a change in estimated future payments, resulting in additional finance income of £9.0 million.

The Group's share of the losses of Astralis was £0.2 million for the first half 2006, compared with £0.6 million in the first half of 2005.

The retained loss increased by £13.7 million to £26.6 million, also due primarily to the fall in revenue and the higher costs as a result of the Flutiform clinical trials.

Earnings before interest, tax, depreciation and amortisation showed a loss of £15.8 million in the first half of 2006, compared with a profit of £3.2 million in the comparable period in 2005.

The loss per share for the first half of 2006 was 3.5 pence, which compares with 2.1 pence in the first half of 2005.

Foreign currency movements did not have a material impact on the results of operations in the first half 2006 compared with the comparable period in 2005.

**Segment information**

Segmental information on revenue and operating loss is as follows:

	6 months to 30 June 2006	6 months to 30 June 2005
	£m	£m
<b>Revenue</b>		
Injectable	3.9	5.1
Oral and Inhalation	21.7	30.9
	<b>25.6</b>	<b>36.0</b>

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<b>Operating (loss)/ profit</b>		
Injectable	(11.7)	(7.2)
Oral and Inhalation	(7.8)	6.9
	<b>(19.5)</b>	<b>(0.3)</b>

The £9.2 million fall in Oral and Inhalation revenue in the first half of 2006 is primarily due to the aforementioned timing of revenue recognition on the up-front payment received on the licensing of US marketing and distribution rights for Flutiform to Kos.

The £14.7 million increase in Oral and Inhalation operating loss is caused principally by the reduction in revenue and the increased costs arising from the start of the Flutiform phase III clinical trials.

The operating loss by segment includes an allocation of corporate costs to each segment.

## Balance sheet

The Group balance sheet as at 30 June 2006 shows total shareholders' equity of £8.1 million (31 December 2005: £31.9 million).

The Group has £69.6 million convertible bonds due May 2024 and £20 million convertible bonds due June 2025 outstanding as at 30 June 2006. On the balance sheet these are reflected as £63.9 million in liabilities and £28.4 million in equity.

In addition the Group has other borrowings at 30 June 2006 of £42.0 million due to Paul Capital. Whilst the contractual arrangements contemplate the payment of a share of our royalty income to Paul Capital, IAS 39; Financial Instruments: Recognition and Measurement requires the Group to record a liability equal to the net present value of the royalties the Group expects to pay Paul Capital over the term of the agreements.

## Liquidity and capital resources

At 30 June 2006 SkyePharma had net cash of £21.8 million, comprising cash and cash equivalents of £22.8 million and a bank overdraft of £1.0 million, compared with £34.3 million net cash at 31 December 2005. Bank and other non convertible debt amounted to £10.3 million at 30 June 2006 (31 December 2005: £9.9 million), consisting principally of a £6.8 million property mortgage secured on the assets of Jago (31 December 2005: £6.9 million). In addition the Group has 6% convertible bonds due May 2024 of £69.6 million (31 December 2005: £69.6 million) and 8% convertible bonds due June 2025 of £20.0 million (31 December 2005: £20.0 million). Net debt (excluding the Paul Capital funding liabilities) amounted to £51.4 million (31 December 2005: £39.2 million).

In the first half 2006 there was a net cash outflow from operating activities of £2.3 million, compared with a net inflow of £4.5 million in the first half of 2005. During the 2006 period the Group spent £1.4 million on property, plant and equipment; and expenditure on intangible assets of £1.1 million, mainly related to the purchase of licenses to intellectual property in the area of pulmonary delivery. The proceeds on disposal of the holding in Vectura Group plc and certain Vital Living Inc securities were £1.3 million.

Borrowings of £6.5 million were repaid in the period, primarily comprising Paul Capital's share of the Group's royalty income. In addition the Group paid £3.1 million of interest during in first half 2006, mainly relating to the convertible bonds.

The results for the period to 30 June 2006 have been formally reviewed and reported on by Ernst & Young LLP the Company's new auditors. The auditors' independent review report is modified in two respects:

They were appointed auditors on 21 August 2006 and did not report on the financial information as presented in the 30 June 2006 financial statements for the period ended 30 June 2005. For that reason they have not reviewed the 30 June 2005 comparatives as would be required for a full review in accordance with Bulletin 1999/4.

Their report contains an emphasis of matter paragraph drawing attention to the uncertainties outlined in Note 1 to the financial statements included in the interim review. Their review opinion is not qualified in this regard.

The auditors' conclusion is that they are not aware of any material modifications that should be made to the financial information as presented for the six months ended 30 June 2006.

## International Financial Reporting Standards

Since the 2005 Interim Report the Group has changed its interpretation of the application of IAS 39 to the Paul Capital funding liabilities. Previously the proceeds received from Paul Capital were treated as a floating rate financial liability, and any change in the estimated future payments to Paul Capital was effectively spread forward and reflected in a reduced implicit interest cost in future years. Following the change in the year ended 31 December 2005, the estimated payments to Paul Capital are discounted using each contract's original effective interest rate, and any change in the estimated future payments to Paul Capital is recognised immediately as an income or expense in the income statement.

The restatement resulted in an increase in the first half 2005 finance costs of £3.6 million, and a decrease in the Paul Capital funding liabilities at 30 June 2005 of £1.7 million.

## Forward looking statements

The foregoing discussions contain certain forward looking statements and are made in reliance on the safe harbour provisions of the US Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations reflected in these forward looking statements are

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reasonable, it can give no assurance that these expectations will materialise. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward looking statements based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. Factors that could cause differences between actual results and those implied by the forward looking statements contained in these Interim Financial Statements include, without limitation, risks related to the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward looking statement to reflect events or circumstances after the date of these Interim Financial Statements.

**Donald Nicholson**

**Finance Director**

**CONSOLIDATED INCOME STATEMENT**

for the six months ended 30 June 2006

		Unaudited 6 months to 30 June 2006	Unaudited 6 months to 30 June 2005 (restated)	Audited 12 months to 31 December 2005 Pre-		
	Notes	£m	£m	exceptional £m	Exceptional £m	Total £m
Revenue	2	25.6	36.0	61.3		61.3
Cost of sales		(13.6)	(14.6)	(29.2)		(29.2)
<b>Gross profit</b>		<b>12.0</b>	<b>21.4</b>	<b>32.1</b>		<b>32.1</b>
Selling, marketing and distribution expenses		(1.6)	(0.5)	(5.9)		(5.9)
Administration expenses						
Amortisation of other intangibles		(1.1)	(1.0)	(2.1)		(2.1)
Other administration expenses		(10.0)	(9.1)	(13.8)	(21.4)	(35.2)
		(11.1)	(10.1)	(15.9)	(21.4)	(37.3)
Research and development expenses		(19.2)	(10.9)	(26.0)		(26.0)
Other income/ (expense)		0.4	(0.2)	(0.4)		(0.4)
<b>Operating loss</b>		<b>(19.5)</b>	<b>(0.3)</b>	<b>(16.1)</b>	<b>(21.4)</b>	<b>(37.5)</b>
Finance costs	3	(9.3)	(12.3)	(22.3)		(22.3)
Finance income	3	2.6	0.4	10.0		10.0
Share of loss in associate		(0.2)	(0.6)	(0.8)		(0.8)
<b>Loss before income tax</b>		<b>(26.4)</b>	<b>(12.8)</b>	<b>(29.2)</b>	<b>(21.4)</b>	<b>(50.6)</b>
Income tax expense		(0.2)	(0.1)	(0.3)		(0.3)
<b>Loss for the period</b>		<b>(26.6)</b>	<b>(12.9)</b>	<b>(29.5)</b>	<b>(21.4)</b>	<b>(50.9)</b>
<b>Basic and diluted earnings per share</b>	4	<b>(3.5p)</b>	<b>(2.1p)</b>	<b>(4.7p)</b>	<b>(3.4p)</b>	<b>(8.1p)</b>

All results represent continuing activities.

See Notes to the Interim Financial Statements.



**CONSOLIDATED BALANCE SHEET**

as at 30 June 2006

	Notes	Unaudited 30 June 2006 £m	Unaudited 30 June 2005 (restated) £m	Audited 31 December 2005 £m
<b>ASSETS</b>				
<b>Non-current assets</b>				
Goodwill		68.7	68.7	68.7
Other intangible assets	5	26.3	27.0	26.8
Property, plant and equipment		34.9	36.5	37.1
Investments in associates	6		16.8	0.2
Available-for-sale financial assets	7	0.4	4.4	1.6
		<b>130.3</b>	<b>153.4</b>	<b>134.4</b>
<b>Current assets</b>				
Inventories		2.3	2.5	3.6
Trade and other receivables		14.8	15.5	14.2
Financial assets at fair value through profit or loss		0.3	0.9	0.4
Cash and cash equivalents		22.8	20.2	34.3
		<b>40.2</b>	<b>39.1</b>	<b>52.5</b>
<b>Total Assets</b>		<b>170.5</b>	<b>192.5</b>	<b>186.9</b>
<b>LIABILITIES</b>				
<b>Current liabilities</b>				
Trade and other payables		(26.9)	(17.4)	(21.0)
Other borrowings	8	(4.3)	(4.5)	(3.4)
Deferred income		(12.0)	(10.8)	(7.7)
		<b>(43.2)</b>	<b>(32.7)</b>	<b>(32.1)</b>
<b>Non-current liabilities</b>				
Convertible bonds	8	(63.9)	(63.4)	(63.6)
Other borrowings	8	(48.0)	(55.4)	(51.1)
Deferred income		(2.4)	(2.4)	(2.9)
Other non-current liabilities		(3.3)	(3.2)	(3.4)
Provisions		(1.6)	(1.6)	(1.9)
		<b>(119.2)</b>	<b>(126.0)</b>	<b>(122.9)</b>
<b>Total Liabilities</b>		<b>(162.4)</b>	<b>(158.7)</b>	<b>(155.0)</b>
<b>Net Assets</b>		<b>8.1</b>	<b>33.8</b>	<b>31.9</b>
<b>SHAREHOLDERS EQUITY</b>				
Share capital		76.6	64.0	76.6
Share premium		345.6	323.3	345.6
Translation reserve		0.6	(0.5)	(1.2)
Fair value reserve		(0.2)	(1.4)	0.2
Retained losses		(452.3)	(389.4)	(427.1)
Other reserves		37.8	37.8	37.8

<b>Total Shareholders' Equity</b>	<b>8.1</b>	<b>33.8</b>	<b>31.9</b>
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See Notes to the Interim Financial Statements.

### CONSOLIDATED STATEMENT OF RECOGNISED INCOME AND EXPENSE

for the six months ended 30 June 2006

	<b>Unaudited</b>	<b>Unaudited</b>	<b>Audited</b>
	<b>6 months to</b>	<b>6 months to</b>	<b>12 months to</b>
	<b>30 June 2006</b>	<b>30 June 2005</b>	<b>31 December 2005</b>
	<b>£m</b>	<b>(restated)</b>	<b>£m</b>
	<b>£m</b>	<b>£m</b>	<b>£m</b>
Net currency translation effect	1.8	0.4	(0.3)
Fair value movements on available for sale investments	(0.4)	(0.9)	0.2
Actuarial gains on defined benefit plans	0.2		
Net profits/ (losses) recognised directly in equity	1.6	(0.5)	(0.1)
Loss for the period	(26.6)	(12.9)	(50.9)
<b>Total recognised income and expense for the period</b>	<b>(25.0)</b>	<b>(13.4)</b>	<b>(51.0)</b>

There were no transactions with equity holders during the period that would require disclosure in accordance with IAS 34; Interim financial reporting.

**CONSOLIDATED CASH FLOW STATEMENT**

for the six months ended 30 June 2006

	Note	Unaudited 6 months to 30 June 2006 £m	Unaudited 6 months to 30 June 2005 £m	Audited 12 months to 31 December 2005 £m
<b>Operating activities</b>				
Cash (used in)/ provided by operating activities	(a)	(2.1)	4.6	(7.6)
Income tax paid		(0.2)	(0.1)	(0.3)
<b>Net cash (used in)/ provided by operating activities</b>		<b>(2.3)</b>	<b>4.5</b>	<b>(7.9)</b>
<b>Investing activities</b>				
Purchases of property, plant and equipment		(1.4)	(1.0)	(2.6)
Purchases of intangible assets		(1.1)	(2.0)	(2.3)
Purchase of shares in associates			(0.2)	(0.2)
Purchase of own shares				(0.4)
Proceeds from disposal of available for sale investments		1.3		1.6
<b>Net cash used in investing activities</b>		<b>(1.2)</b>	<b>(3.2)</b>	<b>(3.9)</b>
<b>Financing activities</b>				
Gross proceeds from rights issue				37.7
Expenses of rights issue				(2.9)
Proceeds from issue of ordinary share capital				0.1
Proceeds from issue of convertible bonds due June 2025			20.0	20.0
Expenses of issue of convertible bonds due June 2025				(1.2)
Repayment of convertible bonds due June 2005			(9.8)	(9.8)
Repayments of borrowings		(6.5)	(5.2)	(7.4)
Interest paid		(3.1)	(2.9)	(6.7)
Interest received		0.7	0.3	0.8
<b>Net cash (used in)/ generated from financing activities</b>		<b>(8.9)</b>	<b>2.4</b>	<b>30.6</b>
<b>Effect of exchange rate changes</b>		<b>(0.1)</b>		<b>0.2</b>
<b>Net (decrease)/ increase in cash and cash equivalents</b>		<b>(12.5)</b>	<b>3.7</b>	<b>19.0</b>
Cash and cash equivalents including bank overdraft at beginning of the period		34.3	15.3	15.3
<b>Cash and cash equivalents including bank overdraft at end of the period</b>		<b>21.8</b>	<b>19.0</b>	<b>34.3</b>

See Notes to the Interim Financial Statements.

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

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	Unaudited	Unaudited	Audited
	6 months to 30 June 2006	6 months to 30 June 2005 (restated)	12 months to 31 December 2005
	£m	£m	£m
<b>Loss for the period</b>	(26.6)	(12.9)	(50.9)
Adjustments for:			
Tax	0.2	0.1	0.3
Depreciation	2.8	3.1	6.2
Amortisation	1.1	1.0	2.1
Impairments			19.4
Fair value loss/ (gain) on derivative financial instruments	0.2	(0.2)	(0.3)
Finance costs	9.3	12.3	22.3
Finance income	(2.6)	(0.3)	(10.0)
Share of loss in associate	0.2	0.6	0.8
Profit on disposal of available for sale financial assets	(0.5)		(0.3)
Other non-cash changes	1.1	1.7	3.2
<b>Operating cash flows before movements in working capital</b>	(14.8)	5.4	(7.2)
<b>Changes in working capital</b>			
Decrease/ (increase) in inventories	1.3	(1.0)	(2.1)
(Increase)/ decrease in trade and other receivables	(0.8)	2.5	4.2
Increase/ (decrease) in trade and other payables	8.2	(2.0)	1.2
Increase/ (decrease) in deferred income	4.1	(0.8)	(3.4)
(Decrease)/ increase in provisions	(0.1)	0.6	(0.3)
<b>Cash (used in)/ provided by operations</b>	(2.1)	4.7	(7.6)

## Notes to the Interim Financial Statements

### 1 Accounting policies General information

SkyePharma PLC (the Company) and its subsidiaries (together the Group) is a speciality pharmaceutical Group which uses its multiple drug delivery technologies to create a product pipeline for out-licensing to marketing partners.

The Company is incorporated and domiciled in United Kingdom, with its registered office at 105 Piccadilly, London W1J 7NJ.

The principal accounting policies adopted in the preparation of these consolidated financial statements are set out below.

#### *(a) Basis of preparation*

In accordance with EU regulations, SkyePharma is required to prepare statutory financial statements which comply with the International Financial Reporting Standards adopted for use in the European Union (IFRS).

The financial statements have been prepared in accordance with International Financial Reporting Standards adopted by the European Union. All IFRS issued by the International Accounting Standards Board (IASB) that were effective at the time of preparing the financial statements and adopted the European Commission for use inside the EU were applied by SkyePharma.

These condensed consolidated financial statements have been prepared in accordance with IFRS and, the interpretations issued by the International Financial Reporting Interpretations Committee (IFRIC) and with those parts of the Companies Act 1985 applicable to companies reporting under IFRS. The financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities. The 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 2005 and in accordance with IAS 34; Interim financial reporting.

The financial statements are unaudited and do not constitute statutory financial statements within the meaning of section 240 of the Companies Act 1985. The results for the period to 30 June 2006 have been formally reviewed and reported on by the auditors. The figures for the year ended 31 December 2005 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 under section 237 (2) or section 237 (3) of the Companies Act 1985.

In order to provide sufficient working capital to fund its strategic priorities, which, as previously reported, include the Group's refocus to concentrate on oral and inhalation products, the Board has determined the need to execute a number of initiatives. Having recently completed an agreement for the licensing of Flutiform in Europe, the Group is negotiating the divestment of its injectable business interests, and the sale of certain non-core assets. The Company's working capital requirements continue to be affected by the structure and timing of transactions which may result from these negotiations. In the event that these initiatives do not provide sufficient funds to meet the Group's short term working capital requirements, and given also that those requirements continue to be affected by the timing and receipt of milestone payments and payments received on the signing of new contracts, the Board has developed a number of contingency plans including the divestment of further non-core assets, various financing arrangements, including obtaining bridging finance, and other strategic initiatives.

The Directors have reviewed the working capital requirements of the Group for the next twelve months and have a reasonable expectation that sufficient funds will be raised from the initiatives in hand and have therefore prepared the financial information contained herein on a going concern basis which assumes that the Company will continue in operational existence for the foreseeable future. The financial statements do not reflect any adjustments that would be required to be made if they were to be prepared on a basis other than the going concern basis.

#### *Use of estimates*

The preparation of the financial statements, in conformity with generally accepted accounting principles, requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates are based on management's best knowledge of the amount, event or actions, actual results may ultimately differ from those estimates.

**(b) Consolidation**

The underlying financial statements comprise a consolidation of the accounts of the Company and all its subsidiaries and includes the Group's share of the results and net assets of its associates.

*Subsidiaries*

Subsidiaries are all entities over which the Group has control. Control is achieved where the Company has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date on which control ceases. The results of subsidiaries acquired or disposed during the period are included in the consolidated income statement from the effective date of acquisition or up to the effective date of disposal, as appropriate.

The Group uses the purchase method to account for the acquisition of subsidiaries. The cost of an acquisition is measured as the fair value of the assets given, equity instruments issued and liabilities incurred or assumed at the date of exchange, plus costs directly attributable to the acquisition. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date, irrespective of the extent of any minority interest. The excess of the cost of acquisition over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If the cost of acquisition is less than the fair value of the group's share of the net assets of the subsidiary acquired, the difference is recognised directly in the income statement.

Inter-company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Subsidiaries' accounting policies have been changed where necessary to ensure consistency with the policies adopted by the Group.

*Associates*

Associates are all entities over which the Group has the power to exercise significant influence but not control generally accompanying a shareholding of between 20% and 50% of the voting rights. Investments in associates are accounted for by the equity method of accounting and are initially recognised at cost. The Group's investment in associates includes goodwill identified on acquisition.

The Group's share of its associates' post-acquisition profits or losses is recognised in the income statement, and its share of post-acquisition movements in reserves is recognised in reserves. The cumulative post-acquisition movements are adjusted against the carrying amount of the investment. When the Group's share of losses in an associate or joint venture equals or exceeds its interest or participation, including any other unsecured long-term receivables, the Group does not recognise further losses, unless it has incurred obligations or made payments on behalf of the associate or joint venture.

Unrealised gains on transactions between the Group and its associates are eliminated to the extent of the Group's interest in the associates. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Associates' accounting policies have been changed where necessary to ensure consistency with the policies adopted by the Group.

**(c) Segment reporting**

The Group's primary segment for IFRS segment reporting is the business segment. A business segment is a group of assets and operations engaged in providing products or services that are subject to risks and returns that are different from those of other business segments.

Geographical regions are the secondary reporting segments. A geographic segment is engaged in providing products or services within a particular economic environment that are subject to risks and return that are different from those of components operating in other economic environments.

Segment reporting reflects the internal management reporting structure and the way the business is managed.

***(d) Revenue recognition***

Revenue comprises the fair value for the sale of goods and services, net of sales taxes, rebates and discounts and after eliminating sales within the Group. Revenue is recognised as follows:

*Contract development and licensing*

Contract development and licensing income represents amounts earned for services rendered under development and licensing agreements, including up-front payments, milestone payments, technology access fees and research and development costs recharged. Revenues are recognised where they are non-refundable, the Group's obligations related to the revenues have been discharged and their collection is reasonably assured. Refundable contract revenue is treated as deferred until such time that it is no longer refundable. In general up-front payments are deferred and amortised on a systematic basis over the period of development to filing. Milestone payments related to scientific or technical achievements are recognised as income when the milestone is accomplished.

*Royalty income*

Royalty income is recognised on an accruals basis and represents income earned as a percentage of product sales in accordance with the substance of the relevant agreement.

*Manufacturing and distribution*

Manufacturing and distribution revenues principally comprise contract manufacturing fees invoiced to third parties and income from product sales. Revenues are recognised upon transfer to the customer of significant risks and rewards, usually upon despatch of goods shipped where the sales price is agreed and collectability is reasonably assured.

***(e) Intangible assets***

*Goodwill*

Goodwill represents the excess of the cost of an acquisition over the fair value of the Group's share of the net identifiable assets of the acquired subsidiary at the date of acquisition. Goodwill is tested annually for impairment and carried at cost less accumulated impairment losses. Goodwill is allocated to cash generating units for the purpose of impairment testing. Each of those cash generating units represents the Group's investment in each country of operation.

*Intellectual property*

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 on a straight line basis over their estimated useful economic lives from the time they are available for use. The period over which the Group expects to derive economic benefits does not exceed 20 years.

*Research and development*

Research expenditure is charged to the income statement in the period in which it is incurred. Development expenditure is capitalised when the criteria for recognising as an asset are met - when it is probable that the project will be a success, considering its commercial and technological feasibility and costs can be measured reliably. Regulatory and other uncertainties generally mean that such criteria are not met. Where development costs are capitalised they are amortised over their useful economic lives from product launch. Prior to product launch the asset is tested annually for impairment.

*Computer software*

Costs that are directly associated with the purchase and implementation of identifiable and unique software products by the Group are recognised as intangible assets. Expenditures that enhance and extend the benefits of computer software programmes beyond their original specifications and lives are recognised as a capital improvement and added to the original cost of the software. Direct costs include the software development employee costs and an appropriate portion of relevant overheads. Software costs are amortised over their useful economic lives, generally a period of 3 to 5 years.

***(f) Impairment of assets***

Assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation or depreciation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. Any impairment loss is charged to the income statement in the period concerned. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash in flows (cash-generating units).

The expected cash flows generated by the assets are discounted using asset specific discount rates which reflect the risks associated with the groups of assets. These risks vary with the nature and the location of the cash generating units.

***(g) Investments***

The Group classifies its investments according to the purpose for which the investments were acquired. Management determines the classification of investments at initial recognition and re-evaluates the designation at every reporting date. The Group has the following categories of investments:

*Available-for-sale financial assets*

Available-for-sale financial assets are non-derivatives that are not acquired to generate profit from short-term fluctuations in price. They are included in non-current assets unless management intends to dispose of the asset within 12 months of the balance sheet date.

Available-for-sale investments are initially recorded at cost, being the fair value of consideration given, plus transaction costs. Subsequently, available-for-sale investments comprising marketable equity securities that are traded in active markets are carried at their fair value as of each balance sheet date.

Unrealised gains and losses arising from changes in the fair value of non-monetary securities classified as available-for-sale investments are recognised in equity. When available-for-sale investments are sold or impaired, the accumulated fair value adjustments in equity are recycled into the income statement as gains and losses from investment securities.

The Group assesses at each balance sheet date whether there is objective evidence that a financial asset or a group of financial assets is impaired. If any such evidence exists for available-for-sale financial assets, the cumulative loss – measured as the difference between the acquisition cost and the current fair value, less any impairment loss on that financial asset previously recognised is removed from equity and recognised in the income statement. Impairment losses recognised in the income statement on equity instruments are not reversed through the income statement.

*Financial assets at fair value through profit or loss*

The Group classifies investments in this category if acquired principally for the purpose of selling in the short term or if so designated by management. Financial assets at fair value through profit or loss are initially recorded, and subsequently carried, at fair value. Realised and unrealised gains and losses arising from changes in the fair value of assets held in this category are included in the income statement in the period in which they arise. Financial assets at fair value through profit or loss are classified as current assets if they are either held for trading or are expected to be realised within 12 months of the balance sheet date.



**2 Segment information**

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

**Revenue by business segment:**

	6 months to	6 months to	12 months to
	30 June 2006	30 June 2005	31 December 2005
	£m	£m	£m
Injectable	3.9	5.1	10.5
Oral and Inhalation	21.7	30.9	50.8
	<b>25.6</b>	<b>36.0</b>	<b>61.3</b>
Revenue earned can be analysed as:			
Contract development and licensing			
Milestone payments	8.3	17.6	22.1
Research and development costs recharged	1.9	1.9	5.5
	10.2	19.5	27.6
Royalties	11.5	12.0	21.7
Manufacturing and distribution	3.9	4.5	12.0
	<b>25.6</b>	<b>36.0</b>	<b>61.3</b>

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