

Preliminary statement of annual results

SkyePharma PLC (LSE: SKP), LONDON, ENGLAND, 25 March 2010

### Summary of Results for the year ended 31 December 2009

	2009	2008
	£'m	£'m
<b>Results</b>		
Revenue	55.9	62.2
Net research and development expenditure	10.3	17.1
Pre-exceptional operating profit	15.1	10.9
Net loss after tax (post exceptional)	(1.4)	(28.7)
Pre-exceptional earnings before interest, tax, depreciation and amortisation ("EBITDA")	18.6	16.3
<b>Net debt and liquidity</b>		
Net debt (total debt less cash*)	107.1	115.8
Liquidity - cash and cash equivalents plus undrawn facilities	29.3	38.0

\* Net debt is as shown in the balance sheet, which is presented under IFRS

### Financial Summary

- Trading in line with Board's expectations - revenues down 10% to £55.9m (2008: £62.2m) due to lower milestones in 2009 and non-recurring manufacturing revenues in prior year
- Pre-exceptional operating profit up 39% to £15.1m (2008: £10.9m), reflecting significantly lower net R&D expenditure, cost savings, product price increases and £1.9 million cash received relating to prior year royalties
- Net loss significantly reduced to £1.4m (2008: loss of £28.7m), post exceptional items, finance charges and tax
- Strong pre-exceptional EBITDA up 14.1% to £18.6m (2008: £16.3m)
- Cash and undrawn facilities of £29.3m at 31 December 2009 (2008: £38.0m)

### Operating Summary

- Flutiform™ in the process of being filed for European approval
- Flutiform™ Phase II studies conducted by Kyorin in Japan continue to make good progress; partnering discussions underway for Canada and Latin America
- Meeting request submitted to US FDA to discuss Complete Response Letter for Flutiform™
- Lodotra™ launched in Germany for treatment of rheumatoid arthritis joint stiffness; approved in 13 countries; US NDA filing expected Q3 2010
- Royalty revenues remain strong, with notable performances by Solaraze® and Requip® Once-a-day
- Partner Somnus secured financing for Phase II programme for SKP-1041 in sleep maintenance
- Formulation work initiated for SKP-1052 for diabetes
- Restructuring of Lyon and Muttenz operating facilities generating annual cost savings of £2.0m

- Frank Condella appointed Chairman; Board further strengthened with appointment of Dr. Thomas Werner; Dr. Anne Brindley appointed EVP Pharmaceutical Development

Commenting on the results, Frank Condella, Non-Executive Chairman, said:

“SkyePharma made progress on a number of fronts during 2009, leading to a substantial increase in pre-exceptional operating profit and a second successive year of strong EBITDA. The Group continued to manage costs carefully and the restructuring of the manufacturing facility in Lyon, France, completed during the year will deliver long-term benefits. Flutiform™ is in the process of being filed in Europe and trials in Japan, the world’s second largest pharmaceutical market, remain on track. In the United States, we are working to address the issues raised by the FDA and will provide an update in due course. We are confident that Flutiform™ has significant potential in the treatment of asthma.”

Trading in 2010 is expected to continue to benefit from the cost reductions and price increases agreed in 2009 and the Board anticipates revenues broadly in line with 2009. The Directors remain confident in the future prospects for the business.”

The results presentation has been published on the Company’s website and a webcast of the analysts’ conference will be available later today.

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**About SkyePharma PLC**

Using its proprietary drug delivery technologies, SkyePharma develops new formulations of known molecules to provide a clinical advantage and life-cycle extension. The Group has twelve marketed products in the areas of oral, inhalation and topical delivery. The Group’s products are marketed throughout the world by leading pharmaceutical companies. For more information, visit [www.skyepharma.com](http://www.skyepharma.com).

**CHAIRMAN’S STATEMENT**

**Overview**

Trading in 2009 was in line with the Board’s expectations, with good progress on a number of fronts during the year, leading to a substantial increase in pre-exceptional operating profit and a sharp reduction in the net loss to £1.4 million.

The expected decrease in revenues, due to lower milestones in 2009 and non-recurring manufacturing revenues in the prior year, was mitigated by beneficial exchange rate effects and price increases for manufactured products. Operating costs were reduced due to lower expenditure on Flutiform™ development, and a number of cost reduction measures. The Group expects to see continuing benefit from these cost reduction measures in 2010 and beyond.

Clinical studies were completed for Flutiform™ in Europe in 2009, and the European Marketing Authorisation Application (“EMA”) is in the process of being filed. Work on Flutiform™ in Japan by the Group’s partner Kyorin Pharmaceutical Company Ltd (“Kyorin”) continues on track and the Group continues to hold discussions with potential partners for Flutiform™ in Canada and Latin America.

The New Drug Application (“NDA”) for Flutiform™ was filed in the United States with the Food & Drug Administration (“FDA”) in March 2009 and a Complete Response Letter was received in January 2010. As previously announced during the review the FDA raised a number of new substantive issues to be addressed which, if undertaken, would involve significant additional clinical work including generating additional data on dose ranging. Whilst Abbott Respiratory LLC (“Abbott”) remains the Group’s partner, it has transferred the NDA to SkyePharma which will allow the Group to interact directly with the FDA. A meeting will take place with the FDA to determine the steps which would need to be taken before the application could be approved.

Among marketed products, Lodotra™ was launched in Germany for the treatment of rheumatoid arthritis joint stiffness, bringing the total number of marketed products to 12. Royalty revenues remained strong, with notable performances from Solaraze® and Requip® Once-a-day.

In the development pipeline, the Group’s development partner Somnus secured funding for the Phase II studies of SKP-1041 in sleep maintenance. Also the Group embarked upon formulation work for a new pipeline candidate, SKP-1052, for diabetes.

The Group’s senior team was further strengthened with the appointment of Dr Anne Brindley as Executive Vice President Pharmaceutical Development based in Switzerland.

### **Financial Highlights**

Revenues for 2009, which were in line with the Board’s expectations, totalled £55.9 million. This was down 10 percent on the £62.2 million reported for 2008, mainly due to lower milestones in 2009 and non-recurring manufacturing revenues in 2008.

The improvement in pre-exceptional operating profit, up by 39 percent to £15.1 million from £10.9 million in 2008 reflected lower research and development expenses resulting from reduced spending on developing Flutiform™, cost savings resulting from restructuring, especially in the Lyon factory, price increases for manufactured products and the receipt early in 2010 of U.S.\$3 million (£1.9 million) of catch up royalty payments from one partner following agreement on the calculation methodology.

Exceptional credits for 2009 totalled £9.8 million (2008: nil) of which £5.0 million was a net cash inflow. £5.1 million arose from the July 2009 agreement with Novartis and a subcontractor on the termination of contracts relating to the Foradil® Certihaler® after the decision was made not to proceed with United States commercialisation of Foradil® Certihaler®. The remaining £4.7 million of exceptional credits are non-cash and primarily relate to the final settlement of amounts due in respect of clinical trial work performed for Flutiform™.

The exceptional charge of £11.2 million (2008: £28.5 million) includes non-cash impairment charges of £8.4 million, of which £5.7 million relates to the Insoluble Drug Delivery® (“IDD®”) goodwill and £2.7 million is a write down of a licence in respect of Flutiform™ in North America. The remaining £2.8 million is a cash charge for employee termination and other costs associated with the restructuring of the Lyon manufacturing facility and the research and development facility in Muttenz, Switzerland.

The net result for 2009 after exceptional items, net finance charges and tax was a significantly reduced loss of £1.4 million (2008: loss of £28.7 million).

The Group posted a second year of strong performance at the pre-exceptional earnings before interest, depreciation and amortisation ("EBITDA") level, which was up 14.1 percent at £18.6 million (2008: £16.3 million).

### **Financial Strength**

As at 31 December 2009 SkyePharma had cash of £27.0 million compared with £35.7 million at 31 December 2008.

A total of £6.6 million (nominal value) of the 6 percent 2024 bonds was converted into ordinary shares during 2009. These conversions have strengthened the Group's Balance Sheet and resulted in an annual cash interest saving of approximately £0.4 million.

### **Board**

Dr Jerry Karabelas stepped down from the Board on 15 May 2009. Jerry served on the Board from 2000, including as Chairman from February 2006 to October 2007. The Board thanks him for his valuable contribution over this period. Frank Condella assumed Jerry's role as Chairman of the Remuneration Committee on his departure.

Dr Thomas Werner was appointed to the Board on 16 May 2009 as a Non-Executive Director. Dr Werner is a senior pharmaceutical executive with over 26 years of experience in the industry. Previously, he was Managing Director and Senior Vice President of GlaxoSmithKline Germany. Prior to that, he held senior positions at GlaxoWellcome Germany, Bristol-Myers Squibb Germany and Convatec Germany. He has also been appointed to the Audit and the Nomination & Governance Committees.

On 31 December 2009 Jeremy Scudamore stepped down as Chairman of the Board due to ill health. Jeremy had been Chairman since October 2007 and the Board thanks him for his valuable contribution over this period. Frank Condella was appointed Chairman in his place.

### **Strategy**

The Group's main focus for the next 12 months on Flutiform™ will be to work with our partners to pursue the registration in Europe and the United States, to advance development in Japan, conclude partnerships for Canada and Latin America and prepare for commercial manufacturing. The Group will also seek to improve its product pipeline and secure new partnerships based on using its proprietary technologies. In addition, there will continue to be a focus on reducing costs to further improve the cashflow and financial results of the Group.

### **Outlook**

Trading in 2010 is expected to continue to benefit from the cost reductions and price increases agreed in 2009 and the Board anticipates revenues broadly in line with 2009 as a whole, with growth in manufacturing revenues offsetting anticipated underlying reductions in royalty revenue from generic competition to Paxil CR™ and Xatral® OD. Compared with the operating result for 2009 (excluding the effect of the £1.9 million royalty catch up payments) the result for 2010 is expected to be lower mainly due to one-off costs of approximately £3.0 million of preparing for commercial manufacturing ready for the launch of Flutiform™ in Europe.

Notwithstanding the issues raised by the FDA regarding Flutiform™ in the United States, the Directors remain confident in the future prospects for the business, with the filing of the EMAA for Flutiform™ in Europe, the good progress with clinical studies in Japan, the future European launches of Lodotra™ and continuing tight control of costs.

SkyePharma thanks its shareholders, bondholders, debtholders, employees and partners for their continued support through 2009 and into 2010.

**Frank Condella**  
**Non-Executive Chairman**

## **BUSINESS REVIEW**

### **CHIEF EXECUTIVE OFFICER'S REVIEW**

With the approval and launch of Lodotra™ in 2009, the Group now has 12 approved products which generated royalty and manufacturing revenues of £42.6 million in 2009 (2008: £41.8 million).

The last twelve months have been a mixed period for progress with Flutiform™, the fixed-dose combination of fluticasone, an inhaled corticosteroid ("ICS"), and formoterol, a long-acting beta agonist ("LABA") in a Metered Dose Inhaler ("MDI"). This remains an important pipeline product for the Group with further progress made including the completion of European clinical studies, the filing taking place in Europe and continued progress with the Phase II clinical studies in Japan. However, as previously announced, and noted in the Chairman's Statement and below, the United States FDA raised a number of new substantive issues in its Complete Response Letter which was received in January 2010.

The pipeline also includes SKP-1041, a novel sleep therapeutic, outlicensed to Somnus Therapeutics Inc ("Somnus") which has recently raised further funding to take the product into Phase II clinical studies. The Group continues to seek additional in-house ideas for new products and commenced formulation work on SKP-1052 in 2009, an oral product for diabetes being developed with a view to out-licensing in 2011 following proof of principle. In addition, the Group continues to seek new partnerships for its proprietary technology and is working on a number of feasibility projects for which it is charging for development on a time and cost basis.

In order to conserve cash and reduce risk, the Group's strategy will continue to focus on out-licensing new product developments after proof of principle and to work on further development on a contract development basis.

During 2009 some substantial price increases were negotiated for products manufactured in Lyon and a number of steps were taken to reduce overhead costs across the business.

Headcount was reduced by over 10 per cent at the Group's research and development facility in Muttenz, Switzerland. At the manufacturing facility in Lyon, France, following consultations with the Works Council, the workforce of over 120 employees has been reduced by approximately one third. In aggregate these measures led to an exceptional charge of £2.4 million in 2009 and will generate annual savings of approximately £2.0 million per annum from 2010 onwards.

In 2010, the Group is rationalising its operations in Muttenz, Switzerland, by closing one of the three buildings currently used and transferring staff to the remaining buildings, reducing space by 33 percent, and ceasing commercial production of Madopar DR®. A charge of £0.4 million has been included in the 2009 income statement for this closure. Discussions are underway with the Group's partner with a view to manufacturing Madopar DR® in the Group's facility in Lyon, France.

## **BUSINESS REVIEW - PRODUCTS**

### **INHALATION PRODUCTS**

#### **Flutiform™**

Flutiform™ is licensed to Abbott in the United States, to Mundipharma International Corporation Limited ("Mundipharma") in the rest of the world (apart from Japan and the Americas) and to Kyorin in Japan. Discussions are continuing with a view to outlicensing Flutiform™ in Canada and Latin America.

#### *Flutiform™ in the United States*

As announced in January 2010, the Group received a Complete Response Letter from the FDA in respect of the NDA for Flutiform™. This letter stated that the FDA could not approve the NDA in its present form and raised a number of new substantive issues to be addressed which, if undertaken, would involve significant additional clinical work including generating additional data on dose ranging. Following this, and in accordance with a prior agreement with Abbott, the NDA was transferred back to SkyePharma. A meeting request has been submitted to the FDA with a view to working with the agency on what steps would need to be taken before the application could be approved.

The FDA has been reviewing the safety of LABAs as a class, including when used in conjunction with an inhaled corticosteroid, as would be the case with Flutiform™. The FDA has stated that it might require additional clinical work to address this matter but not whether any such work would have to be carried out prior to or after any approval of Flutiform™ in the United States.

The NDA included the results of one long-term safety study and four efficacy studies, covering in total nearly 2,300 patients. The primary end points were met in all cases.

Under the license agreement with Abbott it has exclusive rights to market Flutiform™, subject to FDA approval, in the United States. In addition to the U.S.\$25 million (£12.5 million at prevailing exchange rates) received on signing, and the U.S.\$0.8 million (£0.5 million) received on the acceptance of the NDA by the FDA, the agreement with Abbott provides for the group to receive time-dependant milestones on approval together with up to U.S.\$60 million (£37.7 million) in sales related milestones. The royalty rate on sales in the United States escalates upwards from a mid teens percentage.

If Flutiform™ is approved in the United States in 2011 or later, a milestone of U.S.\$18 million (£11.3 million) is due. To the extent that certain of Abbott's development costs (including the costs of any additional studies required by the FDA in support of the NDA) exceed U.S.\$20.5 million (£12.9 million), the excess is recoverable out of up to 25 percent of any approval or post-approval milestones and royalty payments until such time as 100 percent of the excess is recovered.

#### *Flutiform™ in Europe*

As previously announced, all clinical work required for filing the EMA was completed during 2009 and the

application for all three strengths of Flutiform™ is in the process of being filed in March 2010. The launch of the product is planned for 2011.

The primary endpoints were met in all of the clinical studies which, in addition to the data supporting the NDA for the United States, comprised four Phase III clinical studies (including one higher dose strength study) covering approximately 1,200 patients (per protocol set).

Mundipharma has exclusive rights to Flutiform™ in Europe and other territories outside the Americas and Japan. The licensing agreement provides for the Group to earn up to €73 million (£62.5 million) in milestones, of which €15 million (£10.1 million at that time) was paid upfront, €3 million (£2.9 million) was paid on 31 December 2008, up to €15 million (£13.5 million) is due on launch and up to €40 million (£36 million) is sales related. In addition, the Group is entitled to royalties as a percentage escalating upwards from 10 percent on net sales. The development work being carried out for Europe on a higher strength version of Flutiform™ is being funded by Mundipharma and partially reimbursed by the Group through reductions in royalties and sales-related milestones for a limited period of time, and up to a cost of €15 million (£13.5 million) in total. As described in detail in the financial review, the first U.S.\$20 million (£12.6 million) of net milestone payments received after 1 January 2009 in respect of Flutiform™ (from all territories) are to be paid in equal amounts to Paul Capital and CRC in accordance with the relevant agreements.

Under the 2006 EU regulations (Regulation (EC) 1901/2006, as amended by Regulation (EC) 1902/2006), which came into force in 2008, there is a requirement to have an agreed Paediatric Investigation Plan ("PIP"). The Paediatric Committee has reviewed the plans for Flutiform™ and a double blind study in children aged 4-12 years is required to be completed by December 2013. The Group is obliged to reimburse Mundipharma for half of the cost of this work, completed by the end of 2011, up to €3.5 million (£3.0 million) either through a reduction in launch milestones of the same amount, or payable on 30 June 2011 if the amount has not been reimbursed to Mundipharma by that date.

#### *Flutiform™ in Japan*

In April 2008, the Group entered into an exclusive development, distribution and license agreement for Flutiform™ with Kyorin for Japan and has received an upfront milestone payment. Development and approval milestones worth several million pounds are payable to SkyePharma under the agreement and there is a high mid-single digit percentage royalty on net sales. The development costs associated with obtaining approval for the Japanese market will largely be met by Kyorin, which is responsible for clinical studies and regulatory submissions. Development is expected to take several years. Good progress is being made with the two Phase II clinical studies and the development programme remains on track.

#### *Supply of Flutiform™*

Under the agreements with Abbott, Mundipharma and Kyorin, the Group is responsible for supplying Flutiform™ and has committed to capital expenditure totalling €9.4 million (£8.5 million), of which €7.1 million (£6.4 million) has been spent to 31 December 2009 on tooling at two subcontractors. In addition, the Group has committed to capital expenditure of €3.2 million (£2.9 million), which is being funded by a partner (which has a right to claim this amount back no later than 2013, or, if earlier, when the supply chain is outsourced). Of this, €1.6 million (£1.4 million) has been spent to date. The Group has an agreement for the product to be manufactured by sanofi-aventis at its factory in Holmes Chapel, United Kingdom. The Group is responsible for supplying the various components and ingredients to sanofi-aventis and is sourcing these from various suppliers located in Europe.

The Group has also made certain minimum purchase commitments in respect of the Flutiform™ supply

chain, totalling €7.5 million (£6.7 million) to be met by 31 December 2010, as well as further minimum commitments in 2011 and 2012. The Group continues to hold discussions with a number of parties with a view to transferring the responsibility of the Flutiform™ supply chain, although such discussions are at a preliminary stage and in the meantime the Group continues to establish the supply chain in preparation for launch.

In August 2008, the Group entered into agreements with Abbott and Mundipharma relating to payment terms for the supply of Flutiform™. Coupled with agreed terms for supplier credit these were designed to largely eliminate the need for investment in working capital for the Flutiform™ supply chain during the launch phases.

#### **Pulmicort® HFA-MDI**

This HFA-MDI containing AstraZeneca's inhaled corticosteroid Pulmicort® (budesonide) was developed for territories outside the United States for the treatment of asthma to replace the CFC MDI formulation of Pulmicort®. The product is approved in over 35 countries worldwide. The Group earns a mid teens royalty on AstraZeneca's net sales of Pulmicort® HFA-MDI.

#### **Foradil® Certihaler®**

In July 2009 SkyePharma announced that it had reached agreement with Novartis Pharma AG ("Novartis") and with a subcontractor, on termination of the contracts relating to formoterol Certihaler®. The agreements follow the decision not to proceed with United States commercialisation of formoterol Certihaler® as announced in December 2008. Following the termination, SkyePharma retains exclusive rights for the SkyeHaler™ device, used in the formoterol Certihaler®, which was approved in the United States in December 2006 for use as a multi-dose Dry Powder Inhaler ("DPI").

SkyePharma continues to seek other potential applications for its proprietary SkyeHaler™ dry powder inhaler. This is one of only a few DPI devices which have been incorporated in products approved by the FDA, and is the only such device which is not proprietary to a major pharmaceutical company. SkyeHaler™ is a multi-dose reservoir device suitable for acute and chronic therapies with a dose counter and an end of life lock out mechanism.

#### **Licence fees**

In 2009, a development milestone was received in respect of a previously announced 2003 agreement with GlaxoSmithKline ("GSK") to provide access to one of SkyePharma's proprietary formulation technologies for application to the delivery of respiratory drugs either by breath-actuated dry-powder inhaler or by metered-dose aerosol inhaler. The agreement was signed at the end of 2003 and GSK made an initial payment to SkyePharma on signature. If the patented formulation technology is subsequently incorporated into current or future products by GSK, SkyePharma will also be entitled to an additional payment for each such product and a royalty on eventual sales.

### **ORAL AND TOPICAL PRODUCTS**

#### **Xatral® OD**

Xatral® OD (Uroxatral® in the United States) is a once-daily version of sanofi-aventis' Xatral® (alfuzosin hydrochloride), a treatment for the signs and symptoms of benign prostatic hypertrophy ("BPH"). In 2009, reported sales of all forms of Xatral® were €296 million (£266.2 million), down 8.5 percent (using constant exchange rates) compared with 2008. European sales have continued to be reduced by generic competition with sales for 2009 of €93 million (£83.6 million), down 29 percent compared with 2008. In the United States



sales of Uroxatral® were €147 million (£132.2 million), up 16 percent compared with 2008. Sales in other countries were down by 11 percent to €56 million (£50.4 million).

Starting in August 2007, sanofi-aventis and the Group received a series of Abbreviated New Drug Application (“ANDA”) Certifications under paragraph IV relating to Uroxatral® in the United States. Many of the generic manufacturers were sued by sanofi-aventis for infringement of one or both of the Orange Book-listed patents related to the ANDA certifications in various federal district courts throughout the country. Ultimately, the actions were consolidated before the U.S District Court, District of Delaware. The trial against Mylan (the only remaining defendant) involving a single patent belonging to sanofi-aventis is scheduled for May 2010.

SkyePharma earns low single digit royalties on net sales of Xatral® OD (Uroxatral®).

### **Solaraze®**

Solaraze® (diclofenac), a topical gel treatment for actinic keratosis, is marketed in the United States by Nycomed. The distribution and marketing partner in Europe and certain other territories is Almirall. Solaraze® has seen strong growth during 2009 in all territories, with net sales in the United States of U.S.\$60.5 million (£37.3 million), up by approximately 59 percent on 2008. Sales in 2009 by Almirall were €24.3 million (£21.6 million) an increase of 44 percent on 2008. The Group earns a low teens royalty rate on net sales.

### **Requip® Once-a-day**

Requip® Once-a-day is a once daily formulation for Parkinson’s disease which was developed in collaboration with GSK. The new extended release Requip® uses the Group’s patented Geomatrix™ technology and is designed to provide smoother delivery of ropinirole over 24 hours without the peaks and troughs that multiple daily doses invariably deliver. In addition, the new once-daily formulation offers physicians and patients a simple titration schedule and direct conversion from immediate release ropinirole. It also provides for a convenient, once-daily dosing schedule compared with the immediate-release ropinirole, which is dosed three times a day. Extended release Requip® is currently approved in 44 countries worldwide and has been launched in 26 European countries.

The FDA approved Requip® XL™ extended release tablets in June 2008 and the product was launched in the United States in July 2008. In 2009, a number of ANDAs were filed with the FDA for generic versions of ropinirole extended release tablets. There is data exclusivity in respect of the product until June 2011, which may delay any potential generic product entry into the market.

SkyePharma earns low mid single digit percentage royalties on net sales of Requip® Once-a-day. In 2009 sales of Requip® XL™ were £123 million up from £43 million in 2008, with £32 million (2008: £9 million) generated in the United States and £89 million (2008: £34 million) in Europe. Sales in the rest of the world amounted to £2 million.

### **Sular®**

Working in collaboration with Shionogi Pharma, Inc. (“Shionogi Pharma”) formerly Sciele Pharma Inc., a Shionogi Company, the Group developed a new lower-dose formulation of Sular® (nisoldipine), a calcium channel blocker antihypertensive agent, using the Group’s proprietary Geomatrix™ drug delivery system. The product was launched in March 2008.

Sales of Sular® continue to be affected by the sale of a generic version of the old formulation of Sular®

which was launched in 2008.

In February 2009, as part of an ANDA filing, a paragraph IV certification was made by a generic manufacturer in respect of the 25.5mg and 34mg strengths of the new formulation of Sular® and in March 2009 a further paragraph IV certification was filed for the 8.5mg and 17mg strengths of the new formulation. No patent infringement suit was filed within 45 days of receiving notification of the paragraph IV certifications and, therefore, the approval of the ANDA will not be subject to any automatic stay. The impact of any generic launch on sales of the new formulation of Sular® is dependant on a number of factors including the timing of launch, pricing strategy of the generic company and the number and timing of additional generic formulations, if any, that reach the market. If net sales of the new formulation of Sular® are significantly lower following generic entry, the Group's royalty rate would be reduced from a low mid single digit percentage to a low single digit percentage on net sales.

The Group is manufacturing the new formulation of Sular® at its plant in Lyon, France.

### **Paxil CR™**

Paxil CR™ is an advanced formulation of the anti-depressant Paxil® and was developed by the Group with GSK using the Group's Geomatrix™ technology. Sales of Paxil CR™, in 2009 were £54 million, down by 41 percent (using constant exchange rates) compared with 2008 following the entry of generic competition to the market.

### **Triglide®**

Triglide® (fenofibrate), an oral treatment for elevated blood lipid disorders, is marketed in the United States by Shionogi Pharma, and is now being sold alongside Fenoglide®, a fenofibrate product in-licensed by Shionogi Pharma. Triglide® was launched in 2005 and Fenoglide® was launched in February 2008. Triglide® total prescriptions have continued to reduce during 2009 due to the effect of competition. SkyePharma is entitled to receive 25 percent of Shionogi Pharma's net sales, which covers both royalties and manufacturing fees for supply of the product from SkyePharma's plant in Lyon, France. Under an agreement with Shionogi Pharma it agreed to share revenues from Fenoglide® with SkyePharma until the end of 2009.

### **ZYFLO CR® (zileuton) Extended-Release Tablets**

The Group developed an extended release formulation of the oral asthma drug zileuton for Cornerstone Therapeutics, Inc (formerly Critical Therapeutics Inc.). ZYFLO CR® extended-release tablets, taken twice daily, utilise the Group's proprietary Geomatrix™ technology, and the product was approved by the FDA in May 2007 for the prophylaxis and treatment of chronic asthma in adults and children aged 12 years and older. ZYFLO CR® and ZYFLO® (zileuton tablets) are the only FDA-approved leukotriene synthesis inhibitors. SkyePharma receives a high mid single digit percentage royalty on net sales of ZYFLO CR® and also manufactures the product at its facility in Lyon, France.

### **Lodotra™**

In April 2009, Lodotra™, the novel night-time release formulation of low dose prednisone, utilising SkyePharma's proprietary Geoclock™ technology and developed in collaboration with Nitec Pharma AG ("Nitec"), was launched in Germany by Merck KGaA (Nitec's licensee for Germany and Austria). This is the first launch in Europe following approval for the treatment of rheumatoid arthritis and associated morning stiffness, under the European decentralised procedure. Nitec has recently concluded a distribution agreement with Mundipharma for the rest of Europe, and the product has since been approved in 13 countries and is expected to be launched in Denmark, Norway, Finland, Belgium and the Netherlands in

2010.

Nitec continues to work on its programme for United States registration of Lodotra™ and announced in September 2009 that the second and final pivotal Phase III trial required for filing the NDA (a 12-week, multicentre, double blind trial involving 300 patients) had met its primary endpoints. The filing of the NDA with the FDA is targeted to take place in Q3 2010.

The Group receives a mid single digit percentage royalty on net sales and is manufacturing the product at its plant in Lyon, France.

#### **SKP-1041**

Somnus Therapeutics Inc has successfully completed two Phase I studies of the controlled release sleep maintenance drug SKP-1041. The product is a new formulation of zaleplon, a non-benzodiazepine hypnotic agent, which utilises SkyePharma's proprietary Geoclock™ technology for delayed release. The formulation is designed to treat people who have difficulty maintaining sleep but not with sleep onset, and is intended to prevent middle-of-the-night awakening while avoiding residual effects.

The Investigational New Drug Application for SKP-1041 was filed with the FDA in Q1 2009 and planning is underway to commence Phase II trials. Data from the Phase II studies is anticipated to be disclosed in 2011.

In February 2010, Somnus announced the completion of a U.S.\$15 million Series A financing agreement with CTI Life Sciences and Care Capital LLC. The additional infusion of capital is intended to fund the Phase II clinical studies.

Under the agreement with Somnus, SkyePharma could receive up to U.S.\$35 million (£21.6 million) in milestone payments, of which U.S.\$4 million (£2.0 million at that time) was received on signature, U.S.\$1 million (£0.7 million) was received on completion of Phase I studies. Up to a further U.S.\$10 million (£6.3 million) is payable on product approval, and U.S.\$20 million (£12.6 million) is sales related.

SkyePharma is entitled to receive a royalty on future sales escalating upwards from a high mid single digit percentage.

#### **SKP-1052**

In 2009, the Group commenced formulation work on SKP-1052, an oral product for diabetes being developed with a view to out-licensing in 2011 following proof of principle. The project applies the Group's proprietary technology to a generic compound in an innovative approach to the treatment of diabetes.

#### **Feasibility agreements**

The Group continues to work on a number of research and development and out-licensing activities to increase the pipeline of both oral and inhalation products.

#### **Potential share of sales from the former Injectable Business**

The terms of the sale of Pacira Pharmaceuticals Inc. ("Pacira Pharmaceuticals") (formerly the Injectable Business) in 2007 included up to U.S.\$62 million (£38.9 million) in contingent milestone payments and a percentage of sales of certain future products for a fixed period of time. The milestones depend on approval of the products and the achievement of certain launch and various substantial sales targets of EXPAREL™ (formerly DepoBupivacaine™). EXPAREL™ is currently in Phase II and Phase III clinical development for a number of indications with Pacira Inc. ("Pacira"). Pacira announced in 2009 that two Phase III studies had

positive results, meeting their primary endpoints.

In addition, subject to the successful development and launch, the Group will receive 3 percent of net sales worldwide of EXPAREL™.

## **MANUFACTURING**

Manufacturing operations take place in Europe, principally at the Group's Lyon facility in France. At Lyon, the Group presently manufactures five Geomatrix™ products, diclofenac-ratiopharm®-uno, Coruno®, ZYFLO CR®, Sular® and Lodotra™. In addition, the Group manufactures one other oral product, Triglide®, based on its solubilisation technology, at its Lyon facility. The Lyon factory has cGMP status, with approvals from EMEA and United States FDA.

In 2009, a number of price increases, some of which have been substantial, have been agreed with a view to ensuring that product prices more adequately reflect the costs and risks of manufacture.

## **Financial Review**

### **Revenue**

Revenue for 2009 totalled £55.9 million, a decrease of 10 percent on the £62.2 million reported for 2008 mainly due to lower milestones in 2009 and non-recurring manufacturing revenues in 2008, offset by the benefit of exchange translation effects.

Royalty income was £28.9 million (2008: £22.4 million), an increase of £6.5 million (29 percent) primarily due to exchange rate effects but also benefiting from receipt early in 2010 of U.S.\$3 million (£1.9 million) catch up royalty payment from one partner following agreement of the calculation methodology. At constant exchange rates, royalty income declined by 5 percent. Requip® Once-a-day, Solaraze® and Uroxatral® have all seen significant growth in royalties, which has been more than offset by the anticipated decline in revenues from Paxil CR™ and Xatral®.

Contract research and development revenues increased to £9.3 million in 2009 from £8.0 million in 2008 due to exchange rate effects. There was an increase in Flutiform™ development costs charged to partners, but a reduction in revenues at constant exchange rates, due to charges to partners for non-Flutiform™ feasibility work being lower in 2009 than in 2008.

Revenues recognised from signing and milestone payments were substantially lower at £4.0 million in 2009 compared with £12.4 million in 2008. The decrease occurred primarily as the upfront signing payments received for Flutiform™ were largely recognised in 2008 and prior years, and a number of one-off milestones received in 2008 were not repeated in 2009.

Manufacturing and distribution revenue totalled £13.7 million in 2009, a decrease of £5.7 million, compared with £19.4 million in 2008. In 2008, revenues included a £6.2 million non-recurring contribution from Novartis towards maintaining manufacturing capacity for Foradil® Certihaler®. In 2009 this contract was terminated, and amounts receivable are included in exceptional items. Revenues in 2009 have also benefited from a number of substantial price increases negotiated with partners and positive exchange rate effects which have more than offset the decrease in volumes produced.

### **Research and development expenses**

Research and development expenses incurred in 2009 decreased to £19.6 million (2008: £25.1 million). This decrease was primarily due to the completion of the Flutiform™ development program required to file

the NDA in the United States, together with a number of cost saving initiatives undertaken at the Muttenz facility. The Group's net investment in research and development (expenses, net of contract development revenues) totalled £10.3 million (2008: £17.1 million), a reduction of 40 percent. This reflects the reduced spend on developing Flutiform™ in 2009 compared with 2008, the focus on partnered development projects and cost savings achieved by the restructuring undertaken. Much of the balance of the expenditure incurred in 2009 related to the continued development of Flutiform™, particularly in Europe.

### Operating Results

The operating profit before exceptional items was £15.1 million (2008: £10.9 million). Pre-exceptional earnings before interest, tax, depreciation and amortisation were £18.6 million (2008: £16.3 million) as follows:

	<b>2009</b>	<b>2008</b>
	<b>£m</b>	<b>£m</b>
Operating profit before exceptional items	15.1	10.9
Pre-exceptional depreciation and amortisation	3.5	5.4
<b>Pre-exceptional earnings before interest, tax, depreciation and amortisation (pre-exceptional EBITDA)</b>	<b>18.6</b>	<b>16.3</b>

### Exceptional Items

In July 2009, the Group announced that it had reached agreement with Novartis and a subcontractor on immediate termination of the contracts related to Foradil® Certihaler®. The net effect of this agreement has resulted in exceptional income of £5.1 million in 2009 (2008: nil) of which £5.0 million was cash.

The Group has further exceptional credits of £4.7 million (2008: nil) relating to the release of accruals no longer required, mainly relating to the final settlement of amounts due in respect of clinical trial work performed for Flutiform™.

The exceptional charge for 2009 totalled £11.2 million (2008: £28.5 million) of which £2.8 million was a cash cost, with the balance comprised of two non-cash impairments. The cash charge of £2.8 million related to the previously announced workforce reduction at the Group's manufacturing facility in Lyon, France and restructuring of the research and development facility in Muttenz, Switzerland. The charge consists of statutory redundancy and notice payments, the costs expected to be incurred under the social plan (required under French law) and professional costs incurred in finalising the plan. A non-cash charge of £5.7 million (2008: £19.5 million) arose on the impairment of the IDD® goodwill, writing the balance down to £2.1 million. This remaining value is supported by the Board's assessment of future sales for Triglide®. The other non-cash charge was a £2.7 million write down of the book value of a licence taken out in 2005 in respect of Flutiform™ in North America. The value of this licence is unlikely to be recovered before patent expiry and has therefore been fully written off.

### Finance costs and income

Finance costs – interest totalled £13.3 million (2008: £14.1 million), and comprises £6.2 million (2008: £6.5 million) of interest payable on the convertible bonds, £3.7 million (2008: £4.5 million) of interest payable on the CRC finance, £3.0 million (2008: £2.7 million) of interest attributable to the Paul Capital finance, and £0.4 million (2008: £0.4 million) on other bank borrowings.

Finance income of £0.3 million (2008: £0.9 million) relates to bank interest income, the reduction in income

compared with 2008 largely reflecting lower prevailing money market and bank deposit rates.

Finance costs – revaluation consists of a charge of £1.4 million (2008: £3.0 million) arising on the revaluation of the Paul Capital finance and CRC finance. This reflects both (i) the Group's revised assessment of payments to be made by Pacira Pharmaceuticals, on sales of DepoCyt® and DepoDur™ which are paid to Paul Capital and reduce the Group's debt under the Paul Capital finance facility, and (ii) revisions to the timing of prepayments to be made to both Paul Capital and CRC on receipt of certain Flutiform™ milestones as detailed in Note 13: Borrowings.

Foreign exchange translation comprises a charge of £0.2 million (2008: gain of £5.7 million) relating to net translation gains and losses on borrowings and cash denominated in a currency other than the entity's functional currency.

## Result

The loss for the year after exceptional items and taxation was £1.4 million (2008: loss of £28.7 million).

## Earnings per share

The loss per share amounted to 6.0 pence (2008: 247.4 pence). The pre-exceptional loss per share from continuing operations amounted to nil (2008: 1.7 pence). As at 31 December 2009 there were 23,943,162 ordinary £1.00 shares in issue.

In addition there were outstanding as at 31 December 2009 a number of options, bond conversion rights and employee share schemes as follows:

Description	Number of ordinary shares	Exercise price (per share)	Expiry conditions
Deferred consideration (Krypton)	375,000	£30.49 increasing at 10% per annum	None
Employee share option schemes	44,367	£23.75 to £41.76	Various dates 2009 to 2013
Employee share schemes*	735,792	Nil	Various performance and service conditions
Convertible bonds 2024	16,983,023	£3.71	May 2024
Convertible bonds 2025	5,235,602	£3.82	June 2025
<b>Total at 31 December 2009</b>	<b>23,373,784</b>		
Total at 31 December 2008	24,853,895		

\* Employee share schemes include the long term incentive plans and international share purchase plan.

More details of the convertible bonds and share scheme arrangements are set out in Notes 13: Borrowings, 14: Share Capital to the preliminary statement. As at 24 March 2010, the Company's mid-market share price was 47.75 pence.

## Cash flows

During 2009, there was a cash inflow from operating activities of £16.8 million, compared with an inflow of £4.5 million in 2008. During the year the Group spent £4.8 million on property, plant and equipment, mainly relating to the Flutiform™ supply chain.

Borrowings of £7.0 million were repaid as scheduled in the year, primarily comprising amortisation payments of the Paul Capital finance. In addition, the Group paid £12.6 million of interest during 2009, mainly relating to the convertible bonds, Paul Capital finance, CRC finance and the property mortgages. Interest received on cash deposits amounted to £0.3 million.

### Key performance indicators

The Board considers the following Key Performance Indicators (“KPIs”) to be the most relevant to the Group’s operations:

<b>Key financial performance indicators</b>		<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>
Revenue excluding milestones	£m	34.4	30.3	31.2	49.8	51.9
Signing and milestone payments received	£m	24.1	30.0	3.0	3.9	3.0
Research and development expenditure	£m	20.7	26.3	30.3	25.1	19.6
Research and development expenditure net of contract research and development revenue	£m	15.2	24.7	27.1	17.1	10.3
Liquidity	£m	35.6	46.2	33.1	38.0	29.3

<b>Key non-financial performance indicators</b>		<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>
Number of approved and marketable products at year end		10	9	11	12	12
Manufacturing output	Units (millions)	103	98	94	234	145

### Description of KPI’s

#### ***Revenue excluding milestones***

Revenue reflects the level of contract research and development work undertaken for third parties and manufacturing activities, as well as the growth in royalties earned as new products are launched. The £51.9 million for 2009 excludes milestone revenue of £4.0 million and is shown in Note 2: Revenue by income stream to the preliminary statement.

#### ***Signing and milestone payments received***

This KPI shows progress with pipeline products and product sales. The figure of £3.0 million represents the cash milestones received in the year.

#### ***Research and development expenditure***

Research and development expenditure reflects the cost, including direct and indirect overheads, of all research and development activities. A breakdown of the 2009 costs is shown in Note 4: Research and development to the preliminary statement.

#### ***Research and development expenditure net of contract research and development revenue***

This KPI reflects the Group's expenditure on research and development expense net of costs reimbursed by development partners.

### **Liquidity**

This KPI measures the availability of finance to fund current and future activities and to meet debt servicing requirements. Liquidity consists of cash and cash equivalents of £27.0 million, as per the balance sheet, and undrawn facilities of £2.3 million.

### **Balance sheet**

As at 31 December 2009, the Group balance sheet shows total shareholders' equity of £79.6 million deficit (2008: £89.8 million deficit). The reduction in the deficit has arisen mainly due to the issue of 1.8 million shares resulting from a number of bond conversions in 2009 and a translation gain of £5.4 million due to the strengthening of sterling.

### **Borrowings and liquidity**

The Group's total net debt measured in accordance with IFRS comprises:

	<b>2009</b>	<b>2008</b>
	<b>£m</b>	<b>£m</b>
Convertible bonds	58.5	62.7
Paul Capital finance	24.7	28.6
CRC finance	41.6	49.5
Property mortgage	8.0	9.0
Bank overdraft & borrowings	1.2	1.4
Finance lease liabilities	0.1	0.3
<b>Total debt</b>	<b>134.1</b>	<b>151.5</b>
Less cash and cash equivalents	(27.0)	(35.7)
<b>Net debt</b>	<b>107.1</b>	<b>115.8</b>
<b>Net debt (including convertible debt at face value)</b>	<b>131.6</b>	<b>142.7</b>

Total debt has decreased by £17.4 million, primarily due to repayments totalling £7.0 million and the conversion of £6.6 million (at nominal value) of bonds. The remaining movement is due to exchange translation effects.

### **Convertible bonds**

The convertible bonds outstanding at 31 December 2009 comprised £63.0 million 6 percent convertible bonds due May 2024 (2008: £69.6 million) and £20.0 million 8 percent convertible bonds due June 2025 (2008: £20.0 million).

During 2009, £6.6 million (at nominal value) of 6 percent 2024 convertible bonds were converted into ordinary shares at a conversion price of £3.71 per share. This has resulted in the issue of 1,775,647 ordinary shares. A summary of the 2009 movements in the bond value is shown below:

	<b>Nominal Value</b>	<b>Net Book Value</b>
	<b>£m</b>	<b>£m</b>



At 1 January 2009	89.6	62.7
Converted in 2009	(6.6)	(4.8)
Accretion in book value	-	0.6
<b>At 31 December 2009</b>	<b>83.0</b>	<b>58.5</b>

These conversions have reduced the Group's annual cash interest costs by approximately £0.4 million per annum and strengthen the balance sheet through the reduction in debt.

In 2008, the Group renegotiated the terms of the convertible bonds. The £69.6 million May 2024 bonds are convertible into ordinary shares at £3.71 per share (previously 95 pence per share prior to the 1 for 100 share consolidation) and may be called for repayment by the bond holders at par in November 2013, November 2015, November 2017 and November 2020 (previously May 2009, May 2011, May 2014 or May 2019). The £20.0 million June 2025 bonds are convertible into ordinary shares at £3.82 per share (previously 58 pence per share prior to the 1 for 100 share consolidation) and may be called for repayment by the bond holders at par in December 2014, December 2016, December 2018 and December 2021 (previously June 2010, June 2012, June 2015 or June 2020).

### Paul Capital finance

The Group has a fixed amortisable note ("Note") of U.S.\$92.5 million (£58.1 million) due to Paul Capital finance. There is up to an additional U.S.\$12.5 million (£7.8 million) payable if worldwide sales of DepoDur™ (a product of Pacira Pharmaceuticals) reach certain thresholds, which the Board believes is unlikely. The note is repayable in accordance with an amortisation schedule through to 2015.

Pacira Pharmaceuticals was sold on the basis that it retained responsibility to Paul Capital for its existing obligations to make payments based on sales of DepoCyt® and DepoDur™ and, to the extent that payments are made in respect of these, the Group's liability under the Note will be reduced accordingly. The amount of the Group's liability therefore depends on estimates of the sales of DepoCyt® and DepoDur™ by Pacira Pharmaceuticals.

As at 31 December 2009, the net present value of this liability (net of anticipated payments by Pacira Pharmaceuticals to Paul Capital), discounted at an annual rate of 11.2 percent is U.S.\$39.3 million (£24.7 million) compared with the value of U.S.\$41.5 million (£28.6 million) included in the 31 December 2008 balance sheet. As at 31 December 2009 a cumulative total of U.S.\$28.2 million (£16.0 million) had been paid against the Note, including payments made by Pacira Pharmaceuticals totalling U.S.\$4.5 million (£2.6 million).

The following amortisation schedule shows the minimum amounts payable, including payments made and forecast to be made by Pacira Pharmaceuticals, under the Note. These payments are accounted for as payments of principal and notional interest as follows:

	<b>Notional interest</b>	<b>Repayment of principal</b>	<b>Total</b>
	<b>U.S.\$m</b>	<b>U.S.\$m</b>	<b>U.S.\$m</b>
2007 (actual)	6.7	2.9	9.6
2008 (actual)	5.9	3.1	9.0
2009 (actual)	7.4	2.2	9.6
2010	4.1	7.7	11.8
2011	3.0	13.3	16.3
2012	1.6	10.0	11.6

2013	0.6	8.2	8.8
2014	(0.1)	0.2	0.1
<b>Total</b>	<b>29.2</b>	<b>47.6</b>	<b>76.8</b>

The above table:

- (i) shows interest and principal payments on a cash basis (no discounting applied) using the notional interest rate of 11.2 percent which has been applied from inception (based on benchmarking equivalent rates at that time)
- (ii) 2009 includes a valuation adjustment of U.S.\$3.6 million within notional interest
- (iii) excludes the additional payments due if sales of Depodur™ reach certain thresholds
- (iv) includes reductions for estimated future sales-related payments by Pacira Pharmaceuticals for DepoDur™ and DepoCyt®
- (v) includes prepayment of the Note to an aggregate amount of U.S.\$10 million out of 50 percent of milestones and signing fees received and forecast to be received in respect of Flutiform™

### CRC finance

The CRC finance was taken out in 2006 and is a 10 year secured amortising loan facility which at inception totalled approximately £35.0 million at the exchange rates prevailing at that time. The facility comprises initial commitments of U.S.\$35.0 million and €26.5 million repayable over 10 years based on a minimum amortisation schedule. The currencies of the facility and underlying payment schedules related to expected cash flows from the products used as part security thereby providing an approximate natural hedge against currency fluctuations.

The following amortisation schedule shows the interest payable and principal outstanding under the CRC finance as follows:

	Euro component of loan		U.S.\$ component of loan	
	Interest payment in year	Principal outstanding at end of year	Interest payment in year	Principal outstanding at end of year
	Eur'm	Eur'm	U.S.\$m	U.S.\$m
2007 (actual)	2.3	26.5	2.8	35.0
2008 (actual)	3.3	26.3	3.3	34.8
2009 (actual)	2.3	24.5	2.4	32.3
2010	1.9	21.4	1.9	28.3
2011	1.7	17.5	1.5	23.0
2012	1.4	13.4	0.8	17.7
2013	1.2	9.8	0.6	13.0
2014	0.9	6.5	0.5	8.5
2015	0.7	3.1	0.3	4.2
2016	0.2	-	0.1	-
<b>Total</b>	<b>15.9</b>	<b>-</b>	<b>14.2</b>	<b>-</b>

The above table:

- (i) shows interest on a cash basis (no discounting is applied). The interest rates applicable at 31 December 2009 were 6.589 percent on the Euro component (plus an additional 5 percent on the first €7.5 million (£6.7 million)) and 6.1325 percent on the U.S.\$ component

- (ii) shows the minimum amortisation schedule assuming the cumulative milestones and royalties from Coruno®, Lodotra™, and Requip® XL™ are not in excess of the levels triggering the principal to be repaid earlier without penalty
- (iii) includes prepayment of the U.S.\$ loan to an aggregate amount of U.S.\$10 million out of 50 percent of milestones and signing fees received and forecast to be received in respect of Flutiform™

### **Other borrowings and cash**

Bank and other borrowings amounted to £9.3 million at 31 December 2009 (2008: £10.7 million), consisting principally of £8.0 million property mortgages secured on the assets of SkyePharma AG (2008: £9.0 million). The decrease in the amount of the mortgages is due to capital repayments and exchange translation effects.

As at 31 December 2009 SkyePharma had net cash of £27.0 million, comprising cash and cash equivalents of £27.0 million, net of a bank overdraft of nil, compared with £35.5 million net cash at 31 December 2008.

### **Going concern basis**

The Directors have made an assessment of the working capital requirements of the Group for the next twelve months, taking account of revenue projections, operating costs, finance costs, debt repayment obligations, obligations in respect of the Flutiform™ supply chain and supporting the regulatory filings, proposed cost reduction actions and the risks inherent in such forecasts.

After making appropriate enquiries, the Directors have reasonable expectations that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly they continue to adopt the going concern basis in preparing the annual report and accounts.

Whilst not a significant uncertainty affecting going concern, management of the Flutiform™ supply chain involves the Group in a number of commitments including the remaining capital expenditure for production tooling, obligations to prepare for commercial supply, working capital requirements and certain minimum commitments to suppliers. However these factors and the timing of approval and launch of Flutiform™ and related net cash inflows are not critical to the Director's current assessment of going concern.

### **Foreign exchange**

Almost all of the Group's operations are based overseas in Continental Europe and licence royalty payments are typically denominated in various currencies, with sales-related payments based on underlying sales in local currencies. This gives rise to direct and indirect exposures to changes in foreign exchange rates notably the Swiss Franc, Euro and US Dollar. To minimise the impact of any fluctuations, the Group's policy has historically been to maintain natural hedges by relating the structure of borrowings to the underlying trading cash flows that generate them. Exchange translation gains and losses relating to funding (cash and debt) are included in foreign exchange gain or loss on net debt, other realised exchange gains and losses and exchange translation gains and losses are included within the revenue or expense line to which they most closely relate. Where subsidiaries are funded centrally, this is achieved by the use of long-term intercompany loans. Where settlement of these loans is neither planned nor likely to occur in the foreseeable future, they are treated as part of the net investment and exchange differences are taken to reserves. No use has been made of currency options and forward currency contracts during 2009.

### **Forward looking statements**

The foregoing discussions contain certain forward looking statements. Although SkyePharma believes that the expectations reflected in these forward looking statements are reasonable, it can give no assurance that these expectations will materialise. Because the expectations are subject to risks and uncertainties, actual

results may vary significantly from those expressed or implied by the forward looking statements based upon a number of factors. Such forward looking statements include but are not limited to, the timescales for regulatory filings for Flutiform™, the statements under “Outlook”, the forecast sales of Flutiform™, the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma’s ability to manufacture products on a large scale or at all, risks related to SkyePharma’s and its marketing partners’ ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma’s ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward looking statement to reflect events or circumstances after the date of this preliminary announcement.

## CONSOLIDATED INCOME STATEMENT

for the year ended 31 December 2009

	Notes	Year ended 31 December 2009	Year ended 31 December 2008
		£m	£m
<b>Continuing operations</b>			
Revenue	2	55.9	62.2
Cost of sales	3	(15.0)	(19.6)
<b>Gross profit</b>		<b>40.9</b>	<b>42.6</b>
Selling, marketing and distribution expenses		(1.9)	(1.5)
Research and development expenses	4	(19.6)	(25.1)
Corporate costs		(2.9)	(3.5)
Amortisation of intangible assets		(0.6)	(0.7)
Share based payments charge		(0.8)	(0.8)
Other expenses		-	(0.1)
<b>Pre-exceptional operating profit</b>		<b>15.1</b>	<b>10.9</b>
Exceptional credits	5	9.8	-
Exceptional charges	5	(11.2)	(28.5)
<b>Operating profit/(loss)</b>		<b>13.7</b>	<b>(17.6)</b>
Finance costs:			
Interest	6	(13.3)	(14.1)
Revaluation	6	(1.4)	(3.0)
Finance income	6	0.3	0.9
Foreign exchange (loss)/gain on net debt	7	(0.2)	5.7
<b>Loss before tax</b>		<b>(0.9)</b>	<b>(28.1)</b>
Taxation		(0.5)	(0.6)
<b>Loss for continuing operations attributable to the parent</b>		<b>(1.4)</b>	<b>(28.7)</b>
<b>Basic and diluted earnings per share</b>	8	<b>(6.0)p</b>	<b>(247.4)p</b>

See Notes to the preliminary announcement

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME/(EXPENSE)

for the year ended 31 December 2009

	Year ended 31 December 2009	Year ended 31 December 2008
	£m	£m
<b>Loss for the year</b>	<b>(1.4)</b>	<b>(28.7)</b>
<b>Other comprehensive income/(expense) for the year, after tax:</b>		
Exchange differences on translation of foreign operations	5.4	(20.7)
Available for sale financial assets - Impairment	0.3	(0.1)
Actuarial gains /(losses) on defined benefit plans	0.2	(0.1)
<b>Other comprehensive income/(expense) for the year, net of tax</b>	<b>5.9</b>	<b>(20.9)</b>
<b>Total comprehensive income/(expense) for the year attributable to the owners of the parent, net of tax</b>	<b>4.5</b>	<b>(49.6)</b>

See Notes to the preliminary announcement

## CONSOLIDATED BALANCE SHEET

as at 31 December 2009

	Notes	As at 31 December 2009 £m	As at 31 December 2008 £m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Goodwill	9	2.1	7.8
Intangible assets	10	7.0	10.8
Property, plant and equipment		29.8	26.3
		<b>38.9</b>	<b>44.9</b>
<b>Current assets</b>			
Inventories		1.3	1.5
Trade and other receivables		16.5	19.4
Cash and cash equivalents	11	27.0	35.7
		<b>44.8</b>	<b>56.6</b>
Non current assets classified as held for sale	12	-	3.9
<b>Total Assets</b>		<b>83.7</b>	<b>105.4</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables		(13.7)	(26.0)
Borrowings	13	(13.4)	(12.8)
Deferred income		(1.0)	(1.6)
		<b>(28.1)</b>	<b>(40.4)</b>
<b>Non-current liabilities</b>			
Convertible bonds	13	(58.5)	(62.7)
Other borrowings	13	(62.2)	(76.0)
Deferred income		(10.8)	(12.4)
Provisions		(3.7)	(3.7)
		<b>(135.2)</b>	<b>(154.8)</b>
<b>Total Liabilities</b>		<b>(163.3)</b>	<b>(195.2)</b>
<b>Net Liabilities</b>		<b>(79.6)</b>	<b>(89.8)</b>

<b>SHAREHOLDERS' EQUITY</b>			
Share capital	14	98.5	96.7
Share premium		390.2	387.2
Translation reserve		(19.4)	(24.8)
Fair value reserve		-	(0.3)
Own share reserve		(0.2)	(0.2)
Retained losses		(558.1)	(557.8)
Other reserves		9.4	9.4
<b>Total Shareholders' Equity</b>		<b>(79.6)</b>	<b>(89.8)</b>

See Notes to the preliminary announcement

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the year ended 31 December 2009

	Attributable to owners of the parent							Total Shareholders' Equity
	Share capital	Share premium	Translation reserve	Fair value reserve	Own share reserve	Retained losses	Other reserves	
	£m	£m	£m	£m	£m	£m	£m	
As at 1 January 2009	96.7	387.2	(24.8)	(0.3)	(0.2)	(557.8)	9.4	<b>(89.8)</b>
Loss for the year	-	-	-	-	-	(1.4)	-	<b>(1.4)</b>
Other	-	-	5.4	0.3	-	0.2	-	<b>5.9</b>
Total comprehensive income/(expense) for the year	-	-	5.4	0.3	-	(1.2)	-	<b>4.5</b>
Issue of share capital conversions	1.8	3.0	-	-	-	0.1	-	<b>4.9</b>
Share based payments charge	-	-	-	-	-	0.8	-	<b>0.8</b>
<b>At 31 December 2009</b>	<b>98.5</b>	<b>390.2</b>	<b>(19.4)</b>	<b>-</b>	<b>(0.2)</b>	<b>(558.1)</b>	<b>9.4</b>	<b>(79.6)</b>

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the year ended 31 December 2008

	Attributable to owners of the parent							Total Shareholders' Equity
	Share capital	Share premium	Translation reserve	Fair value reserve	Own share reserve	Retained losses	Other reserves	
	£m	£m	£m	£m	£m	£m	£m	
As at 1 January 2008	82.7	382.8	(4.1)	(0.2)	-	(529.8)	9.4	<b>(59.2)</b>
Loss for the year	-	-	-	-	-	(28.7)	-	<b>(28.7)</b>

Other comprehensive expense	-	-	(20.7)	(0.1)	-	(0.1)	-	(20.9)
<b>Total comprehensive expense for the year</b>	-	-	(20.7)	(0.1)	-	(28.8)	-	(49.6)
Issue of share capital - cash	14.0	4.4	-	-	-	-	-	18.4
Own Shares acquired during the year	-	-	-	-	(0.2)	-	-	(0.2)
Share based payments charge	-	-	-	-	-	0.8	-	0.8
<b>At 31 December 2008</b>	<b>96.7</b>	<b>387.2</b>	<b>(24.8)</b>	<b>(0.3)</b>	<b>(0.2)</b>	<b>(557.8)</b>	<b>9.4</b>	<b>(89.8)</b>

## CONSOLIDATED CASH FLOW STATEMENT

for the year ended 31 December 2009

	Notes	Year ended 31 December 2009	Year ended 31 December 2008
		£m	£m
<b>Cash flow from operating activities</b>			
Cash generated by operations	(a)	17.3	5.1
Income tax paid		(0.5)	(0.6)
<b>Net cash generated by operating activities</b>		<b>16.8</b>	<b>4.5</b>
<b>Cash flows from investing activities</b>			
Purchases of property, plant and equipment		(4.8)	(4.2)
Purchases of intangible assets		(0.4)	(0.1)
Interest received		0.3	0.9
<b>Net cash used in investing activities</b>		<b>(4.9)</b>	<b>(3.4)</b>
<b>Cash flows from financing activities</b>			
Repayments of borrowings		(7.0)	(3.0)
Interest paid		(12.6)	(13.2)
Net proceeds from issue of ordinary share capital		-	18.4
Bond modification cost		-	(4.3)
<b>Net cash used in financing activities</b>		<b>(19.6)</b>	<b>(2.1)</b>
<b>Effect of exchange rate changes</b>		<b>(0.8)</b>	<b>4.8</b>
<b>Net (decrease)/ increase in net cash and cash equivalents</b>		<b>(8.5)</b>	<b>3.8</b>
Net cash and cash equivalents at beginning of the year		35.5	31.7
Net (decrease)/increase in cash and cash equivalents		(8.5)	3.8
<b>Net cash and cash equivalents at end of the year</b>		<b>27.0</b>	<b>35.5</b>
<b>Analysis of Net Cash:</b>			
Cash and cash equivalents	11	27.0	35.7
Bank overdraft	13	-	(0.2)
<b>Net cash and cash equivalents</b>		<b>27.0</b>	<b>35.5</b>

See Notes to the preliminary statement

## NOTES TO THE CONSOLIDATED CASH FLOW STATEMENT

### (a) Cash flow from operating activities

	Year ended 31 December 2009 £m	Year ended 31 December 2008 £m
Loss for the year	(1.4)	(28.7)
Adjustments for:		
Tax	0.5	0.6
Depreciation	2.9	4.7
Amortisation	0.6	0.7
Impairments	8.4	25.7
Finance costs	14.7	17.1
Finance income	(0.3)	(0.9)
Aborted transaction costs	-	1.5
Share based payments charge	0.8	0.8
Exchange losses on translation	(0.4)	(5.3)
Other non-cash income	(2.7)	(1.5)
<b>Operating cash flows before movements in working capital</b>	<b>23.1</b>	<b>14.7</b>
<b>Changes in working capital</b>		
Decrease/(increase) in inventories	0.1	(0.1)
Decrease/(increase) in trade and other receivables	1.6	(2.3)
Decrease in trade and other payables	(6.5)	(3.2)
Decrease in deferred income	(1.0)	(4.0)
<b>Cash generated by operations</b>	<b>17.3</b>	<b>5.1</b>

### Notes to the preliminary announcement

The preliminary announcement for the year ended 31 December 2009 was approved by the Board on 24 March 2009.

#### 1 Basis of preparation

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

The preliminary announcement has 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 2006 applicable to companies reporting under IFRS. In preparing this preliminary announcement the Group has consistently applied the accounting policies as set out in the Group's consolidated accounts for the year end 31 December 2008.

The financial information in this preliminary announcement does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006 for the years ended 31 December 2008 and 2009. The financial information for the years ended 31 December 2008 and 2009 has been extracted from the Group's



audited consolidated accounts for the year ended 31 December 2009. The auditors' report on those accounts was unqualified and did not contain a statement under Section 498 (2) or (3) of the Companies Act 2006.

The audited accounts for the year ended 31 December 2008 have been delivered to the Registrar of Companies.

The preliminary announcement has been prepared under the historical cost convention, as modified by the revaluation to fair values of financial instruments at fair value through profit and loss and available for sale financial instruments. The preliminary announcement is presented in Sterling and all values are rounded to the nearest £0.1 million.

### Going concern

The Group's business activities together with the factors likely to affect its future development, performance and position are set out in the Business Review. The financial position of the Group, its cash flows, liquidity position, and debt profile are described in the Finance Review.

The Directors have made an assessment of the working capital requirements of the Group for the next twelve months, taking into account revenue projections, operating costs, finance costs, debt repayment obligations, obligations in respect of the Flutiform™ supply chain and supporting the regulatory filings, proposed cost reduction actions and the risks inherent in such forecasts.

After making appropriate enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the preliminary announcement.

Whilst not a significant uncertainty affecting going concern, management of the Flutiform™ supply chain involves the Group in a number of commitments including the remaining capital expenditure for production tooling, obligations to prepare for commercial supply, working capital requirements and certain minimum commitments to suppliers. However these factors and the timing and approval and launch of Flutiform™ and related net cash inflows are not critical to the Director's current assessment of going concern.

## 2 Revenue by income stream

	Year ended 31 December 2009 £m	Year ended 31 December 2008 £m
Revenue earned is analysed as follows:		
Signing and milestone payments	4.0	12.4
Contract research and development revenue	9.3	8.0
Royalties	28.9	22.4
Manufacturing and distribution	13.7	19.4
<b>Total revenue</b>	<b>55.9</b>	<b>62.2</b>

## 3 Cost of sales

	Year ended 31 December 2009 £m	Year ended 31 December 2008 £m
Manufacturing and distribution	14.2	19.0
Other cost of sales	0.8	0.6
<b>Total cost of sales</b>	<b>15.0</b>	<b>19.6</b>

#### 4 Research & development

	Year ended 31 December 2009	Year ended 31 December 2008
	£m	£m
Clinical trials, supplies and other external costs directly recharged to development partners	3.1	3.3
Other external clinical trial and supply costs	0.7	7.0
Other research and development costs	15.8	14.8
<b>Total research and development</b>	<b>19.6</b>	<b>25.1</b>

#### 5 Exceptional items

		Year ended 31 December 2009	Year ended 31 December 2008
	Notes	£m	£m
<b>Exceptional credits</b>			
Foradil® Certihaler® contract termination	(a)	5.1	-
Exceptional accrual release	(b)	4.7	-
<b>Total exceptional credits</b>		<b>9.8</b>	<b>-</b>
<b>Exceptional charges</b>			
Foradil® Certihaler® asset write down	(a)	-	5.9
Restructuring charges	(c)	2.8	0.8
Goodwill impairment	(d)	5.7	19.5
Intellectual property impairment	(e)	2.7	-
Aborted transaction costs		-	1.5
Impairment on assets held for sale		-	0.8
<b>Total exceptional charges</b>		<b>11.2</b>	<b>28.5</b>

- (a) The exceptional income of £5.1 million on the termination of the Foradil® Certihaler® contracts consists of an amount received from Novartis, net of an amount payable to a subcontractor and costs related to the termination. The amounts were paid in July 2009. In the year ended 31 December 2008 a non-cash exceptional charge of £5.9 million arose, relating to the impairment of assets related to the Foradil® Certihaler®.
- (b) The exceptional credit of £4.7 million relates to the release of accruals no longer required at 31 December 2009. They are mainly related to the final settlement of amounts due in respect of clinical trial work performed for Flutiform™
- (c) The exceptional charge of £2.8 million for 2009 primarily consists of employee termination costs, relocation costs and professional fees related to the restructuring of the manufacturing facility in Lyon, France and the research and development facility in Muttenz, Switzerland.
- (d) At 31 December 2009 the Group incurred a non-cash impairment charge of £5.7 million (2008: £19.5 million), on the IDD® goodwill. The charge has arisen primarily due to a re-estimation of the future cash flows from and anticipated end of life of Triglide® based on the impact of generic competition.
- (e) At 31 December 2009 the Group incurred a non-cash impairment charge of £2.7 million on a licence relating to Flutiform™ in North America. The Group believes the value of this license is unlikely to be recovered before patent expiry and has therefore been fully written off.

#### 6 Finance costs and income

Year ended                      Year ended

	31 December 2009 £m	31 December 2008 £m
<b>Finance cost – interest:</b>		
Interest:		
Bank borrowings	0.4	0.4
Paul Capital finance	3.0	2.7
CRC finance	3.7	4.5
Convertible bonds	6.2	6.5
<b>Total finance cost - interest</b>	<b>13.3</b>	<b>14.1</b>
<b>Finance cost - revaluation</b>		
Cost of revaluation of liabilities due to Paul Capital and CRC	1.4	3.0
<b>Total finance cost - revaluation</b>	<b>1.4</b>	<b>3.0</b>

	Year ended 31 December 2009 £m	Year ended 31 December 2008 £m
<b>Finance income:</b>		
Interest income	0.3	0.9
<b>Total finance income</b>	<b>0.3</b>	<b>0.9</b>

## 7 Foreign exchange (loss)/gain on net debt

	Year ended 31 December 2009 £m	Year ended 31 December 2008 £m
<b>Foreign exchange (loss)/gain on net debt:</b>		
Paul Capital finance	0.2	1.6
CRC finance	0.2	3.7
Foreign denominated cash balances	(0.6)	0.4
<b>Total foreign exchange (loss)/gain on net debt</b>	<b>(0.2)</b>	<b>5.7</b>

The foreign exchange (loss)/gain on net debt arises from translating the closing balance of net debt at the exchange rate as at the balance sheet date.

## 8 Earnings per share

Earnings per share is calculated based on the following information:

	Year ended 31 December 2009 £m	Year ended 31 December 2008 £m
Attributable loss before exceptional items	0.0	(0.2)
Exceptional items	(1.4)	(28.5)
<b>Basic and diluted attributable loss</b>	<b>(1.4)</b>	<b>(28.7)</b>
	Number m	Number m
Basic and diluted weighted average number of ordinary shares in issue	23.4	11.6
Loss per Ordinary Share before exceptional items	0.0	(1.7)p
Exceptional items	(6.0)p	(245.7)p
<b>Basic and diluted loss per Ordinary Share</b>	<b>(6.0)p</b>	<b>(247.4)p</b>

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

## 9 Goodwill

<b>Group</b>	<b>Total £m</b>
<b>Cost</b>	
At 1 January 2008	33.7
<b>At 31 December 2008 and 31 December 2009</b>	<b>33.7</b>
<b>Accumulated amortisation</b>	
At 1 January 2008	6.4
Impairment	19.5
At 31 December 2008	25.9
Impairment	5.7
<b>At 31 December 2009</b>	<b>31.6</b>
<b>Net book value</b>	
<b>At 31 December 2008</b>	<b>7.8</b>
<b>At 31 December 2009</b>	<b>2.1</b>

Goodwill is not amortised but is tested annually for impairment or more frequently if there are indications that goodwill might be impaired. Value in use calculations are generally utilised to calculate the recoverable amount. Key assumptions for the value in use calculations are as follows:

- *Launch dates of products employing these technologies* – Launch dates reflect management’s most recent information on the expected date of launch of products.
- *Sales projections* – These are based on management’s projections, using partner information where available.
- *Discount rates* – The discount rate is calculated using the Capital Asset Pricing model, giving a rate of 15 percent. This rate is adjusted to reflect the specific risk associated with the related product. Approved products’ discount rates may be reduced below 15 percent.
- *Cash Flow projections* – Cash flow projections are usually for 10 years (or to the expiry of the patent if shorter) based on expected product lives. A terminal value is applied where appropriate.
- *Products under development* – No value is attributed to products under development until revenues can be forecast with reasonable certainty.

Goodwill was tested for impairment at both 31 December 2009 and 31 December 2008.

Goodwill at 31 December 2009 and 31 December 2008 relates to the Cash Generating Unit (“CGU”) comprising products and potential products acquired with the acquisition of RTP Canada in 2001/2002 and relates to the Insoluble Drug Delivery (“IDD®”) technology. The IDD® CGU carrying amount (net book value) consists of:

	<b>As at 31 December 2009 £m</b>	<b>As at 31 December 2008 £m</b>
<b>Goodwill</b>		
Beginning of the year	7.8	27.3
Impairment	(5.7)	(19.5)
<b>End of the year</b>	<b>2.1</b>	<b>7.8</b>
Property, plant & equipment	1.5	2.0
<b>Total IDD CGU</b>	<b>3.6</b>	<b>9.8</b>

The recoverable amount for the IDD® CGU has been determined using a value in use calculation using the most recent business plans approved by management which cover a period of 10 years. The pre-tax discount rate used is 12 percent (2008: 12 percent) for approved products and 15 percent (2008: 15 percent) for pipeline products, which is the Group’s average pre-tax discount rate derived from a capital asset pricing model adjusted to reflect specific risk. Cash flows beyond this period are extrapolated using trends and other data. Based on these assumptions, the recoverable amount of goodwill has been calculated as £3.6 million (2008: £9.8 million).

The impairment charge of £5.7 million (2008: £19.5 million) has arisen due to a re-estimation of future cash flows and the anticipated end of life of Triglide® based on the impact of generic competition.

The 2009 and 2008 impairment charges were included within exceptional items in the income statement due to the magnitude of the impairment, as disclosed in Note 5: Exceptional items.

Unless products under development using the IDD® technology reach a stage where revenues can be forecast with reasonable certainty this goodwill will continue to be impaired to reflect the finite life and prospects for Triglide®.

### Sensitivity to changes in assumptions

Management believes that reasonably possible changes to key assumptions would cause the recoverable value of the goodwill to be reduced further. The forecast sales are the key assumption to determine the value of the IDD® CGU. For example, if sales forecasts were reduced due to further erosion of sales by competition in the market by 50 percent the recoverable amount would reduce to £1.6 million, resulting in a further impairment charge of £2.0 million.

## 10 Intangible assets

Group	Intellectual property £m	Software costs £m	Development Costs £m	Total £m
<b>Cost</b>				
At 1 January 2008	29.0	0.6	0.3	29.9
Exchange	14.0	0.2	0.2	14.4
Additions	0.1	-	-	0.1
Disposals	-	(0.1)	-	(0.1)
Transfer	-	0.1	-	0.1
Write-offs	-	(0.1)	-	(0.1)
At 31 December 2008	43.1	0.7	0.5	44.3
Exchange	(3.5)	-	(0.1)	(3.6)
Additions	-	0.4	-	0.4
Disposals	-	(0.1)	-	(0.1)
Transfer	(0.5)	-	0.1	(0.4)
Impairment	(2.7)	-	-	(2.7)
<b>At 31 December 2009</b>	<b>36.4</b>	<b>1.0</b>	<b>0.5</b>	<b>37.9</b>
<b>Accumulated amortisation</b>				
At 1 January 2008	20.4	0.5	0.3	21.2
Exchange	10.5	0.2	0.2	10.9
Amortisation charge	0.6	0.1	-	0.7
Disposals	-	(0.1)	-	(0.1)
Impairment	0.9	-	-	0.9
Write-offs	-	(0.1)	-	(0.1)
At 31 December 2008	32.4	0.6	0.5	33.5
Exchange	(2.6)	(0.1)	(0.1)	(2.8)
Amortisation charge	0.5	0.1	-	0.6
Transfers	(0.5)	-	0.1	(0.4)
<b>At 31 December 2009</b>	<b>29.8</b>	<b>0.6</b>	<b>0.5</b>	<b>30.9</b>
<b>Net book value</b>				
At 31 December 2008	10.7	0.1	-	10.8
<b>At 31 December 2009</b>	<b>6.6</b>	<b>0.4</b>	<b>-</b>	<b>7.0</b>

There are no intangible assets with indefinite useful lives.

Included within intellectual property is £1.8 million (2008: £4.8 million) of assets which are not used in launched products. These assets have not been amortised but have been tested for impairment using the method set out for goodwill in Note 9: Goodwill.

One of the licences, with a value of £2.7 million (2008: £3.0 million) relates to Flutiform™ in North America. The Group believes the value of this license is unlikely to be recovered before patent expiry and has therefore been fully written off.

£4.3 million (2008: £5.2 million) of the intangible assets relate to Solaraze®. These assets are amortised over a 20 year period to 2020, based on the expected useful life of the product.

## 11 Cash and cash equivalents

	Group As at 31 December 2009 £m	Group As at 31 December 2008 £m
Cash at bank and in hand	27.0	30.7
Short term deposits	-	5.0
	<b>27.0</b>	<b>35.7</b>

Cash at bank earns interest at floating rates based on daily bank deposit rates. Short term deposits are made for varying periods of between one day and three months depending on the cash requirements of the Group and earn interest at the respective short term deposit rate. The carrying amount of these assets approximates their fair value as at the Balance Sheet date.

## 12 Non current assets classified as held for sale

As at 31 December 2008 the Group had capitalised assets held at their net realisable value of £3.9 million related to the Flutiform™ supply chain in assets held for sale.

As discussions with one party have ceased, and discussions with a number of other parties remain at a preliminary stage, these assets are recorded within property, plant & equipment as at 31 December 2009.

## 13 Borrowings

Group	Interest rate %	Currency of denomination	As at 31 December 2009 £m	As at 31 December 2008 £m
<b>Current</b>				
Bank overdraft	6.5	Swiss Franc	-	0.2
Bank borrowings	6.5	Swiss Franc	1.2	1.2
Property mortgage	3.9	Swiss Franc	0.4	0.4
Paul Capital finance	11.2	US Dollar	6.3	7.4
CRC finance	EURIBOR + 5.85%	Euro	2.7	1.8
CRC finance	LIBOR + 5.85%	US Dollar	2.8	1.7
Finance lease liabilities	5.5	Swiss Franc	-	0.1
<b>Total current borrowings</b>			<b>13.4</b>	<b>12.8</b>
<b>Non-current</b>				
Convertible 6% bonds due May 2024	9.6	Sterling	46.2	50.5
Convertible 8% bonds due June 2025	14.2	Sterling	12.3	12.2
<b>Convertible bonds</b>			<b>58.5</b>	<b>62.7</b>
Property mortgage	3.9	Swiss Franc	7.6	8.6
Paul Capital finance	11.2	US Dollar	18.4	21.2
CRC finance	EURIBOR + 5.85%/10.85%	Euro	19.3	24.7
CRC finance	LIBOR + 5.85%	US Dollar	16.8	21.3
Finance lease liabilities	5.5	Swiss Franc	0.1	0.2
<b>Other non-current borrowings</b>			<b>62.2</b>	<b>76.0</b>
<b>Total non-current borrowings</b>			<b>120.7</b>	<b>138.7</b>
<b>Total borrowings</b>			<b>134.1</b>	<b>151.5</b>

### Bank overdraft and borrowings

At 31 December 2009 bank borrowings include an overdraft of Nil (2008: £0.2 million (CHF: 0.3 million)) and loan due of £1.2 million (CHF 2.0 million) (2008: £1.2 million (CHF 2.0 million)) with the Basellandschaftliche Kantonalbank. This loan can be terminated on six weeks' notice by either party and bears interest at 6.5 percent per annum. Both amounts are secured on the assets of Skyepharma AG.

### Convertible bonds

In the year ended 31 December 2009 a total of 6,587 of the 6 per cent convertible bonds with a principal

value of £6.6 million were converted into ordinary shares at the conversion price of £3.71 per share. This resulted in the issue of 1,775,467 ordinary shares.

In September 2008 the Group renegotiated its convertible bonds as follows:

The conversion price for the £69.6 million 6 percent convertible bonds due May 2024 was amended from 95 pence per share (with a nominal value of 10p) to £3.71 per share (with a nominal value of £1.00) and the put dates falling in May 2009, May 2011, May 2014 or May 2019 have been replaced with put dates falling in November 2013, November 2015, November 2017 and November 2020.

The conversion price for the £20 million 8 percent convertible bonds due June 2025 was amended from 58 pence per share (with a nominal value of 10p) to £3.82 per share (with a nominal value of £1.00) and the put dates falling in June 2010, June 2012, June 2015 or June 2020 have been replaced with put dates falling in December 2014, December 2016, December 2018 and December 2021.

The renegotiation of the bonds represents a modification to the existing liability, and was accounted for as such. Transaction costs incurred in the renegotiation have been deducted from the book value of the liability and the effective interest rate used to calculate the amortised cost adjusted.

The bonds are included partly in non-current liabilities (2009: £58.5 million, 2008: £62.7 million) and partly in share premium (2009 and 2008: £28.5 million). The total face value of the convertible bonds outstanding at 31 December 2009 is £83.0 million (2008: £89.6 million).

### **Property mortgages**

At 31 December 2009, the Group had two property mortgage facilities with the Basellandschaftliche Kantonbank totalling £8.0 million (CHF 13.1 million) (2008: £9.0 million (CHF 13.7 million)). The mortgage is in two tranches, both secured by the assets of SkyePharma AG. Both bear interest at 3.875 percent per annum and are fully repayable in February 2011.

### **Paul Capital finance**

On 23 March 2007, SkyePharma PLC and its subsidiary, Jagotec AG (together "Jagotec") entered into an agreement with Paul Capital and a subsidiary (together "PCRF"). Pursuant to this agreement, PCRF assigned its existing interests in the royalties and certain milestones from Solaraze®, Xatral® OD, Triglide®, Pulmicort® HFA-MDI, Foradil® Certihaler® and Paxil CR™ ("PCRF Products") in exchange for a fixed amortisable senior note (the "Note") in the amount of US\$105.0 million (£66.0 million) issued by Jagotec. Under the terms of Note minimum amortisation payments are US\$92.5 million (£58.1 million) and these payments are increased by US\$12.5 million (£7.8 million) beginning on 31 March 2011 if worldwide sales of DepoDur™ reach certain thresholds. The Note is repayable on a quarterly basis in accordance with an amortisation schedule beginning on 31 March 2007 through to 31 December 2015. The outstanding amount under the Note as at 31 December 2009 is US\$72.3 million (£45.4 million) (2008: US\$83.6 million (£57.7 million)).

The Note must be prepaid in certain circumstances, including 50 percent of any milestone payments for any Flutiform™ license agreements or 50 percent of any signing fees with respect to Flutiform™ license agreements entered into with regard to any unlicensed territory, in each case received after 1 January 2009, in an amount up to US\$10.0 million. Jagotec must also prepay the Note in an amount equal to 50 percent of the proceeds received upon the disposal of any of the intellectual property related to the PCRF Products. The Injectable Business was sold on the basis that it retained its obligations to PCRF to share royalties received in respect of DepoCyt® and DepoDur™ and to the extent that payments are made in satisfaction of such obligations, the liability of SkyePharma PLC and Jagotec AG under the Note is reduced accordingly. SkyePharma PLC and Jagotec AG have the option to prepay the Note by providing 10 days' prior written notice. Such prepayment amount will be calculated at a discount to the remaining scheduled amortisation payments due more than 12 months after the date of prepayment at a rate of US Dollar LIBOR plus 75 basis points.

The terms of the Note contain representations and warranties and covenants customary for agreements of this type. There is also a covenant (negative pledge) not to grant security over Flutiform™ intellectual property, and the requirement for prior consent from PCRF for certain transactions that could affect PCRF's security and risk. The Note is secured by milestone payments and royalty receipts receivable by Jagotec under license agreements related to the PCRF Products.

In connection with the Note, Jagotec granted PCRF a royalty-free, fully-paid up and worldwide, license or sublicense, as applicable, subject to third party rights, limited to the right to grant sublicenses (through

multiple tiers) under the intellectual property in the Products, which becomes operable following an event of default and in certain other circumstances, pursuant to a License Agreement dated as of 23 March 2007.

The liability was initially recorded at fair value, calculated by discounting the expected cash flows based on management's estimation of a fair market rate at inception. Subsequently the carrying value of the Note is at amortised cost, calculated as the net present value of the expected future minimum payments (net of amounts expected to be paid by the Injectable Business) discounted at 11.2 percent per annum (the effective comparable interest rate at inception).

In 2009 contributions due from Pacira and the timing of prepayments (as described above) have been revised based on the latest forecasts, resulting in an increase in the current valuation (at amortised cost). The income statement charge has been recorded in Note 6: Finance costs and income – revaluation, and amounts to U.S.\$3.0 million (£1.9 million).

At 31 December 2009, the carrying value of the Note was £24.7 million (2008: £28.6 million).

### **CRC Loan**

On 22 December 2006 SkyePharma PLC and various of its subsidiaries entered into an agreement with a specialist lending entity ("CRC"), advised by Christofferson, Robb & Company LLC, for a 10 year secured amortising loan facility, this facility was amended on 23 March 2007. The loan was fully drawn down in 2007.

Key terms of the CRC loan are as follows:

(i) the total loans of US\$35.0 million and €26.5 million are repayable over 10 years based on a minimum amortisation schedule. The schedule was based on expected receipts from milestones and royalties in respect of Coruno®, Lodotra™ and Requip® Once-a-day (the "CRC Products"); In the event that the cumulative milestones and royalties from the CRC Products exceed the minimum principal and interest payments, the excess will be applied to repay principal early without penalty;

(ii) interest is charged on a quarterly basis on the US Dollar facility at the three month US Dollar LIBOR rate plus a 5.85 percent margin and on the EUR facility at the three month EURIBOR rate plus a 10.85 percent margin on the first €7.5 million of the euro facility and a 5.85 percent margin on the balance;

(iii) the loan facility was secured by a comprehensive security package, including pledges of shares of certain key subsidiaries, charges over certain bank accounts, charges over certain intra-group debts, a floating charge over the assets of SkyePharma PLC and charges over or, subject to third party consents being received, assignments of receivables in respect of the CRC Products and Sular® and ZYFLO CR®;

(iv) there is a comprehensive covenant package, including a negative pledge, so further security over the Group's assets may not be granted, nor may certain other transactions that could affect CRC's security and risk be entered into, without prior consent from CRC;

(v) the loan must be prepaid in certain circumstances, including 50 percent of any milestone payments for any Flutiform™ license agreements or 50 percent of any signing fees with respect to Flutiform™ license agreements entered into with regard to any unlicensed territory, in each case received after 1 January 2009 in an amount up to US\$10.0 million. Such prepayments comprise a capital element and an amount based on a pre-agreed schedule to compensate CRC for loss of future interest; and

(vi) CRC was granted a royalty-free, fully-paid up and worldwide license or sublicense, as applicable, subject to third party rights, in favour of CRC limited to the right to grant sublicenses (through multiple tiers) under the intellectual property in the CRC Products, which becomes operable following an event of default and certain other circumstances.

Interest on the US Dollar portion of the CRC finance is charged at three month US LIBOR + 5.85 percent. As at 31 December 2009 LIBOR was 0.2825 percent (2008: 3.76188 percent).

Interest on the first €7.5 million of the Euro portion of the CRC finance is charged at 3 month EURIBOR + 10.85 percent. Interest on the remainder of the facility is charged at 3 month EURIBOR + 5.85 percent. As at 31 December 2009 EURIBOR was 0.739 percent (2008: 5.142 percent).

At 31 December 2009 the timing of future prepayments (as described above) has been revised based on the



latest forecasts, resulting in a small decrease in the current valuation (at amortised cost). The income statement credit has been recorded in Note 6: Finance costs and income – revaluation and amounts to U.S\$.0.8 million (£0.5 million).

The balance as at 31 December 2009 is £42.4 million (net of £0.8 million of costs) (2008: £49.5 million net of £1.0 million of costs).

### Finance lease liabilities

Obligations under hire purchase and finance leases are secured upon the assets to which they relate and as at 31 December 2009 total £0.1 million (2008: £0.3 million).

## 14 Share capital

### Company

The Company's authorised share capital is as follows:

Ordinary Shares	Authorised Shares	
	31 December 2009 £m	31 December 2008 £m
140,000,000 Ordinary Shares of £1.00 each (2008: 140,000,000 shares of £1.00 each)	140.0	140.0
<b>Deferred 'B' Shares</b>		
12,000,000 Deferred 'B' shares of 10p each (2008: 12,000,000 shares of 10p each)	1.2	1.2
<b>Deferred 'C' Shares</b>		
7,334,899,200 Deferred 'C' shares of 1p each (2008: 7,334,899,200)	73.3	73.3

The changes in the Company's issued share capital have been as follows

Issued and fully paid	Ordinary Shares		Deferred 'B' shares		Deferred 'C' shares		Total nominal value £m
	Number	Nominal value £m	Number	Nominal value £m	Number	Nominal value £m	
At 1 January 2008	814,988,636	81.5	12,000,000	1.2	-	-	82.7
Share Split	814,988,636	8.2	-	-	7,334,899,200	73.3	82.7
Share consolidation	8,149,888	8.2	-	-	-	-	-
Issue of share capital - cash	14,017,807	14.0	-	-	-	-	14.0
At 31 December 2008	22,167,695	22.2	12,000,000	1.2	7,334,899,200	73.3	96.7
Issue of share capital - conversion	1,775,467	1.8	-	-	-	-	1.8
<b>At 31 December 2009</b>	<b>23,943,162</b>	<b>24.0</b>	<b>12,000,000</b>	<b>1.2</b>	<b>7,334,899,200</b>	<b>73.3</b>	<b>98.5</b>

### Share capital reorganisation

In September 2008 shareholders approved a reorganisation of the Company's share capital consisting of a share split in which the 814,988,636 shares with a nominal value of 10 pence then in issue were split into 1 interim ordinary share and 9 deferred 'C' shares, both with a nominal value of 1 pence. The deferred 'C' shares have no value.

The share split was immediately followed by a share consolidation from 814,988,636 ordinary interim shares of 1 pence each into 8,149,888 ordinary shares of £1.00 each.

The authorised ordinary share capital was increased from 118,800,000 ordinary shares of 10 pence to

140,000,000 ordinary shares of £1.00 each.

### **Issue of shares**

In 2009 ordinary share capital has been increased by 1,775,467 by the conversion of £6.6 million of convertible bonds.

In September 2008 SkyePharma issued 14.0 million new ordinary shares by way of a placing and open offer. The shares were priced at £1.50 per share and raised £18.4 million, net of expenses.

## **15 Contingencies**

At 31 December 2009 the Company had provided guarantees on various bank borrowings of its subsidiaries as set out in Note 13: Borrowings.

Where appropriate, the Company provides guarantees of performance obligations on behalf of its subsidiary undertakings. The Company has also guaranteed the performance obligations for SkyePharma (Jersey) Limited in respect of the convertible bonds, including the obligation to meet any puts when they fall due.

As described in Note 13: Borrowings, the Injectable Business was sold on the basis that it retains responsibility to Paul Capital for its existing obligations to make payments based on sales of DepoCyt® and DepoDur™. The Group retains responsibility for the full liability under the Paul Capital Note whether or not these payments are made.

The Group is aware that intellectual property may exist in certain territories where, although it is believed that any intellectual property concerned is invalid and/or that no activities are undertaken which would constitute infringement, the Group may wish to enter into negotiations and or take action to deal with these situations. Should any significant activity need to be undertaken in this regard the costs of dealing with these situations are likely to be significant.

## **16 Post Balance Sheet Events**

On 21 January 2010 the Group announced the receipt of a Complete Response Letter from the United States FDA related to Flutiform™. The FDA stated that it could not approve the NDA in its current form and raised a number of substantive issues to be addressed, which, if undertaken, would involve significant additional clinical work.

Further to this on 5 February 2010, the Group announced the NDA was being transferred to SkyePharma, which enables SkyePharma to deal directly with the FDA in any discussions.